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Kintara Therapeutics, Inc. (KTRA - NASDAQ)

Two Phase III Ready Assets

Based on our DCF model and a 15% discount rate, Kintara Therapeutics is valued at approximately $4.00 per share. Our model applies a 60% probability of ultimate approval and commercialization for VAL-083 in GBM and a 50% probability of approval REM-001 in CMBC. The model includes contributions from the United States and Europe. Other regions will be included upon further clarity.

Current Price (9/8/2020)	$1.36
Valuation	**$4.00**

Kintara Therapeutics is an oncology-focused R&D company pursuing an indication in GBM using chemotherapy agent VAL-083 and an indication in CMBC using photodynamic therapy REM-001. The two products were recently joined in a merger by sponsors DelMar Pharmaceuticals and Adgero Biopharmaceuticals.

VAL-083's profile is well-known as it has been assessed in 40+ Ph1 & Ph2 trials sponsored by the NCI. VAL-083 is approved in China for CML and lung cancer and is being investigated in two Ph2 GBM trials in the US and China sponsored by Kintara.

Around year-end 2020, VAL-083 should advance into registrational trials via the GCAR adaptive study for GBM which are expected to yield Ph3 topline results in 2023. Working with the GCAR AGILE study should accelerate results in recurrent and newly diagnosed methylated and unmethylated patients while limiting total cost.

REM-001 is expected to start a confirmatory trial in 2021 which will move into a 100 patient Ph3 trial vetted by regulators following confirmation of dose. The trial is expected to be complete by the end of 2023 followed shortly after by an NDA filing.

Our valuation assumes a 2025 regulatory approval and subsequent large pharma partner deal for commercialization of VAL-083 and a 2024 approval and deal followed by a launch of REM-001.

INITIATION
SUMMARY DATA

52-Week High	**1.40**
52-Week Low	**0.47**
One-Year Return (%)	**116**
Beta	**2.0**
Average Daily Volume (sh)	**992,850**
Shares Outstanding (mil)	**45.2**
Market Capitalization ($mil)	**61.5**
Short Interest Ratio (days)	**0.24**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2020 Estimate	**N/A**
P/E using 2021 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of USD)

	Q1 (Sep)	Q2 (Dec)	Q3 (Mar)	Q4 (Jun)	Year (Jun)
2019	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2020	$0.0 A	$0.0 A	$0.0 A	$0.0 E	$0.0 E
2021					$0.0 E
2022					$0.0 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2019	-$0.88 A	-$0.75 A	-$0.67 A	$0.85 A	-$3.16 A
2020	-$0.21 A	-$0.15 A	-$0.11 A	-$0.09 E	-$0.49 E
2021					-$0.56 E
2022					-$0.64 E

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INITIATING COVERAGE

We are initiating coverage of Kintara Therapeutics (NASDAQ: KTRA) with a current valuation of $4.00 per share. This present value is based on our estimates for a successful Phase III trial for two compounds. The first, VAL-083, is expected to yield topline results in 2023, followed by a new drug application (NDA) and a 2025 launch of the product in selected geographies. The second is REM-001, a photodynamic therapy (PDT) that consists of a drug, a laser light source and a light delivery device which is expected to start a confirmatory trial in 2021 and later convert into a Phase III study generating data by late 2023 followed shortly after by NDA submission and commercialization in 2024.

VAL-083 is being investigated for glioblastoma multiforme (GBM), a deadly type of brain cancer with poor historical survival. Two Phase II trials are underway and we expect a pivotal Phase II/III study to begin before year end that will support the NDA. VAL-083 is a well understood molecule that has been investigated since the late 1970s[1] in clinical trials and is approved in China for two cancer indications. We believe VAL-083's ability to cross the blood brain barrier and produce irreparable double strand DNA breaks in cancer cells make it a particularly attractive tool against GBM. Kintara has received investigational new drug (IND) clearance for a Phase I/II study in ovarian cancer; however, the primary focus for the company remains on late stage clinical assets. The FDA has granted both indications an orphan drug designation and the European Medicines Agency (EMA) has granted orphan status for gliomas, including GBM.

VAL-083 has a differentiated profile which allows the chemotherapeutic to cross the blood brain barrier and overcome resistance common to standard-of-care alkylating agents. VAL-083 can attack cancer cells by forming interstrand crosslinks at the N^7 position of guanine on the DNA of cancer cells. The crosslinks form rapidly and are able to block repair by MGMT[2], leading to lethal double-strand breaks, cell-cycle arrest and apoptosis. Research has also shown that the drug is more readily absorbed by cancer cells as compared to normal cells. VAL-083 is effective against both MGMT-methylated cells and MGMT-unmethylated cells, which allows the agent to treat cancers resistant to temozolomide (TMZ) and nitrosoureas.

GBM is a rare disease, estimated to occur in three of every 100,000 persons. There are almost 12,000 new cases in the United States and 12,000 in the top five EU nations each year. GBM is a particularly aggressive form of cancer that has a median survival of about three months without treatment and 12 to 15 months[3] with treatment. When extending to three and five years beyond diagnosis, the percentage of survivors drops to single digits. The disease mostly affects older adults with a median age of 64[3] with a higher incidence in men and in those of European descent.

Current treatment for GBM is surgery, followed by adjuvant radiation and chemotherapy. Despite the multimodal treatment, the side effects are severe and the survival advantage is measured in months. Two major obstacles to treatment are the ability of therapeutics to cross the blood brain barrier and repair enzyme mediated chemotherapy resistance. Due to these obstacles, the cancer is difficult to treat and almost always recurs; new therapies are desperately needed.

VAL-083 may answer the call to address this unmet need and early clinical trial data suggest it may extend overall survival (OS) compared to standard of care, especially in patients with unmethylated MGMT promoters. The latest data released by Kintara at the American Association for Cancer Research (AACR) 2020 meeting demonstrated an improvement in standard of care and we expect further supportive data from preliminary topline results in 4Q:20. We are optimistic about the upcoming adaptive trial with the Global Coalition for Adaptive Research (GCAR) that is paving a registrational pathway forward for VAL-083 in GBM. The GBM AGILE (Glioblastoma Adaptive Global Innovative Learning Environment) trial will reduce costs and accelerate results for Kintara's NDA.

REM-001 has been investigated in several Phase II and Phase III trials, providing sufficient efficacy and safety data to support its use in cutaneous metastatic breast cancer (CMBC). The product works through an infusion of tin ethyl etiopurpurin (SnET2) suspended in a lipid formulation. Clinical studies of SnET2 indicate it selectively destroys tumor tissue, a likely result of its affinity for the neovasculature present in tumors. The higher metabolism of cancer cells may also accelerate the drug's uptake compared to other cells but the drug remains inactive until exposed to specific wavelengths of light. This allows for precise targeting of the drug's effect and reduces or minimizes a systemic side effect profile on the patient.

[1] Espana, P., *et al.* Phase II Study of Dianhydrogalactitol in Malignant Glioma. Cancer Treat Rep. 1978 Aug;62(8):1199-200.
[2] O^6-methylguanine-DNA methyltransferase (MGMT)
[3] Tamimi, A.F., Juweid, M.; Epidemiology and Outcome of Glioblastoma. Brisbane (AU): Codon Publications; 2017 Sep 27.

CMBC is estimated to affect up to 40,000 women in the United States and a similar number in Western Europe. Globally, there are estimated to be almost 500,000 breast cancer cases that will present with skin metastases. With no other effective treatments, CMBC is an unmet need that may be addressed by REM-001.

Following the consummation of the merger to September 1, 2020, Kintara raised a gross $25 million in cash from multiple closings of a private placement. The company holds Class A, B and C preferred shares which are accounted for in our model. Funds raised to date will enable the completion of two Phase II trials that are underway and prepare VAL-083 to participate in the GBM AGILE study and support the lead in and Phase III study for REM-001. We estimate that AGILE will require $25 million and REM-001 up to $37 million to fund to completion.

Our model forecasts that pivotal GBM AGILE data will be available by late 2023 followed by an NDA submission to the FDA. Kintara will likely work with a partner to commercialize VAL-083 and we anticipate the US and Europe will be the first markets pursued. If successful, VAL-083 will provide a better alternative to GBM patients in a variety of settings. Kintara will also advance REM-001 along a similar timeline with a Phase III trial beginning after a short lead-in study, with Phase III results expected in late 2023 followed shortly after by an NDA filing in and with commercialization in 2024.

INVESTMENT THESIS

Kintara is completing multiple Phase II trials for VAL-083 to treat brain cancer, one of the most difficult malignancies to address. Interim data shows superior activity against GBM tumors compared to first line standard-of-care temozolomide (TMZ). VAL-083 has been researched for decades by the National Cancer Institute (NCI) and has been approved in China for chronic myeloid leukemia and lung cancer. The chemotherapeutic has several features that make it particularly appropriate for GBM, including its ability to cross the blood brain barrier and its mechanism of action which introduces irreversible DNA crosslinks which are not easily overcome by repair enzymes.

With few other options and an average survival time under treatment of 12 to 18 months, patients are in dire need of new therapies that can extend life. VAL-083 may represent a new alternative and is in multiple late-stage Phase II clinical trials in China and the US. Kintara has been granted orphan designation in both the US and Europe for the treatment of gliomas, including GBM, which will provide seven and 10 years of exclusivity in the regions, respectively, if pivotal clinical trials are successful.

Kintara provided interim data from its ongoing Phase II trials at AACR in late June and is expected to provide preliminary topline results in 4Q:20. The announcements will provide a prelude to the recently publicized partnership with the GCAR GBM AGILE study. Selection to participate in the AGILE study is a remarkable achievement as it provides a cleared pathway towards approval along with other benefits, such as active sites, world-class partners and a shared control arm that has already begun enrolling. The design will allow Kintara to examine efficacy in multiple arms, including both methylated and unmethylated populations.

Interim and previous data for VAL-083 has been sufficient to support entry into the GCAR AGILE study. Management expects to start enrolling patients in 4Q:20. The structure of the trial is a seamless Phase II (efficacy and safety) / Phase III (confirmatory) study. The ability to pursue multiple arms will expand the potential market for an approved product and increases the likelihood of success.

VAL-083 presents a differentiated mechanism of action and a favorable safety profile, especially in contrast to other agents currently in use. It is a bifunctional compound that is able to alkylate N^7-guanine to form interstrand crosslinks and force double strand breaks. Unlike TMZ, the response to VAL-083 is not dependent on MGMT promoter methylation status. At the target dose, only a minority of patients presented dose limiting toxicities and the drug is well tolerated.

Standard of care for GBM is surgery followed by radiotherapy and TMZ which frequently meets resistance by the tumor. Second line therapy is lomustine and bevacizumab; however, side effects are severe and benefits are limited. Median overall survival (mOS) for newly diagnosed patients is just over a year and there is a pressing need for better therapies as GBM is notorious for the lack of effective treatments available. Difficulty crossing the blood brain barrier and tumor resistance are two hurdles that have prevented new therapies from succeeding.

The incidence of GBM is estimated at around three per 100,000 or from 11,000 to 12,000 cases in the United States per year and a similar number in the top five EU countries. Based on the wide variety of sources available, we estimate the addressable global population for GBM to be around 40,000 per year. Our model assumes success in the unmethylated population which we estimate at 60% of GBM cases.

We adopt a conservative approach and anticipate VAL-083 to have pricing competitive with other novel chemotherapies. We expect a discount to this level outside of the United States. While our target price is generated based on VAL-083 in the US and Europe, the demand for GBM treatment is broader. Kintara also has a second indication in ovarian cancer which has been granted an orphan designation. This project is on hold while the company focuses on approval for GBM. However, we anticipate adding a valuation component if the company resumes development activity.

Kintara's second late stage asset, REM-001, will soon begin a dose identifying confirmatory study enrolling up to 15 patients as a direct lead in to the Phase III. Extensive studies have been conducted that have characterized the safety and efficacy of REM-001 to address CMBC. The cancer has no effective treatments despite minor benefits from surgery, chemotherapy, radiotherapy and other approaches.

While the US and Western Europe each have near 40,000 CMBC cases every year, the lack of an effective treatment makes an indication here a worthwhile pursuit. We think that pricing above $50,000 per year is appropriate in the United States with an expected minimum of five years of exclusivity. In Europe the price may be halved but the period of exclusivity is doubled.

The pathway forward for the REM-001 PDT platform targets the start of the lead-in portion 2Q:21 followed by a Phase III that may be able to enroll as few as 75 patients depending on the initial signal. Enrollment is targeted to be complete in 2022 with the last patient, last visit one year later. Following a period of analysis and an NDA filing, commercialization is targeted for 2024. We forecast commercialization in both the US and Western Europe in our model.

Kintara Therapeutics was recently formed from the combination of DelMar Pharmaceuticals and Adgero Biopharmaceuticals, the latter of which was developing REM-001 as its lead candidate for CMBC. REM-001 is a PDT platform that combines a light delivery device with a drug to kill tumor cells. Adding REM-001 provides a second Phase III-ready asset and additional pipeline expansion opportunities including future possible indications. This includes cancers such as recurrent basal cell carcinoma nevus syndrome (BCCNS), locally advanced basal cell carcinoma (laBCC), and cutaneous metastatic cancers other than breast, such as lung, ovarian and colon.

Key reasons to own Kintara shares:

- **Phase III ready assets to address an unmet need in GBM and CMBC**
- **VAL-083 is a well-understood chemotherapy agent with long history of use in other cancers**
    - **Granted orphan status for both GBM and ovarian cancer**
    - **Differentiated mechanisms that cross blood brain barrier and block repair enzyme**
    - **Favorable drug safety profile**
- **Acceptance of VAL-083 into the highly regarded GCAR AGILE GBM study**
    - **Provides registrational pathway with top tier partners**
- **REM-001 addresses unmet need in CMBC**
    - **Substantial work completed to characterize safety and efficacy (~1,100 patients in safety database)**
    - **Light activated drug reduces systemic risk**
    - **Small inexpensive trial may be sufficient for approval**
- **Additional indications for VAL-083 and REM-001 in clinical development**

In the following sections we review the chemotherapy space, VAL-083 and its mechanism of action. A review of GBM is presented along with discussion of the disease's prevalence, treatment and risk factors. We report on relevant clinical data, development history and anticipated trial design for the anticipated approval pathway for VAL-083 in GBM and provide a summary of standard-of-care. We expect first sales in 2025 after a favorable trial outcome and successful submission and approval of an NDA. We provide a summary of REM-001 and its clinical history followed by a discussion of the product's mechanism of action, safety and current treatment approaches. CMBC is thoroughly reviewed with disease incidence, risk factors, symptoms, diagnosis and treatment discussed.

After a review of the risks faced by the industry and Kintara specifically, we review competitors and peers along with a profile of the management team members. The body of our report concludes with an in-depth discussion of our model assumptions and an appraisal of Kintara's equity which generates a valuation of $4.00 per share. Both VAL-083 and REM-001 may prove to serve an unmet need for patients with GBM and CMBC, extending survival and/or improving quality of life for a group with few other options.

Chemotherapeutics

Chemotherapy is a type of cancer treatment that is used to inhibit the growth of or destroy cancer cells. The approach interferes with a cell's ability to divide by inhibiting mitosis or by attacking the DNA. Mechanisms of action include prevention of cellular division, replacing or eliminating enzymes or nutrients the cancer cells need to survive and triggering apoptosis. Chemotherapies are systemic approaches that are usually given intravenously, but can also be given through other routes including oral administration. Chemotherapy was first introduced in the 1940s after research on the benefits of nitrogen mustard gas (mechlorethamine) on lymphoid tumors. Despite frequent remission in patients using this technique, further advances were made in the subsequent decade including the complete cure of a human solid tumor using methotrexate in 1953. The 1960s and 1970s experienced increased cure rates using chemotherapy and the introduction of new chemotherapeutic agents such as cyclophosphamide, paclitaxel and cisplatin. In the last decade, combination of chemotherapy with immuno- and targeted-therapy has increased treatment success rates.

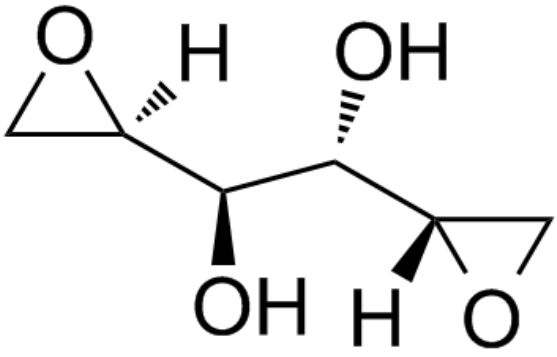
Chemotherapy is frequently administered with other types of cancer treatment including radiotherapy, surgery and immunotherapy. When administered prior to surgery, neoadjuvant chemotherapy attempts to make a tumor smaller and easier to remove. When given after surgery, the drug is intended to destroy any remaining cancer cells. Side effects of the treatment are frequently unpleasant and vary based on chemotherapy type. The systemic toxicity of chemotherapy regimens has improved over the decades but still often result in acute and delayed nausea, myelosuppression, mouth ulcerations and mild cognitive impairments. In addition, long-term side effects from chemotherapy can include an increased risk of developing other types of cancers. Short term side effects include fatigue, loss of appetite, anemia, brain fog, vomiting, diarrhea, hair loss, easy bruising and bleeding, appetite changes, constipation and lack of appetite among others. When chemotherapy is used to kill fast growing cancer cells, it can also have a damaging impact on blood forming cells in the bone marrow, on hair follicles and on cells in the mouth, digestive tract and reproductive system. Some side effects have a long duration, such as damage to the heart, lungs, kidneys or reproductive organs. While side effects can be unpleasant, they are weighed against the need to kill the cancer cells.

There are more than 100 different drugs used in chemotherapy today with the most common approaches including gemcitabine, doxorubicin, vinorelbine, signal transduction inhibitors and platinum-based chemotherapy. The main types of chemotherapy include alkylating agents, antimetabolites, antitumor antibiotics, topoisomerase inhibitors and mitotic inhibitors. Multiple chemotherapy classes can be used together to attack the cancer from different directions which can help decrease the chance the tumor will become resistant. For example, when treating lung cancer, frequently cisplatin and vinorelbine will be used together against the disease. Lower doses of two different drugs can be used to reduce toxicity and in other cases using a combination approach may provide synergies between the agents, such as when chemotherapy is used as an adjuvant treatment.

While the focus of the oncology world has shifted toward contemporary immunotherapies, chemotherapy still plays an important role in the treatment of cancer. In some cases, immunotherapies are not effective in certain types of cancer such as in GBM or they work well in combination with chemotherapy highlighting the importance of this time tested approach.

VAL-083

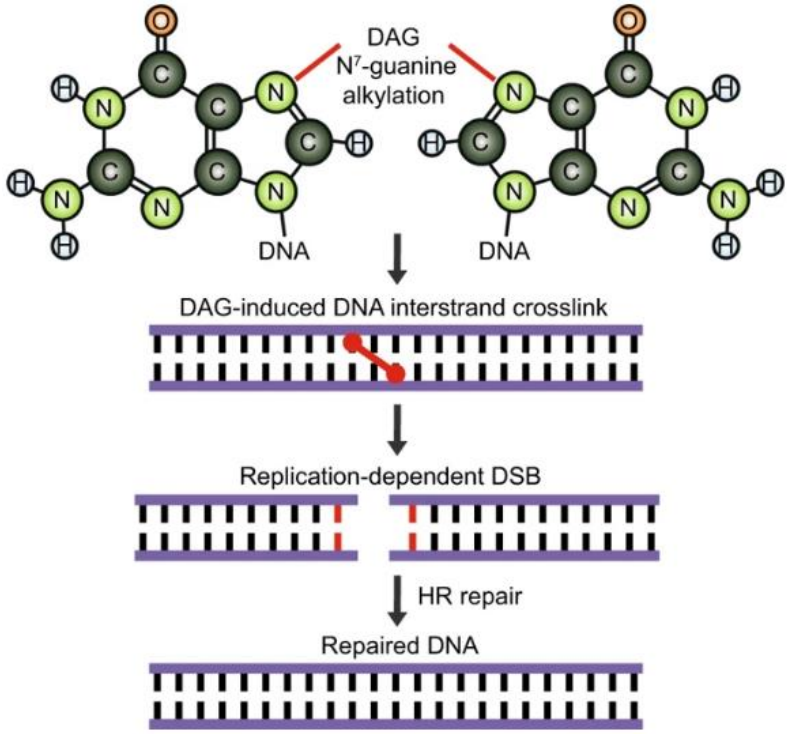
Exhibit I – Chemical Structure of Chemotherapy Dianhydrogalactitol (VAL-083)[4]



[4] Source: https://newdrugapprovals.org/tag/dianhydrogalactitol/.

VAL-083, also known as dianhydrogalactitol, is a DNA damaging, alkylating chemo-therapeutic agent that was first developed by the NCI in the 1970s.[5] The drug is approved in China for treatment of chronic myeloid leukemia and lung cancer. The compound is a bifunctional DNA-targeting agent causing N^7-guanine alkylation[6] and interstrand DNA crosslinks. The crosslinks induce DNA double strand breaks which inhibits cancer cell proliferation. VAL-083 induces cytotoxicity when cells advance to the S-phase with unrepaired N^7-guanine DNA crosslinks. The crosslink damage causes replication-dependent DNA double-strand breaks that prevent repair, resulting in apoptosis.[7] The agent is able to overcome MGMT-mediated drug resistance and has shown the ability to kill MGMT-unmethylated GBM cell lines and cancer stem cells *in vivo*. It maintains cytotoxic activity in mismatch repair deficient cancer cells providing an alternative for treatment-resistant cancers reliant on TMZ and nitrosoureas. The drug also works well with other approaches including poly ADP ribose polymerase (PARP) and topoisomerase inhibitors as well as acting as a radiosensitizer in GBM.

Exhibit II – VAL-083 Mechanism of Action[8]



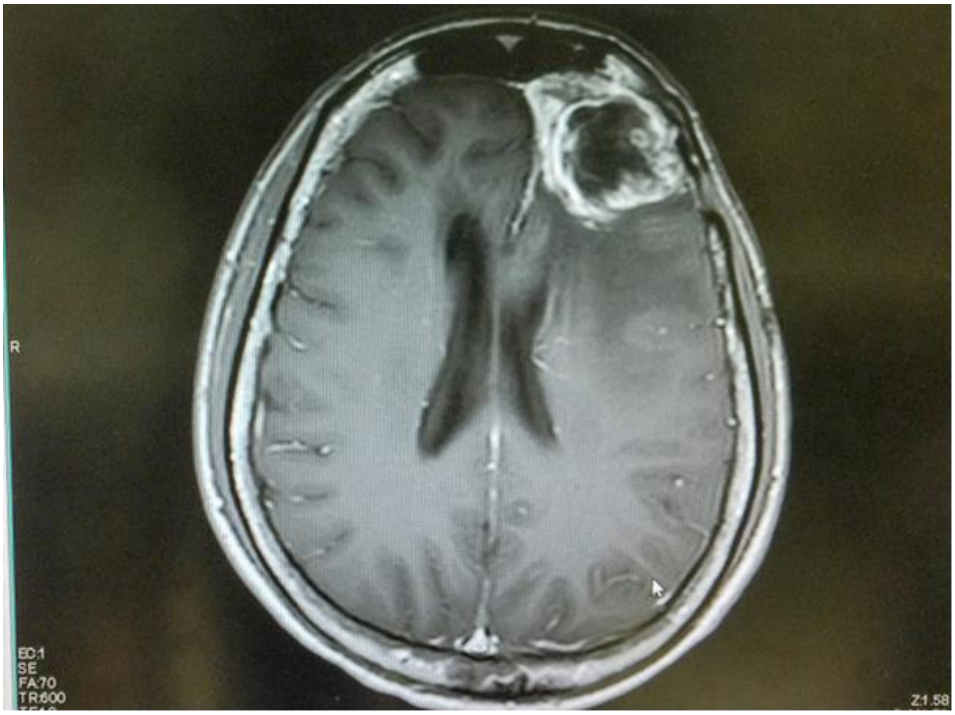
VAL-083 is water soluble and is able to cross the blood brain barrier. This ability has elevated VAL-083 into a group of chemotherapeutic agents that can treat one of the most difficult cancers. In preclinical and clinical studies, VAL-083 has also shown beneficial effects in other tumor types including non-small cell lung cancer (NSCLC), ovarian cancer, leukemia and cervical cancer. It has also displayed synergy with topoisomerase inhibitors[9] and activates the homologous recombination (HR) pathway in GBM and prostate cancer cells, supporting its use as a combination agent.

Glioblastoma Multiforme (GBM)

Glioblastoma multiforme (GBM), also known as a grade IV astrocytoma, is a rare disease but a common type of brain cancer that is hard to treat and notoriously fatal. The cancer is only recognized as grade IV which is very aggressive and most diagnosed patients die within a year. GBM is difficult to treat because the tumor cells are resistant to standard therapies and many drugs have difficulty crossing the blood brain barrier. The brain is susceptible to damage from surgery and other standard of care and only has limited repair capacity presenting additional hurdles to success that prevent a wide surgical margin from being used during tumor removal.

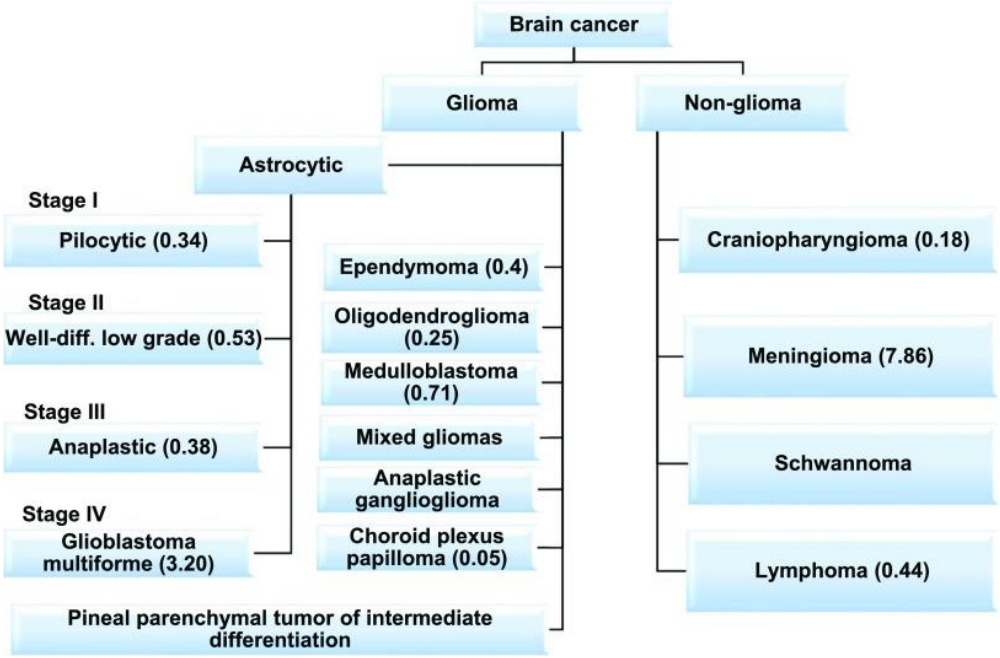
[5] Perry, M.C., *et al.* Phase II Studies of Dianhydrogalactitol and VP-16-213 in Colorectal Cancer. Cancer Treat Rep 60:1247-1250, 1976.
[6] Alkylation of DNA is used in chemotherapy to damage the DNA of cancer cells.
[7] Zhai, B., *et al.* Dianhydrogalactitol induces replication-dependent DNA damage in tumor cells preferentially resolved by homologous recombination. Cell Death & Disease volume 9, Article number: 1016 (2018)
[8] Stasko, N. *et al.* Nitric Oxide-Releasing Macromolecule Exhibits Broad-Spectrum Antifungal Activity and Utility as a Topical Treatment for Superficial Fungal Infections. Antimicrobial Agents and Chemotherapy Jun 2018, 62 (7) e01026-17; DOI: 10.1128/AAC.01026-17
[9] Zhai, B., *et al.* Dianhydrogalactitol (VAL-083) synergizes with topoisomerase inhibitors to overcome homologous recombination repair activity in glioblastoma and prostate cancer cells. AACR, June 2020.

Exhibit III – Image of Glioblastoma WHO Grade IV[10]



The first signs of GBM may be headaches, seizures, vomiting, vision problems, changes in personality and difficulty speaking. After signs are identified and a condition is suspected, a neurological assessment is given to the patient that examines vision, hearing, balance, coordination, strength and reflexes to narrow down the cause. Next steps include an MRI or CT scan to identify the tumor and a biopsy may also be performed. Standard of care treatment for GBM includes surgery to remove as much of the tumor as possible followed by radiation and chemotherapy, frequently using TMZ or carmustine and lomustine. Due to the low survival rate, which is about 40% at one year, and lack of effective therapies, the FDA is more accepting of developmental approaches with novel mechanisms of action and is likely to confer expedited status to promising therapeutic candidates.

Exhibit IV – Brain Cancer Classifications[11]



[10] Source: Shutterstock, MRI brain show left frontal glioblastoma
[11] Shergalis, A., *et al.* Current Challenges and Opportunities in Treating Glioblastoma. Pharmacol Rev. 2018 Jul; 70(3): 412–445.

Molecular Markers

There are several biomarkers that are identified for GBM that are relevant for providing tailored therapy. GBM tumors are heterogeneous and a variety of markers can enlighten the diagnosis and prognosis of the disease and determine the treatment pathway. The primary marker is methylation status of the gene promoter for MGMT. Others include isocitrate dehydrogenase enzyme 1/2 (IDH1/2) mutation, epidermal growth factor receptor (EGFR) overexpression and amplification, glioma-CpG island methylator phenotype (G-CIMP), tumor protein (TP53) mutation and genetic losses of chromosomes.

Methylation Status

An important biomarker for GBM is the promoter methylation status of the tumor cells. Methylated DNA silences the expression of MGMT, an enzyme that can repair certain types of DNA damage. The enzyme is important for fixing strand breaks in normal cells; however, in cancer cells, MGMT can repair the purposeful DNA damage done by certain types of chemotherapy. If a patient is MGMT-methylated, the DNA-repair enzyme MGMT will not be produced, chemotherapy can be allowed to work and the patient will show a better response to standard of care approaches such as TMZ and radiation as promoter methylation blocks expression of the MGMT-mediated DNA repair enzyme. If a patient is MGMT-unmethylated, the MGMT enzyme is expressed and cancer cells intrinsically or rapidly develop resistance to chemotherapy. Unmethylated MGMT is considered an indicator for GBM patients with a particularly poor prognosis. MGMT promoter methylation conveys prolonged survival compared to tumors without methylation. Patients that are MGMT promoter methylated have a worse prognosis but are still prescribed TMZ due to a lack of alternatives. Approximately half to two thirds of GBM cases are classified as unmethylated.[12]

Incidence, Prevalence and Survival

GBM is a rare disease. According to the National Institutes of Health (NIH), it occurs in approximately two to three individuals per 100,000 per year and accounts for 52% of primary brain tumors. The Brain Tumor Registry of Canada finds that four of 100,000 Canadian residents are diagnosed with GBM. The estimated 23,890[13] cases of brain cancer according to the American Cancer Society (ACS) suggests from 7,000 to 12,000 cases in the US per year. The American Association of Neurological Surgeons estimates that 11,000 individuals are diagnosed with GBM each year and 23,000 present with the disease. A variety of sources provide several ranges for median survival. Some sources cite 15 months,[14] while others find 12 to 15 months in their research[15] and yet others from 15 to 16 months.[16] The Cancer Research Institute notes that only a quarter of patients survive for 24 months and less than 10% survive more than five years. Chapter 8 of Glioblastoma,[17] Epidemiology and Outcome of Glioblastoma, notes an incidence rate of 3.19 per 100,000 persons in the US.

Risk Factors, Symptoms and Diagnosis

GBM is associated with age over 50, being male and abnormalities on chromosome 10 or 17. Exposure to radiation from previous cancer treatment or other sources is also a risk factor. Genetic syndromes, including neuro-fibromatosis, tuberous sclerosis and von Hippel-Lindau disease, can also increase the likelihood of developing the disease.

Individuals with GBM may experience a variety of symptoms including headache, nausea or vomiting, confusion, decline in brain function, memory loss, changes in personality, balance, vision and/or speech problems. If the symptoms presented suggest a brain tumor, additional tests will be run. Some of the approaches used include molecular magnetic resonance imaging (mMRI), computerized tomography (CT) scan, magnetic resonance spectroscopy (MRS), needle biopsy and blood or other tests. The pathological diagnosis is made at the time of surgery when tissue is removed and examined by a pathologist.

Treatment

Standard of care for GBM is debulking surgery followed by radiation and chemotherapy. Surgery is a fine balance between removing sufficient amounts of the tumor and leaving enough brain tissue to maintain neurological function. Migrating tumor cells make it difficult to remove the tumor entirely. After healing from the craniotomy, radiation therapy is started which is intended to kill the remaining tumor cells in the nearby tissue. Up to 30 treatments are often given using specialized radiation delivery systems, such as external beam radiation therapy.

[12] Mellai M, Monzeglio O, Piazzi A, Caldera V, Annovazzi L, Cassoni P, et al. MGMT promoter hypermethylation and its associations with genetic alterations in a series of 350 brain tumors. J Neurooncol 2012;107:617–31.
[13] American Cancer Society, Cancer Facts and Figures 2020.
[14] Koshy M, Villano JL, Dolecek TA, Howard A, Mahmood U, Chmura SJ, et al. Improved survival time trends of glioblastoma using the SEER 17 population-based registries. J Neuro Oncol. 2012;107(1):207–12.
[15] Alexander BM, Cloughesy TF. Adult glioblastoma. J Clin Oncol. (2017) 35:2402–9. doi: 10.1200/jco.2017.73.0119
[16] Bi, W.L., Beroukhim, R. Beating the odds: extreme long-term survival with glioblastoma. Neuro Oncol. 2014 Sep; 16(9): 1159–1160. doi: 10.1093/neuonc/nou166
[17] Tamimi, A.F., Juweid, M. Glioblastoma. Brisbane (AU): Codon Publications; 2017 Sep 27.

Chemotherapy is also administered with the standard treatment of TMZ. It is often given every day during radiation therapy in a daily cycle for a month, followed by a month of rest.

TMZ is a DNA-alkylating agent targeting O^6 and N^7 positions of guanine and is currently used as first-line treatment for GBM. The drug induces single and double strand breaks that can fatally damage the cancer cells by preventing the DNA mismatch repair system from finding a complementary base for methylated guanine. This causes long nicks in DNA and blocks the cell cycle, thereby causing apoptosis. Tumor cells eventually evolve to repair this damage allowing MGMT-expressing or mismatch repair-deficient tumors to develop resistance to TMZ. The agent is an oral treatment prescribed for an initial period of approximately six weeks, then cycled on a 5-days-on 23-days-off pattern. TMZ adjuvant therapy is considered in methylated patients. Nitrosoureas are commonly used along or in combination with TMZ.

Other treatments for GBM include bevacizumab (Avastin), polifeprosan 20 with carmustine implant (Gliadel), lomustine (Ceenu) and Optune, a device worn on the head that emits electric fields. Most of these approaches are used in combination with other treatments that include surgery, radiation and TMZ.

Exhibit V – GBM Therapies Approved or In Development[18]

Generic Name	Brand Name	Company	Class	Status
Temozolomide	Temodar	Merck	Chemotherapy	Approved
Tumor treating fields	Optune	Novocure	Electric field	Approved
Bevacizumab	Avastin	Genentech	VEGF inhibitor	Approved
Pembrolizumab	Keytruda	Merck	Checkpoint Inhibitors	Clin Trial
Carmustine implant	Gliadel	Nobelpharma	Alkylating agent	Approved
Lomustine	CeeNU	BristolMyers	Alkylating agent	Approved
N/A	INO-5401	Inovio	DNA	Ph2
N/A	INO-9012	Inovio	DNA	Ph2
N/A	DCVax-L	NW Bio	ADC	Ph3
N/A	SurVaxM	MimiVax	Immunotherapy	Ph2
N/A	TOCA511	Tocagen	Oncolytic virus	Ph3
N/A	TOCA FC	Tocagen	Antifungal prodrug	Ph3
Irinotecan	Onivyde	Ipsen	Topoisomerase inhibitor	Approved

Research and Development

Phase I/II Trial

Kintara launched a Phase I/II study in 2011 to determine the safety and maximum tolerated dose (MTD) of VAL-083 in refractory GBM. Patients enrolled in the trial presented recurrent GBM after surgery, radiation, TMZ and bevacizumab. The Phase I portion of the trial was an open-label, single-arm dose-escalation study, where intravenous VAL-083 was administered for the first three days of a 21 day cycle until the MTD was achieved. 34 patients were enrolled. Daily dosing started at 1.5 mg/m^2 and increased to 50 mg/m^2. No drug-related serious adverse events (SAE) were reported. Myelosuppression was mild at doses ≤40 mg/m^2 but dose limiting toxicities (DLT) consisting of thrombocytopenia were observed at 50 mg/m^2. 40 mg/m^2 was confirmed as the MTD.

The Phase II portion of the study enrolled an additional 14 patients for further safety analyses and dosing at the MTD with the final patient enrolled in October 2015.

Phase II Trial, China

In 2017 a single-arm, biomarker driven, Phase II open label study in newly diagnosed MGMT-unmethylated GBM patients was launched at Sun Yat-sen University in Guangzhou, China. The trial, in collaboration with Guangxi Wuzhou Pharmaceutical Company, enrolled 29 newly diagnosed patients and is ongoing.[19] The study is made up of two parts. The first is a dose confirmation exercise that has evaluated VAL-083 at 20, 30 and 40 mg/m^2 per day, administered intravenously along with x-ray therapy to confirm MTD. The drug is administered for the first three days of a 21-day cycle. The second, ongoing, part is an expansion phase that is evaluating another 20 patients at

[18] Source: Analyst work using various sources.
[19] Trial was fully enrolled as of February 19, 2020

the target dose, also in conjunction with x-ray therapy. Based on the work conducted in part 1, a dose of 30 mg/m^2 per day was selected. Endpoints and data collection for the investigation are:

- Tumor response as assessed by the Response Assessment in NeuroOncology
- Progression free survival (PFS) at six months
- Overall survival (OS) compared to historical results in the target population
- Pharmacokinetic (PK) assessments of VAL-083 in plasma and cerebrospinal fluid

Kintara has completed enrollment of the first-line study in China. An update for the trial was presented at the AACR virtual meeting June 22, 2020 in a poster entitled "Phase 2 trial of dianhydrogalactitol (VAL-083) in patients with newly diagnosed MGMT-unmethylated glioblastoma." The results are being compared to a historical control of TMZ with a median PFS of 6.9 months. Nine patients of the 29 included in the study had not progressed as of May 15, 2020. Interim data finds a PFS of 8.7 months, broken down by dose as provided in the following exhibit.

Exhibit VI – Interim mPFS & Survival from Diagnosis[20]

	Tanguturi et al, 2017[9]	Starting Dose of VAL-083			
		Overall	20 mg/m^2/d	30 mg/m^2/d	40 mg/m^2/d
Median PFS (months) (95%CI)	6.9 (5.0-12.5)	8.7 (6.4-11.2)	3.0 (-)	8.7 (6.0-12.0)	9.9 (9.3-9.9)
Number Progressed (%)	-	20/29 (68.9%)	1/1 (100%)	17/25 (68%)	2/3 (66.7%)
Number of deaths (%)	-	11/29 (37.9%)	1/1 (100%)	10/25 (40.0%)	0/3 (0%)

Despite the greater mPFS for the 40 mg/m^2/d, this cohort only included three subjects. In other studies, the 40 mg dosage had been associated with a higher rate of dose limiting toxicities including Grade 3 and 4 hematological toxicities and a greater level of myelosuppression. The toxicities sometimes required a delay in the start of subsequent cycles of treatment, thereby reducing the total area under the curve over the treatment cycles. This has led to the selection of 30 mg/m^2/d as the target dose for future trials.

Phase II Trials, MD Anderson

In November 2017, a 48 patient (later amended to 83) trial was launched at the University of Texas MD Anderson Cancer Center in patients presenting MGMT-unmethylated GBM. It was designated "Study of VAL-083 in Patients With MGMT Unmethylated, Bevacizumab-naïve Glioblastoma in the Adjuvant or Recurrent Setting." The biomarker driven enrollment process divided subjects into two groups to determine the mOS in MGMT-unmethylated recurrent GBM patients in the first group and find PFS in newly diagnosed GBM patients requiring adjuvant therapy after chemotherapy with TMZ and radiotherapy.

Group 1 (Recurrent)
This arm will evaluate the efficacy of VAL-083 with an endpoint of mOS in patients with MGMT-unmethylated recurrent GBM and be compared to a historical control using lomustine. It will enroll up to 83 patients, with 35 initially treated at 40 mg/m^2 per day and up to 48 patients initially treated at the selected go-forward treatment dose of 30 mg/m^2 per day.

As of May 28, 2020, the cutoff date for interim analysis for presentation at AACR 2020, 72 of 83 patients had completed at least one 21-day cycle of treatment. DLTs were explored in Group 1 during the first cycle of treatment with a materially higher level of DLTs for the 40 mg/m^2 group as compared to the 30 mg/m^2 group. Taken in concert with other data at 40 mg/m^2, the safety results provide additional support for the shift to 30 mg/m^2 dosing in future studies.

[20] O'Brien, B.J., *et al.* Phase 2 study of dianhydrogalactitol (VAL-083) in patients with MGMT unmethylated, bevacizumab naïve glioblastoma in the adjuvant or recurrent setting. AACR, June 2020.

Exhibit VII – Cycle 1, Group 1 (Recurrent) Dose Limiting Toxicities[21]

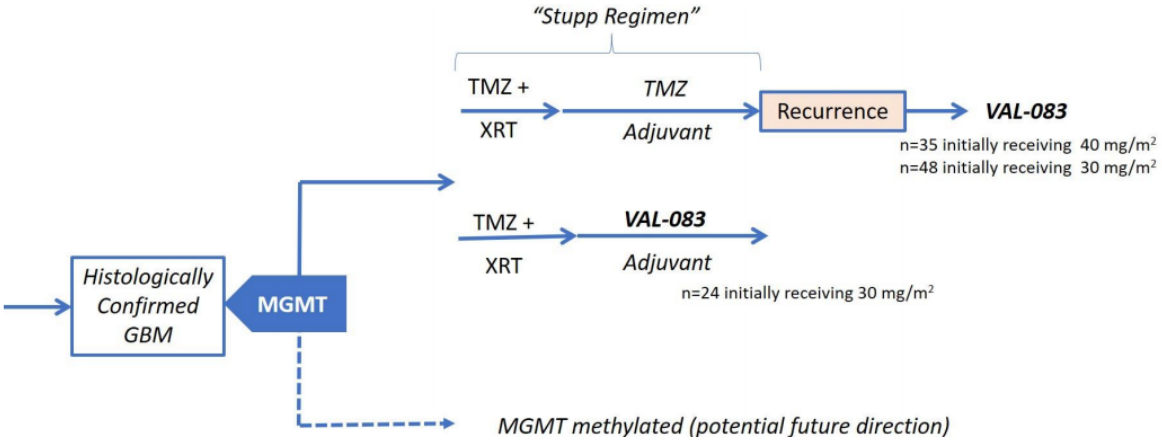
Number and Percent of Subjects with DLT, as defined below	40 mg/m²/d (n=35)	30 mg/m²/d (n=37)	All (n=72)
Number of subjects with DLT*	8 (22.9%)	3 (8.1%)	11 (15.3%)
DLT due to Hematological toxicity	8 (22.9%)	2 (5.4%)	10 (13.8%)
DLT due to Non-hematological Grade 3/4 toxicity	1 (2.8%)	1 (2.7%)	2 (2.7%)
Dose reduction (Cycle 2)	9 (25.7%)#	2 (5.4%)##	11 (15.3%)

Of the 35 subjects in the 40 mg cohort, 31 or 88.6% had died and of the 37 subjects in the 30 mg cohort, 20 or 54.1% had died as of May 28. mOS was 7.1 months for the total group, 6.5 months for the 40 mg group and 8.5 months for the 30 mg group. Survival is compared against the historical control of 7.2 months which includes patients treated with lomustine alone. Results are interim only and are not yet mature as 21 patients remain alive as of the cutoff date.

Group 2 (Adjuvant)
This arm will evaluate the efficacy of VAL-083 when given as adjuvant therapy after chemoradiation with TMZ. Median PFS in newly-diagnosed patients with MGMT-unmethylated GBM will be compared to the historical control of TMZ. It will enroll up to 36 patients who have completed chemoradiation treatment with TMZ without adjuvant TMZ.

As of May 28, 2020, 25 patients had been enrolled and 19 patients had completed at least one 21-day cycle of treatment. All 25 patients enrolled were alive as of the cutoff date and enrollment is continuing. Five of 19 subjects (26.3%) exhibited disease progression, 14 of 19 (70%) subjects were continuing treatment and one subject discontinued treatment and was in follow-up.

Exhibit VIII – MD Anderson Study Design[22]



Conclusions from the Phase II trial find that myelosuppression is the most common side effect and that it typically resolved spontaneously without pharmaceutical intervention. The 30 mg/m² per day dosage was better tolerated than the 40 mg target with the trial investigators concluding that VAL-083 is well tolerated as adjuvant treatment in unmethylated MGMT GBM. The researchers established that VAL-083 may provide an alternative therapy for TMZ, which has limited efficacy in patients with unmethylated MGMT GBM.

Phase III Trials

In a June 4, 2020 release, Kintara (operating as DelMar) announced that it had been selected to participate in the Global Coalition for Adaptive Research (GCAR) GBM AGILE (Glioblastoma Adaptive Global Innovative Learning Environment) pivotal study. GCAR is an international partnership including some of the world's leading clinical, translational, and basic science investigators. The group is working on development projects in GBM to advance

[21] O'Brien, B. *et al.* Phase 2 study of dianhydrogalactitol (VAL-083) in patients with MGMT-unmethylated, bevacizumab-naïve glioblastoma in the recurrent and adjuvant setting. AACR, June 2020
[22] O'Brien, B. *et al.* Phase 2 study of dianhydrogalactitol (VAL-083) in patients with MGMT-unmethylated, bevacizumab-naïve glioblastoma in the recurrent and adjuvant setting. AACR, June 2020

effective therapies in promising biomarker defined populations. GBM AGILE is uniquely designed as a long-standing platform which will evaluate multiple investigational therapies for newly diagnosed or recurrent GBM to determine if new treatments are an improvement over standard of care. Unlike traditional trials that evaluate one therapy at a time, GBM AGILE may test several therapies or treatment arms simultaneously. The organization has invited Bayer to also participate in the trial with its multikinase inhibitor regorafenib. One of the key benefits of the structure is a shared control arm that has already started enrolling. Not only will this reduce the number of additional subjects needed when Kintara begins enrolling, it will also allow them to share the cost of the arm with other participants. Currently there are 24 US sites enrolling patients and more sites in the EU, Canada and China are expected to be added in 2H:20. Another important benefit of the structure is that new treatment arms can be quickly added and evaluated at any time, while under-performing drugs are dropped from the trial. GCAR selected GBM as a target indication due to the high death rate and lack of other effective therapies. The trial design is a seamless Phase II (Efficacy and Safety) / Phase III (Confirmatory) trial that can provide pivotal data for approval.

Participation in the program is a huge win for Kintara as it includes industry-recognized luminaries in the GBM oncology space. The FDA has cleared the trial design and has provided a letter of support to GCAR and trial sites are already enrolling. This saves months of time, effort and cost for Kintara and provides an independent affirmation of VAL-083. The adaptive trial design is another plus that can expand the target population appropriate for VAL-083.

Kintara anticipates that the first part of the trial will enroll 100 to 150 patients in three GBM subtypes: newly diagnosed methylated, newly diagnosed unmethylated and recurrent. The cost of this part is estimated to be approximately $15 million. Upon a successful signal, the adaptive trial will then move into the second part which will extend the enrollment of part 1 and add 50 more patients. Cost for second part is estimated to be $10 million.

The nod of confidence from GCAR was recognized by the National Brain Tumor Society and the National Foundation for Cancer research which awarded a loan to Kintara to advance VAL-083 into the AGILE program. The $500,000 loan will help promote both of these organizations' missions to improve cancer treatment.

Adverse Events and Safety Profile

Myelosuppression, which includes thrombocytopenia and neutropenia, has been a common adverse event that has resolved spontaneously. DLTs in the Group 1 recurrent cohort at MD Anderson were almost a quarter of subjects for the 40 mg/m^2 group (see Exhibit VII above), but declined substantially when the dose was reduced to 30 mg/m^2. Safety and side effects are a relative factor in GBM treatment due to the short expected survival time and high fatality rate. Three subjects experienced an SAE, possibly related to VAL-083 in the newly-diagnosed group, while 10 subjects have experienced a possibly drug-related SAE in the recurrent group, and one patient has experienced a possibly drug-related SAE in the adjuvant group as of the latest update. Lomustine is known for its harsh side effects including hematological toxicity and even if VAL-083 only provides similar efficacy, it may be more tolerable for patients and preferred over the alternative.

Other Indications

In addition to multiple settings in GBM, VAL-083 is also being investigated in ovarian cancer and pediatric brain tumors. Both of these programs are on hold pending further financing. The FDA cleared an IND for the ovarian indication for a Phase I/II, open label trial called Recurrent Platinum Resistant Ovarian Cancer (REPROVe). In this study, ovarian patients that have progressed after platinum–based chemotherapy will be included in the trial. The study may be done in combination with PARP inhibitors. The FDA has granted VAL-083 orphan status in ovarian cancer. VAL-083 has also demonstrated the ability to treat pediatric brain tumors including SHH-p53 mutated medullo-blastoma in preclinical and human studies. The pediatric tumors indication has also been granted orphan status and Kintara anticipates advancing this program upon receiving specific funding. A successful study in pediatric patients could provide an additional six months of marketing exclusivity for VAL-083.

REM-001 Program

Prior to the formation of Kintara Therapeutics, REM-001 was being developed by Adgero Biopharmaceuticals Holdings which operated as a private company based in New Jersey. Adgero was founded in 2007 and in 2012 acquired the REM-001 technology which was initially developed by Miravant Medical Technologies. Miravant has since ceased operations. The REM-001 compound was at an advanced stage of development and had been the basis for an NDA in a non-cancer indication that received an approvable letter but was not pursued for business reasons. Along with the technology acquisition, the transfer of the cleared investigational new drug (IND) application originally submitted by Miravant was recognized by the FDA. Adgero, now Kintara, is developing a PDT platform that combines a drug and a light emitting device. The Phase III ready candidate, REM-001, uses light sensitive compounds that produce free radicals of oxygen when exposed to specific wavelengths of light. The REM-001 therapy product consists of a laser light source, a light delivery device and the REM-001 drug product. The drug component is tin ethyl etiopurpurin (SnET2) suspended in a lipid formulation. This second generation product has several benefits as compared to earlier versions including the reduction of time post-treatment that a patient has to avoid sunlight. Kintara is pursuing cutaneous metastatic breast cancer (CMBC) with REM-001 and is expected to launch a lead-in to a Phase III trial in the coming months.

Cutaneous Metastatic Breast Cancer

Breast cancer is the most common type of cancer in the United States for women. While treatment is effective for this disease through a combination of chemotherapy, radiotherapy and surgery, some patients will advance to metastatic breast cancer. A subset of this group will contract CMBC. CMBC occurs when breast cancer cells spread to the skin and form anywhere from months to years after the initial breast cancer. In women with cutaneous metastases, the most common source is breast cancer.

Cancer cells replicate to form tumors; they progress via a series of key mutations that affect the cells and as tumors enlarge, they can invade surrounding tissues. Often, cancer is described in stages based on the spread of the tumor. If the tumor is early stage and remains *in situ,* it is labeled Stage 0; the most advanced cancers are Stage IV. There are multiple types of breast cancer, the most common of which are: ductal carcinoma in situ, invasive ductal carcinoma, inflammatory breast cancer and metastatic breast cancer.[23] Ductal carcinomas (in situ/invasive) are cancers of the cells lining the breast milk ducts. CMBC, or breast cancer that has invaded skin tissue, results from lymphatic embolization, hematogenous or contiguous dissemination and manifests as papulonodular neoplastic lesions.[24]

Incidence, Prevalence & Risk Factors

Breast cancer is one of the most common cancers with an estimated 2 million new cases worldwide in 2018, and the ACS estimates 276,480 new US cases in 2020.[25] In women, this accounts for 30% of all new cancer cases and the second leading cause of cancer-related deaths. According to the Metastatic Breast Cancer Network (MBCN), from 20% to 30% of breast cancer cases are initially diagnosed as metastatic; however, the proportion of metastatic cancer increases as the disease progresses. This suggests near 150,000 metastatic breast cancer cases in the US.[26] Breast cancer is the most common malignancy to cutaneously metastasize with metastases appearing in 24% of breast cancer cases.[27] After adjusting for the ratio of metastatic and cutaneous cases, this suggests nearly 40,000 episodes per year. Other sources find in excess of 20% of breast cancer cases are associated with metastatic cutaneous lesions, or about 55,000 women.[28] Worldwide, there are approximately 2 million new breast cancer cases per year[29], in which approximately 480,000 will present with skin metastases. It is estimated that 1 in 8 US women will develop invasive breast cancer over a lifetime and there are approximately 3.5 million women with a history of breast cancer in the United States.[30] For those who develop CMBC, company sponsored interviews with physicians indicate treatment options are limited and an effective treatment would be well received.

The incidence of breast cancer also varies by country, with Belgium, Luxembourg and the Netherlands having incidence of over 100 per 100,000, perhaps an indication of either environmental or genetic factors. While the risk

[23] https://www.nationalbreastcancer.org/types-of-breast-cancer/
[24] Bittencourt Mde J, Carvalho AH, Nascimento BA, Freitas LK, Parijós AM. Cutaneous metastasis of a breast cancer diagnosed 13 years before. *An Bras Dermatol*. 2015;90(3 Suppl 1):134-137. doi:10.1590/abd1806-4841.20153842
[25] American Cancer Society, Cancer Facts and Figures 2020
[26] American Cancer Society, Breast Cancer Facts & Figures 2019-2020.
[27] Krathen RA, Orengo IF, Rosen T. Cutaneous metastasis: a meta-analysis of data. *South Med J*. 2003;96(2):164-167. doi:10.1097/01.SMJ.0000053676.73249.E5
[28] Nava, G., *et al.* Metastatic cutaneous breast carcinoma: A case report and review of the literature. Can J Plast Surg. 2009; 17(1): 25–27.
[29] https://www.wcrf.org/dietandcancer/cancer-trends/breast-cancer-statistics
[30] https://www.breastcancer.org/symptoms/understand_bc/statistics

factors for cutaneous metastasis are not fully understood, the risk of premenopausal breast cancer is correlated with genetic makeup, consumption of alcohol, greater birthweight and adult height; it was also found that vigorous physical activity, greater body mass and lactation protect against breast cancer.[31] Genetic factors include mutations of BRCA1 and BRCA2 genes. From 5-10% of breast cancers can be linked to documented gene mutations; women having BRCA1 or BRCA2 mutation can have up to a 72% or 69% risk of developing breast cancer in their lifetime, respectively. Having both mutations increases risk in younger women.[32] Hereditary factors include being related to women that also have breast cancer before the age of 45 or ovarian cancer at any age. Women of Ashkenazi Jewish descent are also at higher risk as is having dense breast tissue.[33] Many of the risk factors that affect the risk of breast cancer pre-menopause or before age 45 also affect all women; by far, the largest risk factor, other than sex, is age.[34] As women age, the accumulation of unavoidable genetic mutation increases, even without inheritance; also, women with longer hormonal duration (earlier menstruation and later menopause) are exposed to hormones longer, increasing their risk; hormone replacement therapy increases risk the same way.[35]

Symptoms, Diagnosis & Treatment

Mastectomy follow-up becomes increasingly important given the risk of delayed cutaneous metastasis. Early identification is key in treatment. Cutaneous metastasis arising from visceral malignancies appear generally (80%) as cutaneous or subcutaneous nodules, commonly on the chest; these nodules can be flesh colored, pink or violet.[36] Less commonly, the lesions can present elsewhere: on the scalp, neck, abdomen, back and upper limbs.[37] Often, the cutaneous lesions do not appear until long after the treatment of the original tumor. Other presentations of cutaneous metastatic cancer include telangiectatic carcinomas, erysipeloid carcinomas, 'en cuirasse' carcinomas, alopecia neoplastica and zosteriform type.[38] Other cutaneous conditions may also be present, including acute/chronic cutaneous change or infections such as erysipelas, cellulitis or candidiasis.[39]

Diagnosis of CMBC can be performed through a visual exam or with a biochemical marker. The onset of a rash that is tender and swollen are initial signs which can be followed up by histological evaluation. Other early indications of CMBC in patients with breast cancer include erythema, a breast mass, breast enlargement and inflammation.

Current treatment for CMBC can include systemic chemotherapy and biologic agents such as Paclitaxel and Trastuzumab.[40] Treatments for cutaneous presentation are similar to those used in the original cancer and will include surgery, radiotherapy, and electrochemotherapy which can further focus treatment.[41] Surgical excision of CMBC is usually not feasible and standard of care treatments are limited in their efficacy.

Drug-Device Combination

The REM-001 combination therapy has several benefits compared to the shortcomings inherent to other CMBC treatments. It can be targeted toward the tumor site, presents minimal systemic effects and can be used in combination with other approaches. For REM-001, historical trial results demonstrated a complete response in over 80% of evaluable tumor sites.

The CMBC program was launched in the 1990s by Miravant which conducted several small trials including several Phase II/III trials and a Phase III trial that all together enrolled about 150 subjects. Results were promising in terms of safety and efficacy but Miravant instead decided to pursue SnET2 in the larger market of ophthalmology with an initial focus on macular degeneration. Miravant abandoned the CMBC program in 1998 but followed patients' progress providing a valuable safety dataset that supported a pivotal Phase III trial in ophthalmology and a subsequent NDA and approvable letter.

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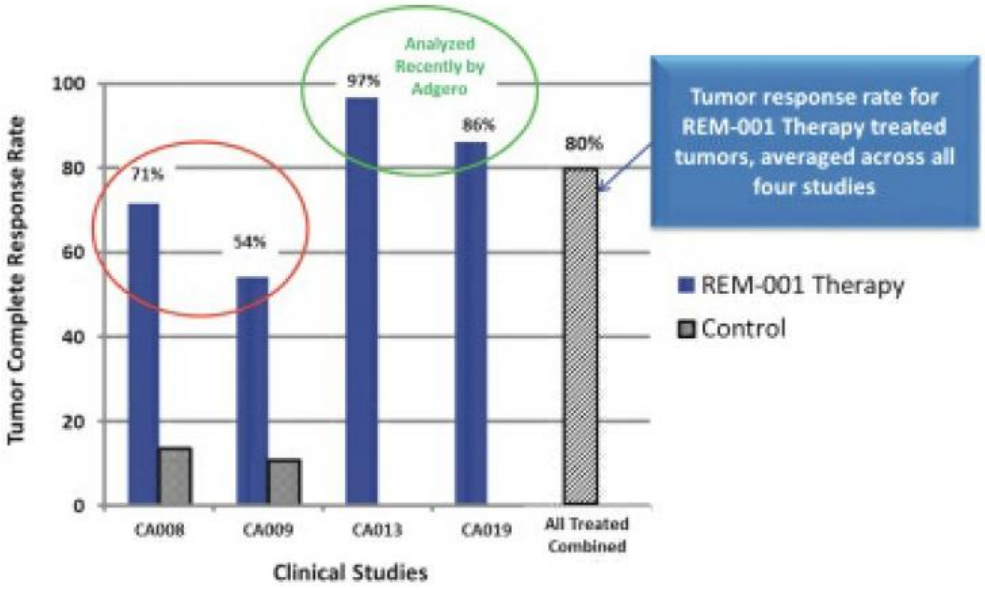
[31] https://www.wcrf.org/dietandcancer/cancer-trends/breast-cancer-statistics
[32] https://www.breastcancer.org/symptoms/understand_bc/statistics
[33] https://www.cdc.gov/cancer/breast/young_women/bringyourbrave/breast_cancer_young_women/risk_factors.htm?s_cid=byb_sem_027
[34] https://www.breastcancer.org/symptoms/understand_bc/statistics
[35] https://www.cdc.gov/cancer/breast/basic_info/risk_factors.htm
[36] Krathen RA, Orengo IF, Rosen T. Cutaneous metastasis: a meta-analysis of data. *South Med J*. 2003;96(2):164-167. doi:10.1097/01.SMJ.0000053676.73249.E5
[37] https://breastcancernow.org/information-support/facing-breast-cancer/secondary-metastatic-breast-cancer/secondary-breast-cancer-has-spread-skin-skin-metastases
[38] Mordenti C, Peris K, Concetta Fargnoli M, Cerroni L, Chimenti S. Acta dermatovenerologica. 2000. Cutaneous metastatic breast carcinoma; p. 9. < wwwmfuni-ljsi/acta-apa/acta-apa-00-4/mordenti.html> (Verson current at July 21, 2008)
[39] Bittencourt Mde J, Carvalho AH, Nascimento BA, Freitas LK, Parijós AM. Cutaneous metastasis of a breast cancer diagnosed 13 years before. *An Bras Dermatol*. 2015;90(3 Suppl 1):134-137. doi:10.1590/abd1806-4841.20153842
[40] Bittencourt Mde J, Carvalho AH, Nascimento BA, Freitas LK, Parijós AM. Cutaneous metastasis of a breast cancer diagnosed 13 years before. *An Bras Dermatol*. 2015;90(3 Suppl 1):134-137. doi:10.1590/abd1806-4841.20153842
[41] https://breastcancernow.org/information-support/facing-breast-cancer/secondary-metastatic-breast-cancer/secondary-breast-cancer-has-spread-skin-skin-metastases

Clinical Trials

Four Phase II/III studies were conducted with REM-001 for CMBC. An initial Phase I dose escalation trial was used to identify the dose used in subsequent Phase II and higher trials. REM-001 Phase I doses ranged from 0.1 mg/kg to 1.2 mg/kg and light doses from 100 to 200 J/cm^2. A dose of 1.2 mg/kg and 200 J/cm^2 yielded over an overall response rate of over 90% and was selected for further clinical study.

The four Phase II/III trials also used a drug dose of 1.2 mg/kg and light dose of 200 J/cm^2. The four trials were designated CA008 (32 patients), CA009 (36 patients), CA013 (56 patients) and CA019 (25 patients). Primary endpoints for CA008 and CA009 were objective tumor response rate, quality-of-life change, device performance and patient safety. The tumor response rate for CA008 and CA009 was a mean of 33% and 39% respectively; however, the strength of the data was suspect due to the low number of observations and the presence of only two control lesions. Clinical success was also used as an endpoint and was 60% and 50% for CA008 and CA009, respectively. Results suggested a treatment benefit. CA013 and CA019 used similar endpoints; however, they excluded measurement by paired response and did not include control lesions in the analysis. Clinical success in these groups was 88% and 83%, respectively. Shortcomings in these trials included excluding or severely limiting enrollment for patients on chemotherapy and removal of patients who changed their chemotherapy. This eliminated patients receiving standard of care from consideration, reducing the addressable population for the trial.

Exhibit IX – Complete Response for REM-001[42]



Adverse events for the studies were pain and photosensitivity. There were 17 SAEs that were judged to be possibly, probably or definitely related to treatment. The SAEs were not deemed to be life threatening and no deaths occurred.

Phase III Trial Design

In October 2017, the company held a Type B face-to-face guidance meeting with FDA to sketch out the design of a Phase 3 trial in CMBC. In May 2018, Adgero held a Type B end-of-Phase II meeting with FDA that focused on its plans for addressing chemistry, manufacturing and control (CMC) and device elements related to advancing REM-001 for CMBC. During these interactions FDA provided guidance on a number of clinical parameters it wants measured in the clinical trial and addressed CMC and device plans. Based on FDA's responses, Kintara plans to conduct a Phase III clinical trial in CMBC to test the safety and efficacy of REM-001 for marketing approval. In June 2018, Kintara's predecessor company Adgero submitted to FDA a Phase III protocol and statistical analysis plan incorporating feedback received from the agency at the October 2017 meeting. The company has also undertaken extensive discussions with several clinical research organizations to carry out the Phase III trial and has received five detailed proposals.

The anticipated Phase III trial design will be constructed as a multi-center study conservatively enrolling 100 to 150 CMBC patients with prior radiation and chemotherapy. The Phase III will be preceded by a confirmatory trial treating patients at a lower dose than that used by in the previous studies. Kintara management believes that if the

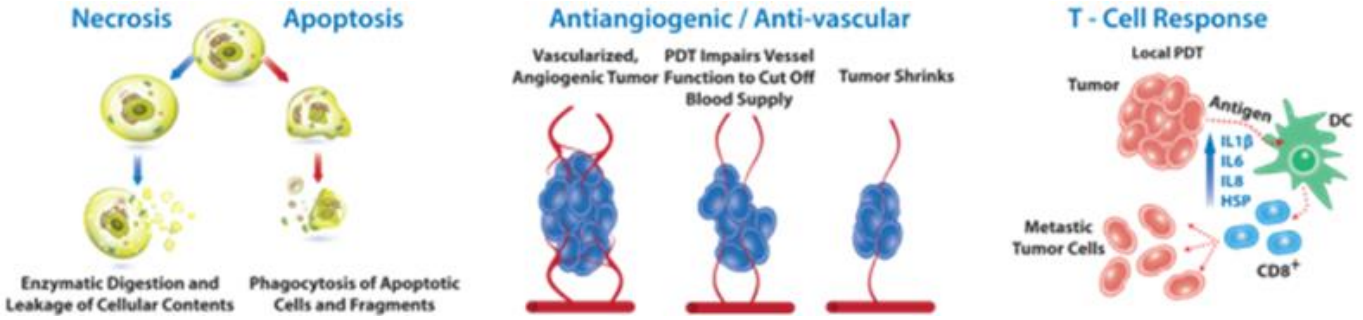
[42] Source: Kintara (DelMar Pharmaceuticals) Proxy Statement/Prospectus, July 2, 2020. p. 176

lead-in segment of the trial provides a strong and consistent signal, analysis of the proposed population may reduce the number of required enrollees to achieve statistical significance by a third. Management estimates that the lead-in confirmatory trial will cost approximately $7 million for the 15 patients enrolled, and from $20 to $30 million for the main body of the study.

Mechanism of Action

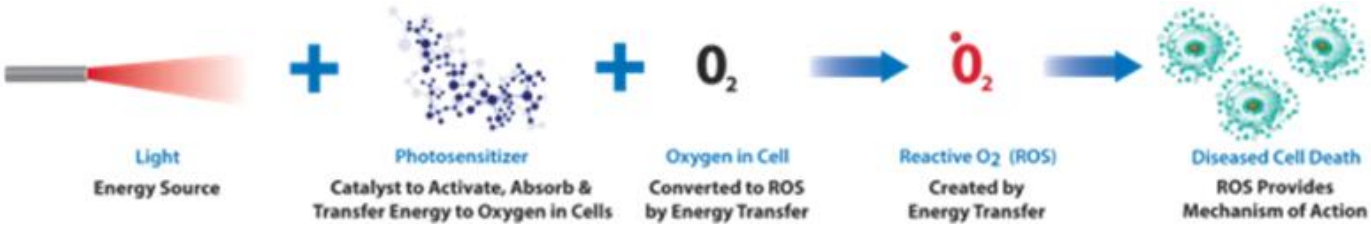
See here[43] for video explaining the mode of action for the PDT drug. REM-001 is able to bring about destruction of cancer cells through multiple mechanisms of action. This is achieved through apoptosis, necrosis, vascular destruction and immune activation. REM-001 is a light activated drug which acts as a catalyst upon absorbing light energy to generate reactive oxygen species (ROS) that, in turn, initiate various mechanisms. **Apoptosis** is engaged when the ROS alter mitochondria membrane permeability to allow the release of activators that initiate apoptosis. High doses of ROS can overwhelm a cell and induce cellular **necrosis** while also creating permeability in micro-vessels and bringing about fatal damage to the tumor's blood supply through **anti-angiogenesis**. Research indicates that PDT treatments can also able to induce an immune response, including the activation of CD8+ T cells to attack tumor cells.

Exhibit X – Mechanism of Action of REM-001[44]



The REM-001 active pharmaceutical ingredient (API) is a metal-based compound that is taken up by cancer cells due to their higher metabolism called tin ethyl etiopurpurin (SnET2).

Exhibit XI – Activation of REM-001[45]



Safety

REM-001 remains inactive when not exposed to the specific wavelengths of light in the activating laser. REM-001 has been used in more than 1,100 patients in prior clinical trials and was reviewed by the FDA in an NDA for age related macular degeneration (AMD). The FDA responded to the submission with an approvable letter[46] contingent upon completion of a Phase III trial. Treatment related adverse events were largely related to pain, edema and transient photosensitivity which resolved during the course of the studies.

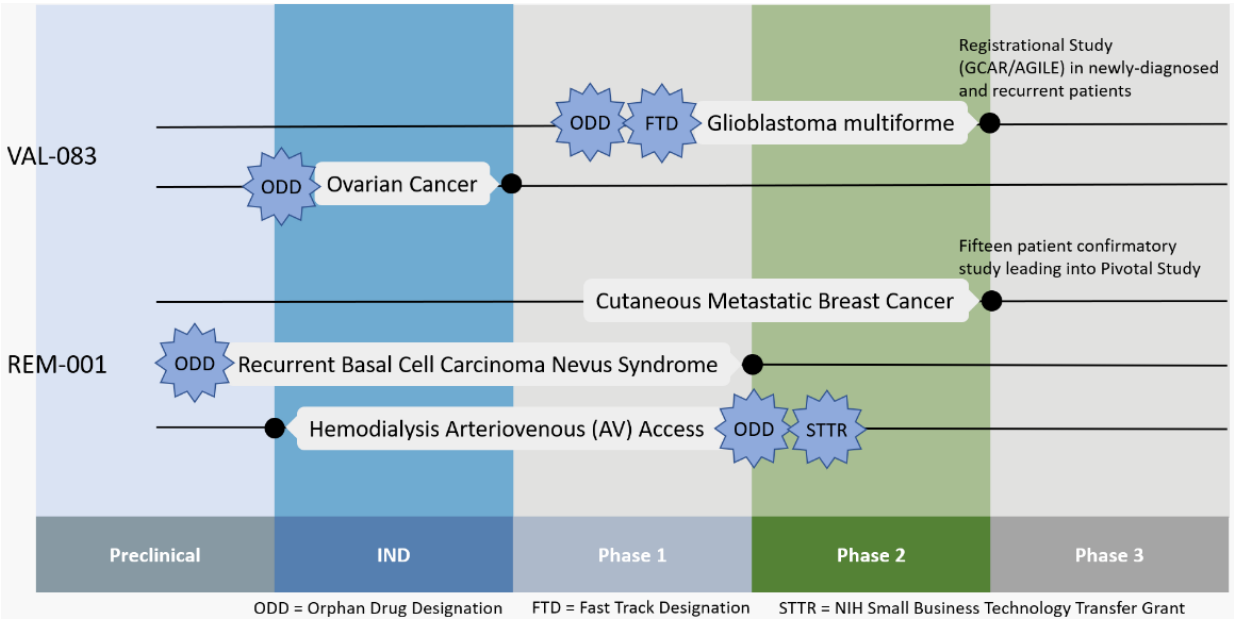
A benefit of using a photosensitizing compound is that it remains inactive until exposed to a specific wavelength of light. However, patients should avoid extended exposure to bright light and direct sunlight. Based on the company's assessment, avoiding bright light for two to four weeks following treatment should be sufficient to avoid related adverse events.

[43] https://www.kintara.com/pipeline/rem-001/cutaneous-metastatic-breast-cancer
[44] Source: Kintara website, accessed September 2020
[45] Source: Kintara website, accessed September 2020
[46] The FDA discontinued the use of approvable letters with the final rule published in July 2008.

Development Pipeline

Kintara's pipeline consists of two candidates, VAL-083 and REM-001. For VAL-083, GBM is the active indication being investigated in multiple settings with ovarian cancer cleared for clinical trials with an orphan designation granted. Ovarian and pediatric brain tumor programs are on hold pending sufficient funding. REM-001's primary indication is in CMBC, with follow-on indications for recurrent BCCNS and hemodialysis arteriovenous access, both of which have been granted an orphan designation. Both follow-on indications are on hold pending the raise of additional capital specifically for their advancement. Below is a graphic summary of the company's pipeline.

Exhibit XII - VAL-083 Development Pipeline[47]



Chemistry, Manufacturing and Control (CMC)

Guangxi Wuzhou Pharmaceutical Company (Guangxi) is the manufacturer for VAL-083 used in the trials conducted in China and Chemi SPA, a subsidiary of Italfarmaco, is manufacturing the drug product used in the studies at MD Anderson and for future clinical trials. Testing is performed by Chemi SPA and WuXi AppTec.

One of the benefits of participating with GCAR is the world-class partners that will provide contract research organization (CRO) and laboratory services. IQVIA, which is the largest CRO in the world, will be providing trial management services and Covance will provide laboratory services.

With respect to REM-001, Kintara expects to adapt the quality standards of its product to meet the currently recommended regulatory requirements. The FDA has indicated that Kintara may use light delivery devices that have been shown to be functionally equivalent to the devices previously cleared in prior trials. Since mid-2018 Kintara has engaged a contract manufacturer which has manufactured the starting material for its API, manufactured two API lots under GMP and has stability testing underway. Kintara is currently working to undertake GMP manufacture of finished drug product for use in its clinical trial.

Manufacturing and Supplies

Manufacturing for REM-001 was developed over a decade long period and has been historically produced at commercial scale by a contract manufacturer. The company has engaged a manufacturer for the SnET2 active pharmaceutical ingredient (API) and is in late stage discussions with other contract manufacturers to manufacture the REM-001 drug product.

The lasers used for the light source will be different from those used in the original Miravant studies. FDA feedback suggests that a new laser can be used if shown to be similar to the previously used device. The company has identified several manufacturers for this device which is essentially a commodity product.

[47] Source: Kintara Corporate Website, Accessed September 2020.

Merger Transaction Combining DelMar with Adgero

On June 10, 2020, predecessor company DelMar announced the intended acquisition of privately held Adgero Biopharmaceuticals. The transaction was designed to convert each share of Adgero common stock into shares of Kintara common stock in a ratio that gives former DelMar shareholders 50.5% and Adgero shareholders 49.5% voting ownership in the company. Following shareholder approval and the transaction closing, the company's name changed to Kintara Therapeutics and continues to trade on the NASDAQ, now under the ticker symbol KTRA. The new board for the company will include four members designated by DelMar, two by Adgero and one member that will be mutually agreed to by the parties. The company will move forward with each advancing their lead Phase III oncology assets in parallel. A special shareholder meeting was held on August 14, 2020 to vote on the merger proposal which was approved.

Intellectual Property

Although the primary patents for VAL-083 have expired, there are newer patents related to the synthesis, indications and purification of the drug that continue to provide market defensibility. Chemical synthesis of VAL-083 was initially developed by the NCI, which was improved by Kintara. Thirteen patents have been granted in the US and 20 have been granted worldwide for VAL-083. Kintara provides a listing of 33 pending and granted patents in its filings regarding the method of synthesis of dianhydrogalactitol, improved methods for analyzing and determining impurities in the drug and the use of the drug to treat a variety of cancers among others. All of Kintara's primary indications for VAL-083 have been granted orphan status which provides seven years of exclusivity in the United States following FDA approval for that indication.

REM-001's intellectual property was largely developed by Miravant and is based on scientific and regulatory data, product know-how and eight issued US utility patents, some of which have expired or are near expiration. With most patents expected to expire prior to approval, REM-001 will rely on exclusivity protection when approved which is expected to be five years in the United States[48] and up to eleven years in Europe.

Corporate Milestones

Kintara is conducting multiple clinical trials for GBM in VAL-083 and will soon launch a pivotal study for REM-001. The focus for the company is to complete the various Phase II trials underway and begin the GCAR registrational effort and the REM-001 study before year end 2020. Below we list key milestones that have occurred in the last year and anticipated future events.

- AACR – June 2020
- Completed enrollment, newly diagnosed GBM – 1Q:20
- Acquisition of Adgero announced – June 2020
- NBTS & NFCR Loan in Support of GCAR – June 2020
- Complete enrollment, recurrent GBM – 3Q:20
- Merger Vote/Merger Close – August 14, 2020
- Launch GCAR AGILE registration study, stage 1 – 4Q:20
- Initiate CMBC confirmatory trial – 1H:21
- Top-line preliminary results for Newly Diagnosed Phase I GBM study – 4Q:20
- Top-line preliminary results for Recurrent Phase 2 GBM study – 1Q:21
- Top-line preliminary results for Adjuvant Phase 2 GBM study – 2Q:21
- CMBC confirmatory trial results & Phase III start – 2H:21
- GCAR AGILE registration study, stage 2 – 1Q:22
- CMBC trial complete – 2023
- CMBC NDA filing - 2024
- GCAR AGILE top-line results – 2023

[48] There is a small chance that REM-001 could be granted orphan status.

RISKS

All investments contain an element of risk that reflects the uncertainty of a business and what it will ultimately achieve. Some investments exhibit higher predictability, with current cash flows and established sales. These enterprises will have a lower level of perceived risk while other companies that are developing an undefined, new technology have a much higher level of perceived risk.

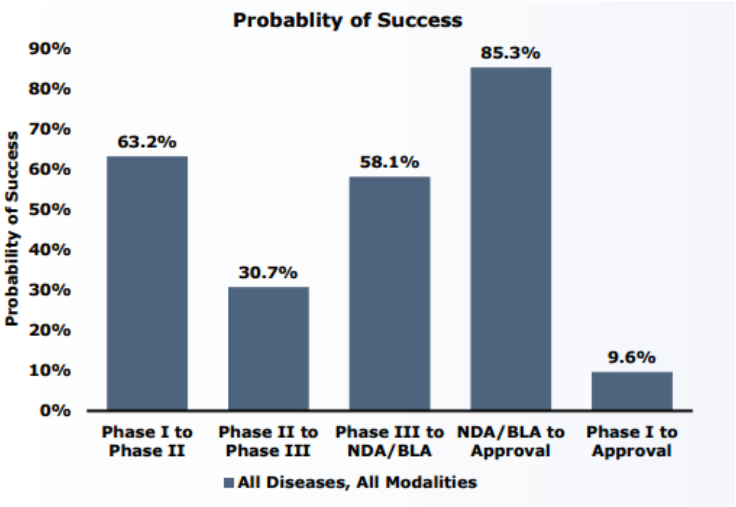
The biotechnology space includes companies at both ends of the spectrum: mega-cap pharmaceutical powerhouses that have multiple products currently generating revenues, and small operations with a handful of employees conducting pre-clinical studies. Many of the risks faced by the large pharmaceutical companies and smaller biotechnology-focused firms are similar; however, there are some hazards that are particular to smaller companies that have not yet established themselves or their products.

For smaller, early-stage companies, investing in drug development is a lengthy process. The timeframe for conducting pre-clinical research to eventually commercializing a drug can take from 12 to 15 years or even longer given market and company-specific conditions. And with, on average, only one in one thousand preclinical compounds eventually making it to the market, the risks are substantial.

Even if a company has a strong, experienced team that is developing a therapy with a high likelihood of success and a large addressable market, securing funding may be difficult. Access to financing comes and goes in cycles. During periods of improving confidence, capital may be easy to obtain; however, during a liquidity crisis or a period of heightened risk perception, even companies with bright prospects may be in trouble if they are dependent on the financial markets to fund their work. If capital is needed to sustain operations and it is not readily available, the company may be forced to suspend research and development, sell equity at a substantial discount to previous valuations and dilute earlier shareholders. A lack of funding may leave potentially promising therapies without a viable route to progress or force a company to accept onerous terms.

All drugs must navigate the regulatory approval process in the US, EU, Japan and other countries before commercialization in those regions. Success is uncertain and may take years depending upon the needs and desires of the determining authority. Substantial expense is undertaken to bring a molecule or compound through clinical trials and address all of the regulatory agencies' concerns. Companies that have a long history of research success in drug development, with opinion leaders and experts advocating for the product in the field, are better positioned to face regulatory hurdles and gain acceptance by payors and providers. Previous success with the FDA or other regulatory agencies is another attractive attribute for sponsors. Some accelerated pathways to approval are available such as those outlined in the Orphan Drug Act and the Breakthrough Therapy designation; however, changes in sentiment or perceived safety could change the regulatory environment to demand a more thorough process and these pathways may be extended or additional requirements may be put in place.

Exhibit XIII – Success of Phased Trials and Regulatory Approval[49]



[49]Clinical Development Success Rates 2006-15. David Thomas, Justin Burns, John Audette, Adam Carroll, Corey Dow-Hygelund, Michael Hay.

Kintara, as a clinical stage oncology product development company, bears a variety of company specific risks. Initially, the company faces risks related to drug development and access to capital. After registrational data has been generated, the company faces commercialization risks related to either partnering or marketing the candidate.

The company will initially rely on fundraising to sustain its efforts until it can generate revenue. Kintara recently raised $25 million adding to its $5 million balance at the end of March 2020. Based on our estimates, this provides sufficient capital to support operations until the second half of calendar 2021. If Kintara is unable to source additional capital at that time, the company may need to halt its clinical trials.

Kintara bears risks related to the execution of the trials, as well as trial outcomes. Clinical trials are subject to regulatory requirements and require working with partners, contractors and patients. In orphan indications, due to the scarcity of individuals with the target disease, full enrollment may be difficult. Assuming successful enrollment, the trial must also meet its endpoints and demonstrate efficacy. Clinical trials for orphan indications are smaller, have less diversity and use surrogate endpoints that may not completely correlate with OS.[50] Kintara's lead candidate, VAL-083, is currently in two Phase II clinical trials, one, as a monotherapy in recurrent TMZ-resistant MGMT-unmethylated GBM, and the other, in combination with X-ray therapy in newly-diagnosed MGMT-unmethylated GBM. Candidate REM-001 will start a Phase III trial in the near term in a small population; however, it is unlikely it will qualify for orphan status. There is no guarantee that any candidate in Kintara's pipeline will be granted marketing approval. Many of Kintara's indications have been granted orphan status, which provides tax and marketing incentives; however, orphan designation by definition implies a smaller market than that available to non-orphan indications.

Once clinical trials are complete and marketing approval granted, biotechnology firms must commercialize. Successful marketing requires acceptance by the medical community and is frequently difficult for small, inexperienced companies that must hire a new sales force. In many cases, clinical-stage biotech companies establish partnerships with pharmaceutical firms that carry the drug through the final stages of clinical trials and then to market. Kintara management has indicated that partnering is a likely route. There may be few suitors for VAL-083 or REM-001 which can limit the ultimate value of the product to Kintara shareholders.

For orphan indications, the cost of research, development and marketing the drug may be challenging to spread across a large population and high prices are required to achieve a sufficient return. Research by Chambers *et al.* concludes that largest US private health plans restrict orphan drug coverage in one third of coverage decisions and that the restrictions are correlated with disease prevalence and annual cost.[51] This condition could limit the ultimate penetration potential for a drug that addresses an orphan indication. VAL-083, as a chemotherapy and a DNA-targeting small-molecule, is expected to command a price lower than the more prominent immuno-oncology drugs.

Kintara Therapeutics has not reported any material disruption to its operations as a result of the coronavirus pandemic. The company's primary focus is its Phase II clinical trials which are being conducted by partners in the US and China. A resurgence of the coronavirus may impact data collection in these locations and could delay the reporting of results. Travel restrictions and reallocation of resources also affect the manufacture and distribution of drug product and availability of physicians and patients to conduct clinical trials. Hospitals where clinical trials are conducted are at risk of high demand for services related to the coronavirus pandemic that may draw away resources. The presence of large numbers of individuals infected with the coronavirus may dissuade patients from keeping appointments for on-site visits, negatively affecting enrollment and increasing the withdrawal rate. The pandemic may also delay the start of the GCAR trial if sites are closed. COVID-19 has impacted capital markets and while it appears that capital remains available for companies with attractive prospects, the pandemic may create new disruptions and increase risk perception of capital providers, thereby closing this door in the future.

While we have discussed a broad variety of risks above, we believe that our forecast parameters, discount rates, success probabilities and valuation metrics address these eventualities and our target price reflects an assumption of these risks faced by all biotechnology companies.

[50] Kesselheim AS, Myers JA, Avorn J. Characteristics of Clinical Trials to Support Approval of Orphan vs Nonorphan Drugs for Cancer. JAMA. 2011;305(22):2320–2326. doi:10.1001/jama.2011.769

[51] Chambers JD, Panzer AD, Kim DD, Margaretos NM, Neumann PJ. Variation in US private health plans' coverage of orphan drugs. Am J Manag Care. 2019;25(10):508- 512.

Competitors, Peers and Competing Therapies

Kintara Therapeutics' lead candidates are VAL-083, a first-in-class chemotherapy targeting resistant solid tumors and/or orphan cancer indications and REM-001, a PDT to treat CMBC. Its competitors and peers generally include cancer-oriented clinical stage firms, especially those working on GBM and CMBC. A search of clinicaltrials.gov finds over 230 studies underway in these indications either Phase II or Phase III that are not yet recruiting, recruiting or active and have completed enrollment.

Some of the companies that are directly working on studies in GBM include Bayer with its kinase inhibitor candidate regorafenib. Several checkpoint inhibitors are also participating in clinical trials, such as Merck's pembrolizumab and Bristol-Myers' nivolumab; however, success has been hard to come by for this class due to the difficulty that antibodies have in crossing the blood brain barrier. Eli Lilly is studying abemaciclib in Phase II studies and Ziopharm is researching its investigational product Ad-RTS-hIL-12 in combination with veledimex to see if it will prompt the body's immune system to fight GBM. DNA medicines are also pursuing treatment as Inovio continues a Phase II trial in GBM with its INO-5401 candidate in collaboration with Regeneron. There are numerous other studies underway; however, the failure rate for this indication has been high, leaving the field wide open for a candidate that can show improved results.

Treatments for CMBC include chemotherapy, radiation therapy, surgery, cryotherapy, and other approaches. Other companies developing treatments that are similar to Kintara's approach and include IGEA Medical in Europe. Pinnacle Biologics, a subsidiary of Advanz Pharma (TSX: ADVZ), has an approved PDT product called Photofrin but it is not approved for cutaneous lesions. Other PDT companies such as Biofrontera focus on topical treatments of less serious dermatological conditions such as Ameluz for actinic keratosis.

IGEA Medical is an electrochemotherapy company that uses electroporation to permeabilize cancer cells and allow chemotherapeutic drugs to enter. IGEA is headquartered in the UK with its parent in Italy. The company uses its IGEA CLINIPORATOR device combined with chemotherapy to treat cancers such as melanoma and non-melanoma skin cancers (including basal cell carcinoma, squamous cell carcinoma, Kaposi's sarcoma); local recurrences or skin metastases from breast cancer, and head and neck cancers including oral cancer. The products are not available in the US.

Pinnacle Biologics is a specialty pharmaceutical company that commercializes Photofrin PDT. Photofrin (porfimer sodium) is indicated for esophageal cancer, endobronchial cancer and high-grade dysplasia in Barrett's Esophagus. The therapy consists of a two-stage process that requires the administration of drug and light. Sales in 2020 are estimated to be about $60 million.[52]

Biofrontera's Ameluz is a prescription drug for the lesion-directed and field-directed PDT of actinic keratoses of mild- to-moderate severity on the face and scalp with red light, using an LED lamp. The product combines PDT with Ameluz gel (5-aminolevulinic acid) and is intended for cutaneous use.

[52] Source: Evaluate Pharma Accessed August 2020.

Exhibit XIV – Peers and Competitors[53]

Ticker	Company	Price	MktCap (MM)	EV (MM)	Therapeutic Area
ABBV	Pharmacyclics	$90.22	$159,223	$235,244	Bruton's tyrosine kinase inhibitor for cancer
AGEN	Agenus	$3.95	$725	$680	Immuno-oncology
AGIO	Agios Pharma	$39.29	$2,715	$2,028	Small molecule targeting grow th factor pathw ay in cancer
BAYRY	Bayer	$16.15	$60,243	$91,337	Regorafenib for GBM
BFRA	Biofrontera	$7.42	$166	$178	Commercializes Ameluz
CLDX	Celldex Tx	$11.26	$441	$235	Antibody & protein based therapy for cancer/Rindopepimut
CLVS	Clovis Oncology	$5.18	$457	$806	Cancer treatments w ith focus on precision medicine
CXRXF	Advanz Pharma	$2.98	$303	$304	Parent of Pinnacle Bio, w hich commercializes Photofrin
EPZM	Epizyme	$12.67	$1,286	$1,086	Epigenetic medicines for cancer
GSK	Tesaro	$38.97	$97,757	$118,917	Oral poly ADP ribose polymerase inhibitor for ovarian cancer
IMGN	ImmunoGen	$3.44	$601	$404	Antibody-drug conjugates for treatment of cancer
IMUC	ImmunoCellular Tx	$0.03	$1	($2)	Stem-cell derived T-cells/ICT-107
INCY	Incyte	$89.73	$19,624	$18,066	Oral JAK1/JAK2 inhibitors for rheumatoid arthritis
INFI	Infinity Pharma	$0.95	$56	$15	Oral P3K-gamma inhibitor for cancers
INO	Inovio	$9.61	$1,610	$1,337	INO-5401 in Ph2 for GBM w ith Regeneron
KPTI	Karyopharm Tx	$14.76	$1,085	$912	Nuclear export inhibition for cancer
MACK	Merrimack Pharma	$3.73	$50	$34	Liposomal irinotecan for pancreatic adenocarcinoma
MGNX	MacroGenics	$26.43	$1,430	$1,223	DART,TRIDENT & FC Ab engineering optimization platforms
MREO	OncoMed Pharma	$2.67	$66	$64	Anti-TIGIT monoclonal antibody for pancreatic cancer
MRK	Merck	$83.33	$210,762	$225,815	Temodar (GBM)
NBIO	Nascent Biotech	$0.06	$4	$4	Ecto-domain vimentin targeting antibodies
NVS	Endocyte	$87.33	$199,872	$219,232	Small molecule drug conjugates
NWBO	Northw est BioTx	$0.64	$477	$475	Dendritic cell-based immunotherapy for cancer/CDVax-L
ONTX	Onconova Tx	$0.21	$37	$10	Small molecules for Myelodysplastic Syndromes
PBYI	Puma Bio	$9.65	$383	$384	Antibodies for cancer
PFE	BIND Tx	$35.93	$199,659	$227,394	Accurins targeting hematological and solid tumors
RHHBY	Genentech	$43.88	$300,512	$301,327	Avastin (GBM)
SGEN	Seattle Genetics	$146.48	$25,487	$24,591	Monoclonal-antibody-drug conjugates for treatment of cancer
ZIOP	Ziopharm Oncology	$2.46	$527	$374	Engineered T Cells targeting patient-unique neoantigens
Pvt	Beactica				Small-molecule allosteric LSD1 modulators
Pvt	Boston Biomedical				Cancer stemness pathw ays and tumor antigens
Pvt	Empirica Tx				CD133-targeting CAR-T cell therapy
Pvt	IGEA Medical				Electrochemotherapy using Cliniporator device
KTRA	Kintara Tx	$1.36	$15.6	$15.4	Developing VAL083 for GBM & REM-001 for CMBC

[53] Price and market capitalization data is as of September 8, 2020. Source: Analyst work and Zacks Research System.

MANAGEMENT PROFILES

Saiid Zarrabian, President, Chief Executive Officer and Director

Mr. Zarrabian has served as Kintara's (through predecessor company DelMar) director since July 7, 2017, CEO since November 3, 2017, and President since January 1, 2018. From 2014 to 2015 he operated a private personal business. Since October 2016 Mr. Zarrabian has served as an advisor to Redline Capital Partners, SA, a Luxembourg-based investment firm. From 2012 to 2014 he served as Chairman and member of the Board of La Jolla Pharmaceutical Company during which time the company transitioned from an OTC listed company to a NASDAQ listed company. From 2012 to 2013 he served as President of the Protein Production Division of Intrexon Corporation, a synthetic biology company. He has also previously served as CEO and member of the Board of Cyntellect, Inc., a stem cell processing and visualization Instrumentation company, as President and COO of Senomyx, Inc., a company focused on discovery and commercialization of new flavor ingredients, and as COO of Pharmacopeia, Inc., a former publicly-traded provider of combinatorial chemistry discovery services and compounds, where he also served as President & COO of its MSI Division. In addition, Mr. Zarrabian has served on numerous private and public company boards, including at Immune Therapeutics, Inc., Exemplar Pharma, LLC, Ambit Biosciences Corporation, eMolecules, Inc. and Penwest Pharmaceuticals Co. His other experience includes COO at Molecular Simulations, COO of Symbolics, Inc., and as R&D Director at Computervision, Inc.

Scott Praill, Chief Financial Officer

Mr. Praill, CPA, BSc. has been Kintara's CFO (through predecessor company DelMar) since January 29, 2013 and previously served as a consultant to the company. From 2004 to 2012 Mr. Praill was an independent consultant providing accounting and administrative services to companies in the resource industry. Mr. Praill served as CFO of Strata Oil & Gas, Inc. from June 2007 to September 2008. From November 1999 to October 2003, Mr. Praill was Director of Finance at Inflazyme Pharmaceuticals Inc. Mr. Praill completed his articling at Price Waterhouse (now PricewaterhouseCoopers LLP) and obtained his Chartered Professional Accountant designation in 1996. Mr. Praill obtained his Certified Public Accountant (Illinois) designation in 2001. Mr. Praill received a Financial Management Diploma (Honors) from British Columbia Institute of Technology in 1993, and a Bachelor of Science from Simon Fraser University in 1989.

Dennis Brown, PhD, Chief Scientific Officer

Dr. Brown founded DelMar Pharmaceuticals and has served as CSO and director of the company since its inception in early 2013. Dr. Brown will continue serving Kintara as CSO. Dr. Brown has more than thirty years of drug discovery and development experience. He has served as Chairman of Mountain View Pharmaceuticals' Board of Directors since 2000 and is the President of Valent. In 1999 he founded ChemGenex Therapeutics, which merged with a publicly traded Australian company in 2004 to become ChemGenex Pharmaceuticals (ASX: CXS/NASDAQ: CXSP), of which he served as President and a Director until 2009. He was co-founder of Matrix Pharmaceutical, Inc., where he served as Vice President (VP) of Scientific Affairs from 1985-1995 and as VP, Discovery Research, from 1995-1999. He also previously served as an Assistant Professor of Radiology at Harvard University Medical School and as a Research Associate in Radiology at Stanford University Medical School. He received his B.A. in biology and chemistry (1971), M.S. in cell biology (1975) and Ph.D. in radiation and cancer biology (1979), all from New York University. Dr. Brown is the inventor of many issued U.S. patents and applications, many with foreign counterparts.

John Liatos, Senior Vice President, Business Development, Director

Mr. Liatos has served as Senior Vice President, Business Development and a Director since August 2020. He previously served as Adgero's interim CEO since April 2018, CFO since October 11, 2017 and a director of Adgero since April 2020. Mr. Liatos has over 20 years of financial and operational experience in the private equity and venture capital industries. Since 2008, Mr. Liatos has served as Co-Founding Partner at Aceras BioMedical, an investment vehicle focused on forming and managing new companies to acquire and develop pre-commercial stage biomedical assets. While at Aceras, Mr. Liatos was involved in the overall formation and business strategy of the Aceras portfolio companies, including functioning as interim CFO and COO through the first twelve to eighteen months of operations for such portfolio companies. From 2005 to 2008, Mr. Liatos served as CFO to Paramount Biosciences, LLC, a drug development and biotechnology investment firm. From 1997 to 2005, Mr. Liatos worked as a Senior Associate for private equity firm Gefinor USA, Inc., from 1995 to 1997, as a Senior Associate at RJR Nabisco, Inc. in Financial Reporting and Consolidations and from 1992 to 1995, as an auditor for Richard A. Eisner & Company, LLP. Mr. Liatos earned a B.S. in Business Administration from the Citadel. Mr. Liatos' business executive knowledge and experience qualify him to serve on the combined company's board of directors.

Steven Rychnovsky, PhD. Vice President, Research and Development

Dr. Rychnovsky has served as Kintara's VP of R&D since August 14, 2020. Previously he was Adgero's VP of Operations and Product Development since 2016 and has held similar positions with Adgero since 2012. Dr. Rychnovsky is co-founder of Adgero and has experience in all aspects of the PDT developed by Miravant Medical Technologies, and its wholly-owned subsidiaries, a former public pharmaceutical and research development company (collectively, "Miravant") and, since 2012, Dr. Rychnovsky has worked with Dr. Pilkiewicz to develop Adgero's business strategy and plans for commercialization of REM-001. From 2008 to 2012 Dr. Rychnovsky served as a consultant to St. Cloud Investments, maintaining the Miravant assets and identifying a party to license or purchase those assets and pursue commercial development. In 2012, Dr. Rychnovsky was a co-founder of Endocole, LLC, a medical device company. He worked with Endocole from 2012 to 2015, where he focused on raising initial grant financing and worked in the development and preclinical testing of its proof-of-concept device and was a co-inventor of Endocole's key intellectual property. EndoCole has completed its initial preclinical studies and is currently raising private funding to initiate a clinical study. From 2008 to 2012, Dr. Rychnovsky was a Senior Research Physicist at Sotera Defense Solutions, Inc., a Naval Research Laboratory optical nanotechnology group focused on applied research in optical materials and devices. From 2003 to 2008, Dr. Rychnovsky served as the Cardiovascular Program Manager at Miravant, where he invented key elements of Miravant's cardiovascular technology. Dr. Rychnovsky also served as the Director of Systems and Engineering at Miravant where he managed the team responsible for development of Miravant's PDT light delivery technology. During his time at Miravant, Dr. Rychnovsky was involved in new product development for its cancer, ophthalmology and cardiovascular programs, including clinical development of REM-001 and related PDT technology. Dr. Rychnovsky earned a B.S. in electrical engineering from Iowa State University, an M.S. in electrical engineering from the University of Minnesota, and has a Ph.D. in photonics from the University of Iowa.

Greg Johnson, (Acting) Head of Operations

Mr. Johnson has more than 25 years of experience in Biotech and Clinical Research, with recognized expertise in strategic planning, project management and operations management, as well as in electronic data capture and the implementation and use of computerized systems in a clinical research setting. Mr. Johnson is a principal with Cagley Johnson Consulting Inc. Prior to founding his consulting company, he was COO then President and CFO for MedGenesis Therapeutix (2007-2017). Mr. Johnson previously held a number of senior roles at PRA International (1992-2007; now PRA Health Sciences) in four different countries. Mr. Johnson earned an M.Sc. in clinical research from Liverpool John Moores University, is certified (PMP) by the Project Management Institute and is a Fellow of the Institute of Clinical Research (FICR).

Financial and Operational Results

Kintara, while still operating as DelMar, reported its fiscal third quarter 2020 results on May 13, 2020 for the three and nine month periods ending March 31, 2020.[54] The 10-Q filing was simultaneously submitted to the SEC. During the period, the company published a peer-reviewed summary of interim results in the journal Glioma for the Phase II trial being conducted in China as first line treatment. Shortly after publication, the final patient was enrolled in the trial and the company guided toward an August readout of initial data. The adjuvant study at MD Anderson also hit a milestone with over 50% enrollment in early March and 90% enrollment after the end of the quarter in early May 2020. June was a busy month for the company with announcements of selection to participate in GCAR's AGILE study, the announcement of the intent to acquire Adgero and presentation of several posters at AACR updating the scientific community on Phase II study status. DelMar rounded out the month announcing the award of a $500,000 loan by the NBTS and NFCR in support of the upcoming AGILE study.

The most notable achievement for the company was successful approval of the merger between DelMar and Adgero by stockholders on August 14th, forming Kintara. Following the closure, management was able to raise additional capital of $25 million to launch the Phase III VAL-083 and REM-001 programs.

Prior to the merger, DelMar consumed $2.0 million in expenses in its third quarter, 18% more than prior year amounts. Research and development was $0.9 million, increasing 22% on higher clinical development costs related to the number of subjects enrolled. This was partially offset by a decline in preclinical work. General and administrative expenses of $1.1 million expanded 15% with a rise in professional fees and share-based compensation. A variety of financial items netted $18[55] thousand to the bottom line resulting in a loss of ($2.0) million or ($0.17) per share. This compares to a ($1.7) million loss in 3Q:19 and a ($0.67) per share loss.

The balance sheet held $5.0 million in cash and equivalents and no debt as of fiscal third quarter end March 31, 2020, reflecting steady use of cash since the first quarter capital raise of $6.6 million. DelMar holds 648,613 shares of Series B preferred stock that is expected to have converted to approximately 162,153 equity shares prior to June 2021 and 278,530 shares of Series A preferred stock, which we consider the equivalent of debt. Cash burn for 3Q:20 was ($1.4) million compared to ($1.5) million in 3Q:19.

Following the end of the quarter and in conjunction with the closing of the merger with Adgero, the successor company raised $25 million in a series of closings ending on September 1st, 2020. Series C preferred stock was issued to raise these funds. It is initially convertible into 21.5 million shares of common stock and if held until the fourth anniversary of the issuance could add up to 36.6 million additional shares.

We anticipate an increase in cash burn from a near $2 million per quarter rate to a near $5 million rate as two Phase III programs move forward over the next few months.

[54] DelMar has a fiscal year calendar ending June 30.
[55] This includes a foreign exchange gain of $2.4 thousand, interest income of $17.0 thousand and preferred stock dividend of ($1.5) thousand for a net $17.9 offset to the quarterly loss.

VALUATION

VAL-083 is an alkylating chemotherapy that has been under investigation for decades by the NCI and is approved for two cancers in China. The drug is able to cross into the brain and induce interstrand cross-links in GBM tumors that trigger apoptosis and slow or reverse the advance of cancer. Although only about 40,000 new cases are diagnosed every year, GBM is one of the most aggressive cancers and most individuals diagnosed at this stage do not live much longer than a year with standard of care therapy. The lack of effective treatment highlights the need for new approaches, prompting Kintara to advance VAL-083 in multiple Phase II trials. We anticipate that by year end, the agent will contribute to a multi-part adaptive study that is expected to generate registrational data in unmethylated GBM by 2023. We forecast regulatory approval in 2024 and commercialization in 2025. VAL-083 has been granted orphan status by the FDA and EMA which provides seven years of exclusivity in the US and 10 years of exclusivity in Europe.

GBM is a rare disease that affects approximately 0.003% of the population, with a higher incidence in those of European descent. We see the primary setting for VAL-083 in MGMT-unmethylated patients, which we conservatively estimate to be about 60% of the total. This equates to just under 7,000 cases apiece in the US and top five EU countries[56] which are the primary regions where we anticipate commercialization. We forecast 50% penetration during the first year the drug is available, rising to 90% penetration by year four. Market share drops to zero in year eight, upon expiration of orphan exclusivity in the United States and in year 11 for European countries. Cost of a cycle of treatment is estimated to be $12,000 in the US (in 2025) and $6,000 in Europe (in 2025) growing at 3% per annum with each patient receiving an average of 6 cycles.

Our forecasts do not attach any value for commercialization outside of the US and Europe, although regions such as Japan and Oceana may be attractive markets in the future. We assume that a partner with a sales force already in place will license VAL-083 after approval and pay a 28% royalty on sales which is net of an estimated 2% royalty to be paid to Valent. Generally, deals of this type include upfront, milestones and royalties, and in this case we reflect the entire value of the arrangement in the royalty payment. As we expect a partner to commercialize VAL-083, we do not forecast future commercialization costs.

REM-001 is a PDT that combines an infused drug with a light source to provide targeted cancer treatment. The lead indication for this therapy is in CMBC, a relatively small population of cancer patients, although, also one that does not have an effective treatment and is particularly amenable to the PDT approach. We assume product sales in both the US and Western Europe. Population increase is forecast to be 1% per year and drug price inflation 3% per year.

Based on our review, we forecast an addressable market of from 24 to 25,000 patients in the US, which represents 60% of the 40,000 CMBC cases that we identify in our incidence discussion. Assuming approval, we anticipate first sales for REM-001 in late 2024 and an increase in penetration to 22% of the addressable market by 2026. Following the end of exclusivity in 2029, we anticipate a four percentage point decline in penetration each successive year until 2033. This yields a peak number of almost 5,800 treatments in 2029 and revenues of near $380 million in the US. Pricing is expected to be $56,000 (in 2024) per course of treatment in the US growing at 3% per year.

In Western Europe, we anticipate an addressable market of similar size to that in the United States; however, exclusivity is expected to endure for 11 years and pricing is expected to be above $32,000 per course of treatment (in 2025), also growing at 3% per annum. We anticipate a one year delay in commercialization relative to the US due to pricing negotiations in the EU-5 with first sales in 2025. Revenues are expected to grow to over $260 million by the final year of exclusivity in 2035.

We project that a partner will commercialize REM-001 on behalf of Kintara. Royalty revenues for all REM-001 sales are expected to be a net 24%, after subtracting the contractually obliged 6% owed to previous developers of the therapy.

We provide our operating cost estimates in the income statement at the end of this report until 2022. In 2023 to 2025, we forecast total cash operating costs of $27.7 million, $26.5 million and $5.6 million. In 2026 and beyond there is only minimal G&A forecast; however, we anticipate additional products to be advanced after approval of the lead programs and we will add the anticipated revenues and costs when new indications are actively pursued.

[56] Germany, UK, France, Italy and Spain.

Taxes are expected to be 26%, a combination of 21% federal and 5% state which will be recognized after working through accumulated net operating losses. We assume all warrants and options with an exercise price below $4 to be exercised which adds $16 million in cash and almost 14 million shares. Another 22 million shares are added to reflect the converted Series C preferred stock, which does not include any future stock dividends. We add other capital raise shares reflecting the need for future funds to complete the studies of 42 million shares. We also add the expected converted Series B shares. From our calculated firm value, we subtract the value of the Series A shares, assuming them to be equivalent to perpetual debt.

Our valuation approach employs a discounted cash flow model. Assumptions include a discount rate of 15% and no terminal value. To our net present value (NPV) we attach a 56% probability of FDA approval and ultimate commercialization for VAL-083 and REM-001. This is the weighted product of the two candidates. We apply a higher than normal 60% estimated probability for VAL-083 based on a successful product meeting an unmet need, participation in the highly regarded GCAR study and a substantial safety database that has been generated over decades of product use. We apply a standard 50% probability of success for REM-001 based on our assessment of available data.

We take a conservative stance in our forecasts and see the potential for wider geographical penetration and improved pricing depending on partner agreements and the number of settings in which Kintara's candidates demonstrate efficacy. The determinant for many of the variables in our model will be the ultimate safety and efficacy profile as demonstrated in pivotal trials. We will update our model accordingly as data is made available.

Based on the assumptions identified in our discounted cash flow model, we generate a current valuation of $4.00 per share.

CONCLUSION

Kintara is developing a pair of well-researched therapies in oncology with several characteristics that make the candidates particularly amenable to addressing GBM and CMBC. For VAL-083, the ability to cross the blood brain barrier and overcome DNA-repair enzyme resistance combined with the agent's affinity to be absorbed by cancer cells provides a mechanism of action that may provide superior safety and efficacy to current standard of care. In the case of REM-001, the targeted nature of the approach avoids systemic exposure and addresses many of the shortcomings of surgery, chemotherapy and radiotherapy.

The company presents two Phase III ready assets that are mere months away from beginning their first registration study. VAL-083 was accepted to participate in the GCAR AGILE study for GBM, an adaptive trial that provides a shared control arm, 24 sites that are already recruiting GBM patients and world-class partners to run the trial. Additionally, the FDA has already cleared the trial protocol which will streamline the effort in terms of time and cost. Not only will DelMar be able to evaluate newly-diagnosed, unmethylated patients, where VAL-083 is expected to have the greatest benefit, but also methylated and recurrent patients.

While Kintara is only actively pursuing an indication in GBM with VAL-083, another indication for ovarian cancer is ready to advance following the receipt of additional funding. The indication is ready for the clinic as the IND has been cleared and orphan status granted.

GBM is also an orphan indication and there are only about 40,000 cases globally per year. Of the 40,000, we estimate there are ~25,000 MGMT-unmethylated, chemotherapy-resistant patients. Existing treatments do not provide long-term remission and there is a severe unmet need for new approaches. Survival using approved treatments is only slightly longer than a year on average and initial data suggests that VAL-083 can delay progression for several months with an improved safety profile.

Clinical trials to date have demonstrated improved PFS and OS in newly diagnosed and recurrent settings respectively. There are two Phase II studies underway that have shown an OS improvement of several months compared to historical control along with a favorable safety profile with myelosuppression as the most common adverse event observed. Results of these studies will help guide the protocol for the AGILE study, which we anticipate will begin before year end.

Assuming a favorable outcome from the AGILE trial in 2023 and approval in 2024, we anticipate commercialization by a partner in 2025. Strength of the data and safety profile will determine uptake rates and pricing; however, based on data available to date, we anticipate high levels of penetration in MGMT-unmethylated patients given the lack of other treatments and pricing at the high end of available chemotherapies.

The other Phase III ready asset, REM-001, has undergone several Phase II and III clinical trials that have demonstrated proof of concept for this photodynamic approach to treating cutaneous lesions. Kintara has consulted extensively with the FDA to develop a trial design that should generate pivotal registrational data following a short lead in study to evaluate a lower dose.

A readout from the CMBC trial in 2023 followed shortly after by an NDA and commercialization in 2024 is the anticipated pathway to the market for REM-001. The therapy will address a largely unmet need in CMBC which has limited options for treatment.

In conjunction with the successful closing of the DelMar and Adgero merger, Kintara raised $25 million in funds to launch its two trials and provide sufficient resources until the second half of 2021. We anticipate the VAL-083 registrational trial to begin prior to year-end 2020 and the lead-in REM-001 trial in the first half of 2021.

Key reasons to own Kintara shares:

- **Phase III ready assets to address an unmet need in GBM and CMBC**
- **VAL-083 is a well-understood chemotherapy agent with long history of use in other cancers**
  - **Granted orphan status for both GBM and ovarian cancer**
  - **Differentiated mechanisms that cross blood brain barrier and block repair enzyme**
  - **Favorable drug safety profile**
- **Acceptance of VAL-083 into the highly regarded GCAR AGILE GBM study**
  - **Provides registrational pathway with top tier partners**
- **REM-001 addresses unmet need in CMBC**
  - **Substantial work completed to characterize safety and efficacy (~1,100 patients in safety database)**
  - **Light activated drug reduces systemic risk**
  - **Small inexpensive trial may be sufficient for approval**
- **Additional indications for VAL-083 and REM-001 in clinical development**

Based on our analysis of VAL-083 and REM-001 and the clinical trial data generated to date, we see a path forward to commercialize these therapies for GBM and CMBC respectively. Our valuation work takes into account commercialization of both candidates in the United States and EU-5 and assumes a 60% and 50% probability of ultimate success for VAL-083 and REM-001 respectively. The opportunity for these oncology offerings extends to additional geographies and a partner may eventually move into these markets. Based on the assumptions included in our valuation section, we estimate a valuation of $4.00 per share.

PROJECTED FINANCIALS

Kintara Therapeutics, Inc. - Income Statement

Kintara Therapeutics, Inc.	2019 A	Q1 A	Q2 A	Q3 A	Q4 E	2020 E	2021 E	2022 E
Total Revenues ($US)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Research & Development	$3,662	$721	$712	$899	$1,100	$3,432	$15,550	$24,450
General & Administrative	$4,736	$914	$1,054	$1,078	$1,000	$4,045	$4,155	$4,400
Income from operations	($8,398)	($1,635)	($1,766)	($1,976)	($2,100)	($7,477)	($19,705)	($28,850)
Change in Fair Value of Derivative	($434)	$0	$0	$0	$0	$0	$0	$0
Foreign Exchange Loss	$18	($0)	$2	($2)	$0	($1)	$0	$0
Interest Income	($61)	($29)	($28)	($17)	($10)	($84)	($40)	($40)
Other Items	$126	$0	$0	$0	$0	$0	$0	$0
Preferred Stock Dividend	$80	$2	$3	$1	$0	$6	$0	$0
Pre-Tax Income	($8,129)	($1,608)	($1,743)	($1,958)	($2,090)	($7,399)	($19,665)	($28,810)
Provision for Income Tax	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	**($8,129)**	**($1,608)**	**($1,743)**	**($1,958)**	**($2,090)**	**($7,399)**	**($19,665)**	**($28,810)**
Reported EPS	**($3.16)**	**($0.21)**	**($0.15)**	**($0.11)**	**($0.09)**	**($0.49)**	**($0.56)**	**($0.64)**
YOY Growth	*58%*	*-75.8%*	*-79.7%*	*-83.8%*	*-89.6%*	*-84%*	*15%*	*14%*
Basic Shares Outstanding	2,575	7,539	11,408	18,000	23,500	15,112	35,000	45,000

Source: Company Filing // Zacks Investment Research, Inc. Estimates

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HISTORICAL STOCK PRICE

Kintara Therapeutics, Inc. – Share Price Chart[57]



[57] Source: Zacks Research System

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