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Allarity Therapeutics, Inc. (ALLR: NASDAQ)

ALLR: IXEMPRA Clinical Update

Research Note

IXEMPRA® Phase II First Look

Allarity Therapeutics, Inc. (NASDAQ: ALLR) offered a sneak peek of the European Phase II clinical trial evaluating the efficacy of Ixempra. The trial is being conducted in metastatic breast cancer (mBC) patients selected using the drug response predictor (DRP) diagnostic. 36 patients were screened, of which five produced a score above the 67% DRP cut off score initially selected for the trial. Of the five subjects enrolled, there have been four evaluable cases producing results.

The four evaluable subjects produced promising signs of response to DRP-guided therapy. Results included:

- One partial responder (PR) (tumor shrinkage of 66%);
- One partial responder (PR) (tumor shrinkage of 59%);
- One patient experienced 24 weeks of stable disease;
- One patient experienced 19 weeks of stable disease.

Ixempra has been previously approved in the United States. Pivotal trials as outlined in the Ixempra label produced a an objective response rate (ORR) of 12.4% and a clinical benefit rate (CBR) of 24.8% in metastatic or locally advanced breast cancer. While the results between the two trials are not directly comparable, the data provide context for interpreting Allarity's results.

Ixempra was approved in the United States more than a decade ago, but withdrawn from the European Medicines Agency (EMA) in 2009 as the product did not provide sufficient evidence of a benefit-risk balance as disclosed in an EMA press release. With an expected improvement in efficacy due to the ability of the DRP diagnostic to identify those patients that will benefit most, we anticipate that Allarity will be able to make a stronger argument for approval compared to that of Bristol-Myers.

The low proportion of patients that met the screen (5/36 or 14%) encouraged Allarity to adjust the DRP cutoff score, a change that was announced in a March 28th press release. Allarity will also increase the number of sites available in order to increase enrollment. While the lower DRP cutoff may result in a population that is on average less responsive than the small, four patient sample size, the screen should still identify those that will respond better than the population as a whole.

Reverse Stock Split and Capital Raise

It is clear that Allarity has been subject to the vicissitudes of the equity markets and despite having multiple attractive assets with potential to meet unmet need for cancer patients, the shares have suffered. Allarity's immediate need is for capital to keep the company afloat while it runs active trials and potentially generates sufficient data to attract a partner or other deep-pocketed investor that recognizes the potential of dovitinib, stenoparib and Ixempra.

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To return to compliance with NASDAQ rules, Allarity executed a reverse stock split effective after the close on June 28, 2023. The ratio of old shares to new shares is 40:1. The proposal to conduct the reverse stock split was approved at a special meeting of stockholders on June 23, 2023.

Prior to the 40:1 reverse split, Allarity raised $7.5 million gross with a public offering of 2.9 million shares and 7.1 million pre-funded warrants at $0.75 per share. The closing of the offering took place on April 21. Each share and pre-funded warrant include a common warrant with an $0.85 exercise price and a five-year duration. Concurrent with the capital raise, Allarity received a $350,000 loan from partner 3i and subsequently entered into a modification and exchange agreement which allowed the conversion of shares of preferred stock into warrants, equity shares and other series of preferred stock while also adjusting the exercise price of warrants.

In a July 6, 2023 press release, Allarity announced the pricing of an $11 million offering subject to reasonable best efforts. The capital raise intends to offer 2.4 million common stock shares at a price of $4.50 along with a warrant for each share with a $4.50 exercise price. Previous warrants associated with the $7.5 million April 19th raise will be repriced from a split adjusted $34/share to $4.50. On July 11, Allarity filed an 8-K announcing the close of the public offering.

Allarity Pipeline

We discuss the latest trial information for the Phase II studies for Ixempra and Stenoparib in our April 17th Note titled ALLR: Clinical Update.

Exhibit I – Allarity Primary Pipeline[1]

		PHASE 1/1b	PHASE 2	PHASE 3	NDA	STATUS/ PARTNER
Dovitinib	Pan-tyrosine kinase inhibitor	Combination Rx with Stenoparib – 2nd + line Ovarian Cancer				
Stenoparib	PARP and tankyrase inhibitor	3nd line Ovarian Cancer				
IXEMPRA	Microtubule inhibitor	2nd line Metastatic Breast Cancer				US Approved and out-licensed to Allarity in EU

Drug Response Predictor (DRP®) Platform

DRP is a type of precision medicine which uses genetic or molecular profiling to develop therapeutics. The approach takes into account an individual's variability in genes, environment and lifestyle, helping providers identify treatment and prevention approaches that are individually tailored.

DRP provides a systematic approach to identify patients sensitive to a particular therapy. The primary steps in the process include:

- Evaluation of an established panel of cancer cell lines that have been treated with the drug candidate:
  - The effort correlates the genetic expression profile of cell lines that are sensitive or resistant
  - The NCI-60 panel is used to identify and characterize the effectiveness of novel compounds
  - The impact of over 25,000 expressed genes is examined
- Identification of the specific mRNA & microRNA that are correlated with either response or resistance to that drug using DRP's bioinformatics algorithm
- Generation of a DRP companion diagnostic specific to the drug which identifies a subpopulation of cancer patients most likely to respond
- Validation of the DRP companion diagnostic using retrospective analysis.

In most cases, 50 to 100 biomarkers are sufficient to differentiate a tumor so that DRP can identify a drug as a matching candidate. The next step in the process is to validate the findings using retrospective data and to test the predictive capacity of the DRP. A cutoff score for patients is determined which optimizes the balance of favorable and unfavorable factors.

[1] March 2023 Allarity corporate presentation.

Summary

Allarity continues to advance its Phase II trials evaluating Ixempra and stenoparib and will continue the Phase Ib combination study with dovitinib and stenoparib. The company provided a first look at Phase II Ixempra results, highlighting either stable disease or tumor shrinkage for all evaluable patients. We expect to see improved enrollment in the Ixempra trial following an adjustment to the DRP score threshold and addition of new trial sites. Recent capital raises have led to dilution, but have allowed the company to continue its clinical work while it identifies a more stable investor base. We see the ability to address an unmet need in the company's pipeline of assets and with stenoparib in particular as a differentiated entry into the PARP inhibitor class that offers tankyrase inhibition, low myelotoxicity and blood brain barrier penetration.

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