Gemini Therapeutics Announces Presentation of Previously Released Data from Its Ongoing Phase 2a Study of GEM103 at EURETINA 2021 Virtual

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- Study shows well-tolerated safety profile with no increased risk of CNV, complement regulation, reduction in inflammatory state and supports bi-monthly dosing

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Gemini Therapeutics, Inc. (Nasdaq: GMTX), a clinical stage precision medicine company developing innovative treatments for genetically defined age-related macular degeneration (AMD), today announced that Raj Maturi, M.D., Adjunct Clinical Assistant Professor of Ophthalmology at Indiana University School of Medicine and an investigator in the ReGAtta study, presented Gemini's previously released initial results from its ongoing Phase 2a study at EURETINA 2021 Virtual held from September 9-12, 2021. The ReGAtta study is an open-label, single-arm dose escalation study of GEM103 in genetically-defined patients with geographic atrophy (GA) secondary to dry AMD.

“The initial results presented at EURETINA 2021 highlight the potential of GEM103 as a new treatment method for AMD and add to the understanding of its safety profile, mechanism of action, and duration, all of which will inform late-stage trial design,” said Samuel Barone, M.D., Chief Medical Officer at Gemini. “Results thus far demonstrate that GEM103 continues to be well-tolerated. In addition, GEM103’s ability to regulate complement is evidenced through a rapid and sustained reduction of biomarkers elevated in AMD and pharmacokinetics support bi-monthly intravitreal dosing.”

Summarized observations from the ongoing Phase 2a ReGAtta study, as of May 2021, presented at EURETINA 2021 include the following:
For the 62 patients with GA enrolled, no systemic serious adverse events related to GEM103 were observed as of the May 2021 snapshot. Ocular adverse events observed were related to the intravitreal procedure and are commonly associated with IVT procedure. Ocular inflammation was rare, mild and did not result in interruption of GEM103 administration. No choroidal neovascularization (CNV) was detected via retinal imaging.

Repeat dosing with GEM103 resulted in rapid and sustained increased levels of complement factor H (CFH) in aqueous humor and supports the evaluation of every other month dosing in late-stage development studies. GEM103 demonstrated the ability to regulate complement in patients with GA, with treatment resulting in a reduction of elevated complement biomarkers and a dose dependent reduction in overall inflammatory state converging at 90 days. Timing of biomarker reductions was consistent with the accumulation of CHF with repeat dosing.

Information on Gemini Therapeutics, including GEM103 and initial ReGAtta data, and presentations made at EURETINA 2021 Virtual are available on Gemini Therapeutics' website under the Investors & Media section: Events and Presentations.

About the Phase 2a ReGAtta Study

The ongoing Phase 2a, multi-center, open-label, multiple ascending dose study of GEM103 in genetically-defined patients with GA secondary to dry AMD is designed to investigate safety and tolerability, PK, exploratory ocular biomarkers, and measures of retinal anatomy and function and not assess efficacy of GEM103 in GA. GEM103 is delivered monthly by an intravitreal injection and PK and biomarkers of complement regulation are determined from aqueous humor sampling. To date, the study has enrolled 62 patients with gene variants that have been linked to the progression of dry AMD from early to late-stage. The study's design allowed for imbalances in GA baseline characteristics and does not inform GA efficacy and does not allow comparisons with uncontrolled fellow eye with similar imbalances.

About GEM103

Gemini's lead program, GEM103, is a pioneering precision medicine approach, targeting trial enrichment with genetically defined patients. GEM103 targets a genetically defined subset of age-related macular degeneration (AMD) patients with complement dysregulation. Of the 15 million dry AMD patients in the United States, approximately 40% (or six million) have variants in the complement factor H (CFH) gene. Such loss of function variants are associated with increased dry AMD disease risk. GEM103 is believed to be the first ever recombinant complement regulator and is a full-length and human, recombinant complement factor H (rCFH) protein. When delivered by intravitreal injection, we believe GEM103 has the potential to address unmet medical need in genetically defined AMD patients by circumventing the complement dysfunction resulting from CFH loss of function
variants and slowing the progression of their retina disease. The U.S. Food and Drug Administration (FDA) granted Fast Track Designation for GEM103 for the treatment of dry AMD in patients with CFH loss of function gene variants.

About Dry Age-Related Macular Degeneration (AMD)

Age-related macular degeneration (AMD) is a progressive retinal disease affecting millions of older adults, and the leading cause of irreversible blindness in the western world. Symptoms, which include blurry vision, loss of night vision and loss of central vision, make activities of daily living such as reading, driving and even recognizing faces progressively more difficult. Third-party reports indicate there are approximately 16 million patients with AMD in the United States alone. Dry AMD, which results from an interaction of environmental and genetic risk factors, represents about 90% of that population (or about 15 million) in the US compared to about 1.4 million with wet AMD. Genetic risk of developing dry AMD is significant, with approximately 70% attributable risk of advanced disease to heritability, while aging and smoking confer the strongest non-genetic risk. CFH risk variants occur in approximately 40% of patients with dry AMD and these patients have a significantly increased risk of developing the disease as well as progression from intermediate AMD to GA. The complement system, of which CFH is a regulator, is dysregulated in patients with these risk variants, and results in amplification of aberrant inflammatory responses in the eye. Over time, this dysregulation leads to damage to the macular region of the retina.

About Gemini Therapeutics

Gemini Therapeutics is a clinical stage precision medicine company developing novel therapeutic compounds to treat genetically defined age-related macular degeneration (AMD). Gemini's lead candidate, GEM103, is a recombinant form of human complement factor H protein (CFH) and is designed to address both complement hyperactivity and restore retinal health in patients with AMD. GEM103 is currently in a Phase 2a trial in dry AMD patients with a CFH risk variant and a Phase 1/2a study in patients with neovascular age-related macular degeneration with or at risk for macular atrophy. Gemini has generated a rich pipeline including recombinant proteins, gene therapies, and monoclonal antibodies and is advancing a potentiating antibody for CFH, GEM307, into clinical development for treatment of systemic diseases.

For more information, visit [www.geminitherapeutics.com](http://www.geminitherapeutics.com).

Availability of Other Information About Gemini Therapeutics

Investors and others should note that we communicate with our investors and the public using our website [www.geminitherapeutics.com](http://www.geminitherapeutics.com), the investor relations website [https://investors.geminitherapeutics.com/](https://investors.geminitherapeutics.com/), and on social media [Twitter](https://twitter.com) and [LinkedIn](https://www.linkedin.com), including but not limited to investor presentations and investor fact sheets.
U.S. Securities and Exchange Commission filings, press releases, public conference calls and webcasts. The information that Gemini posts on these channels and websites could be deemed to be material information. As a result, Gemini encourages investors, the media, and others interested in Gemini to review the information that is posted on these channels, including the investor relations website, on a regular basis. This list of channels may be updated from time to time on Gemini’s investor relations website and may include additional social media channels. The contents of Gemini’s website or these channels, or any other website that may be accessed from its website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

**Gemini’s Forward-Looking Statements**

Certain statements in this press release and the information incorporated herein by reference may constitute “forward-looking statements” for purposes of the federal securities laws. Our forward-looking statements include, but are not limited to, statements regarding our or our management team’s expectations, hopes, beliefs, intentions or strategies regarding the future, including those relating to the success, cost and timing of our product development activities and clinical trials, whether such data, when final, will be consistent with interim reported data, the timing to commence future clinical trials, the potential attributes and benefits of our product candidates, including GEM103, the reliability of the interim or final results of studies relating to safety and possible adverse effects resulting from the administration of our product candidates, our ability to obtain and maintain regulatory approval for our product candidates, our projected cash runway and our ability to obtain funding for our operations when needed. Forward-looking statements include statements relating to our management team’s expectations, hopes, beliefs, intentions or strategies regarding the future. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intends,” “may,” “might,” “plan,” “possible,” “potential,” “predict,” “project,” “should,” “will,” “would” and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. These forward-looking statements are based on current expectations and beliefs concerning future developments and their potential effects. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described under the heading “Risk Factors” in Gemini’s most recent Annual Report on Form 10-K filed with the SEC, as well as discussions of potential risks, uncertainties, and other important factors included in any of our future filings with the SEC. Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Some of
these risks and uncertainties may in the future be amplified by the ongoing COVID-19 pandemic and there may be additional risks that we consider immaterial, or which are unknown. It is not possible to predict or identify all such risks. Our forward-looking statements only speak as of the date they are made, and we do not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

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