Gossamer Bio Announces Addition of Two CNS-Penetrant BTK Inhibitors to its Product Candidate Pipeline: GB5121 & GB7208

October 11, 2021

SAN DIEGO--(BUSINESS WIRE)--Oct. 11, 2021-- Gossamer Bio, Inc. (Nasdaq: GOSS), a clinical-stage biopharmaceutical company focused on discovering, acquiring, developing and commercializing therapeutics in the disease areas of immunology, inflammation and oncology, today announced the addition of two CNS-penetrant Bruton's tyrosine kinase (BTK) inhibitors to its product candidate pipeline.

Gossamer plans to initiate first-in-human studies of the first of these candidates, GB5121, in the fourth quarter of 2021. Gossamer intends to develop GB5121 in CNS-oncology indications, including relapsed / refractory primary CNS lymphoma (PCNSL), for which a potentially registrational Phase 1b / 2 study is expected to initiate in the first half of 2022.

The second product candidate, GB7208, is currently in IND-enabling studies and is expected to enter the clinic in the second half of 2022. In a BTK-dependent pre-clinical disease model, GB7208 demonstrated superior outcomes vs. tolebrutinib, a BTK inhibitor being studied in a broad Phase 3 program for multiple sclerosis (MS).

"We are thrilled to be able to share our latest product candidates, the CNS-penetrant BTK inhibitors GB5121 and GB7208," said Faheem Hasnain, Chairman, co-founder and CEO of Gossamer Bio. "These two promising product candidates are the result of intensive internal research, and we are excited to advance them into the clinic where there remains a high unmet need in treating malignant brain tumors and neurologic diseases."

"BTK inhibitors have emerged as an important class of treatment, particularly in oncology, but existing molecules have not been optimized for the treatment of central nervous system disorders," said Laura Carter, Ph.D., Chief Scientific Officer of Gossamer Bio. "GB5121 and GB7208 were designed specifically with these disorders in mind, and in pre-clinical models, they have been shown to be potent, highly selective BTK inhibitors, with potentially best-in-class brain penetrance and target occupancy."

GB5121: Oral, CNS-Penetrant, Irreversible BTK Inhibitor for Treatment of PCNSL

- Superior CNS penetration in preclinical models compared to other BTK inhibitors in development for oncology
- Highly selective for BTK, with no non-TEC kinases inhibited at greater than 50% in a broad kinome scan
- First-in-human Phase 1 clinical trial expected to initiate in the fourth quarter of 2021
- First-in-patient Phase 1b/2 clinical trial in patients with relapsed / refractory CNS lymphoma expected to initiate in the first half of 2022
- Relapsed and refractory PCNSL provides potential accelerated path to registration

GB7208: Oral, CNS-Penetrant, Irreversible BTK Inhibitor for Treatment of MS

- Potentially best-in-class brain penetrance among BTK inhibitors being developed for neuroinflammatory and neurodegenerative diseases based on pre-clinical models
- In a BTK-dependent pre-clinical disease model, demonstrated superiority vs. tolebrutinib, a CNS-penetrant BTK inhibitor in Phase 3 development for MS
- Potent inhibition of microglia inflammation in vitro and in vivo
- First-in-human Phase 1 clinical trial expected to initiate in the second half of 2022

Gossamer will host a conference call and webcast today, Monday, October 11, 2021, for investors and analysts at 2:30pm ET to discuss its new product candidates. As part of the event, Gossamer Bio management will be available for questions.

Details below:

Conference Call and Webcast

Gossamer will host a conference call and live audio webcast today, Monday, October 11, 2021, at 2:30 pm ET to discuss its new product candidates. The live audio webcast may be accessed through the "Events / Presentations" page in the "Investors" section of the Company's website at www.gossamerbio.com. Alternatively, the conference call may be accessed through the following:

Conference ID: 4165598
Domestic Dial-in Number: (833) 646-0603

International Dial-in Number: (929) 517-9782
Live Webcast: https://edge.media-server.com/mmc/p/4jha6kh9

A replay of the audio webcast will be available for 30 days on the “Investors” section of the Company's website, www.gossamerbio.com.

About Gossamer Bio

Gossamer Bio is a clinical-stage biopharmaceutical company focused on discovering, acquiring, developing and commercializing therapeutics in the disease areas of immunology, inflammation and oncology. Its goal is to be an industry leader in each of these therapeutic areas and to enhance and extend the lives of patients suffering from such diseases.

Forward-Looking Statements

Gossamer cautions you that statements contained in this press release regarding matters that are not historical facts are forward-looking statements. These statements are based on the Company’s current beliefs and expectations. Such forward-looking statements include, but are not limited to, statements regarding: the anticipated timing of initiation of clinical trials for our product candidates and plans to advance our product candidates; the potential clinical benefits and market potential of our product candidates; and plans to rapidly advance GB5121 through a potential accelerated path to registration. The inclusion of forward-looking statements should not be regarded as a representation by Gossamer that any of its plans will be achieved. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in Gossamer’s business, including, without limitation: potential delays in the commencement, enrollment and completion of clinical trials; disruption to our operations from the ongoing global outbreak of the COVID-19 pandemic, including clinical trial delays; the Company’s dependence on third parties in connection with product manufacturing, research and preclinical and clinical testing; the results of preclinical studies and early clinical trials are not necessarily predictive of future results; the success of Gossamer’s clinical trials and preclinical studies for its product candidates; regulatory developments in the United States and foreign countries; unexpected adverse side effects or inadequate efficacy of our product candidates that may limit their development, regulatory approval and/or commercialization, or may result in recalls or product liability claims; Gossamer’s ability to obtain and maintain intellectual property protection for its product candidates; Gossamer’s ability to comply with its obligations in collaboration agreements with third parties or the agreements under which it licenses intellectual property rights from third parties; Gossamer may use its capital resources sooner than it expects; and other risks described in the Company’s prior press releases and the Company’s filings with the Securities and Exchange Commission (SEC), including under the heading “Risk Factors” in the Company’s annual report on Form 10-K and any subsequent filings with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Gossamer undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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