Gossamer Bio Announces GB004 Topline Results from Phase 2 SHIFT-UC Study in Ulcerative Colitis and Provides Corporate Update

April 25, 2022

— Study did not meet primary or secondary endpoints at week 12—

— GB004 Phase 2 SHIFT-UC Study to be terminated for lack of treatment benefit—

— Target enrollment reached in Phase 2 TORREY Study of seralutinib in PAH; topline results expected in 4Q22 —

— As of March 31, 2022, Gossamer estimates that its cash, cash equivalents and marketable securities were approximately $272 million —

SAN DIEGO--(BUSINESS WIRE)--Apr. 25, 2022-- 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 topline results from its Phase 2 SHIFT-UC Study clinical trial studying GB004 in patients with mild-to-moderate active ulcerative colitis (UC).

Neither GB004 treatment arm met the primary or secondary endpoints at week 12. Based on the totality of the available data, Gossamer will terminate the ongoing treat-through and open-label extension portions of the Phase 2 SHIFT-UC Study for lack of treatment benefit.

“While we are disappointed with these results, we want to thank the patients, caregivers and investigators who participated in and contributed to this clinical trial,” said Faheem Hasnain, Co-Founder, Chairman and Chief Executive Officer of Gossamer Bio.

“I am proud of our team’s efforts in trying to advance a new mechanism of action for patients with ulcerative colitis. Looking forward, we are eagerly anticipating topline results from our Phase 2 TORREY Study of seralutinib in PAH in the fourth quarter and the initiation of our Phase 1b/2 STAR CNS Study of GB5121 in patients with primary CNS lymphoma later this quarter.”

The Phase 2 SHIFT-UC Study (NCT04556383) enrolled 236 patients with mild-to-moderate active UC who were treatment naïve to approved biologic therapies. The clinical trial assessed the effects of GB004 added to background therapy of 5-aminosalicylate (5-ASA) with or without systemic steroids during a 36-week placebo-controlled period and a 24-week open-label extension period. In the placebo-controlled period, two active dose regimens of GB004 were compared to placebo (GB004 480mg once-daily [QD], n = 78; GB004 480mg twice-daily [BID], n = 80; placebo, n = 78). The primary endpoint was the proportion of participants with clinical remission, as defined by the modified Mayo Score, at week 12.

Neither statistically significant nor clinically meaningful differences were observed for the primary endpoint at week 12 (GB004 480mg QD: 15.4%; GB004 480mg BID: 22.5%; placebo: 17.9%). There were also no meaningful differences in secondary endpoints, including histologic and mucosal healing endpoints, for either GB004 treatment group relative to placebo at week 12. An assessment of available 36-week data showed no meaningful improvement on efficacy endpoints.

The safety and tolerability profile of GB004 observed in the trial was generally consistent with prior clinical trials. Dizziness, nausea and somnolence were the most commonly reported adverse events among GB004-treated patients, with incidences higher than placebo. Adverse events were generally mild in severity.

Corporate Updates

- Seralutinib (GB002) Phase 2 TORREY Study in pulmonary arterial hypertension (PAH) enrolled its 80th patient in April 2022.
- Topline results from ongoing Phase 2 TORREY Study are expected to be released in the fourth quarter of 2022.
- As of March 31, 2022, Gossamer estimates that its cash, cash equivalents and marketable securities were approximately $272 million.

Conference Call and Webcast

Gossamer’s management team will host a conference call and live audio webcast at 8:30 a.m. ET today, Monday, April 25, to discuss its Phase 2 SHIFT-UC topline clinical trial results.

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: 2924955
Domestic Dial-in Number: (833) 646-0603
International Dial-in Number: (929) 517-9782
Live Webcast: https://edge.media-server.com/mmc/p/rizdexja

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 termination of the Phase 2 SHIFT-UC trial; the anticipated timing of initiation and enrollment of clinical trials for our product candidates, including the expected initiation of the Phase 1b/2 STAR CNS study of GB5121 in patients with primary CNS lymphoma; plans to advance our product candidates; expectations on the timing of data readouts from our clinical studies, including the timing of topline results for the Phase 2 TORREY study for seralutinib; and the Company’s estimated cash and cash equivalents as of March 31, 2022. 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 COVID-19 pandemic, including clinical trial delays and clinical site staff shortages; 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; interim results do not necessarily predict final results and one or more of the outcomes may materially change as the trial continues and more patient data become available and following more comprehensive audit and verification procedures; 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; potential changes in estimated cash and cash equivalents based on the completion of financial closing procedures and release of complete first quarter 2022 results; 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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