Gossamer Bio Announces Topline Results for Phase 2 Trials of Oral GB001 in Asthma and Chronic Rhinosinusitis

October 13, 2020

- Primary endpoint of asthma worsening not met in LEDA Study, however consistent numeric reductions ranging from 32-35% observed across all three GB001 groups -

- Statistically significant improvements in key secondary endpoint of time to first asthma worsening of 28% and 30% observed for 20 mg and 60 mg doses of GB001, respectively; 23% improvement observed in 40 mg group -

- TITAN Study in chronic rhinosinusitis did not meet primary or secondary endpoints -

- Gossamer to hold webcast to discuss trial results at 8:00 am EDT -

SAN DIEGO--(BUSINESS WIRE)--Oct. 13, 2020-- 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 2b LEDA trial in patients with moderate-to-severe eosinophilic asthma and its Phase 2 TITAN trial in patients with chronic rhinosinusitis.

"While we did not achieve statistical significance on the primary endpoint in the LEDA Study, we are encouraged by the consistent results observed for all three doses of once-daily, oral GB001 therapy across the primary and secondary endpoints," said Sheila Gujrathi, M.D., Co-Founder and Chief Executive Officer of Gossamer. "We believe these data provide important information for designing a well-powered Phase 3 program for GB001 in severe asthma. We plan to engage in global regulatory discussions in order to inform our thinking around potential partnerships or strategic alternatives for this program."

"The results of the robust LEDA Study are meaningful and help us to further understand the DP2 pathway in asthma," said Bruce Levy, M.D., Chief, Division of Pulmonary and Critical Care Medicine at Brigham and Women's Hospital and Professor of Medicine at Harvard Medical School. "I believe GB001 as an oral treatment has the potential to serve the high unmet need of patients with uncontrolled severe asthma."

LEDA Phase 2b Trial Design

The LEDA trial enrolled 480 patients with uncontrolled, moderate-to-severe eosinophilic asthma and assessed the effect of oral GB001 add-on therapy to standard of care over 24 weeks, comparing three dose groups of once-daily, oral GB001 (20 mg, n=120; 40 mg, n=118; and 60 mg, n=122) to placebo (n=120).

The primary endpoint, asthma worsening, included five components and was chosen for its sensitivity in detecting deterioration in clinical outcome measures known to be correlated with exacerbations. A patient was considered to have experienced asthma worsening if they met any of the five components by Week 24. This endpoint has previously been used in the context of steroid withdrawal studies, including a prior Phase 2 trial of GB001.

LEDA Primary and Secondary Endpoint Results

The primary endpoint of the trial was not met, though consistent and meaningful numeric reductions in the odds of asthma worsening as compared to placebo were observed across all GB001 groups: 33% (p=0.1425), 32% (p=0.1482), and 35% (p=0.1086), for the GB001 20 mg, 40 mg, and 60 mg groups, respectively. In addition, statistically significant improvements in the key secondary endpoint of time to first asthma worsening as compared to placebo were observed for GB001 20 mg and 60 mg (28% and 30% risk reduction, p=0.0466 and p=0.0304, respectively), with GB001 40 mg also demonstrating a numeric improvement (23%, p=0.1222).

Consistent reductions for each GB001 group as compared to placebo were seen across all individual components of the asthma worsening endpoint. In a post-hoc analysis, the odds of experiencing severe asthma worsening (i.e. meeting three or more worsening components), were significantly reduced in all three GB001 groups as compared to placebo (72%, 88%, and 81% reductions, p=0.0044, 0.0003, and 0.0008, for GB001 20 mg, 40 mg, and 60 mg, respectively).

In addition to the primary endpoint of asthma worsening, the expected Phase 3 registrational endpoint of annualized severe exacerbation rate, or AER, was evaluated as a secondary endpoint. While AER is typically formally evaluated in large Phase 3 studies with a one-year duration, reductions as compared to placebo were seen for each GB001 group (GB001 20 mg: 20%; 40 mg: 25%; 60 mg: 11%), although the reductions were not statistically significant.

Numeric improvements in lung function, as measured by morning peak expiratory flow and pre-bronchodilator FEV1, and asthma control, as measured by the Asthma Control Questionnaire were also observed for all three GB001 groups compared to placebo.

The trial also provided the opportunity to investigate subgroups based on clinical characteristics and biomarkers. In a post-hoc analysis, a subgroup of patients was preliminarily identified with enhanced treatment response that could allow for the enrollment of an enriched patient population in future studies. We will continue to analyze the clinical data collected in the study, including further characterization of this subgroup.

Overall, the Phase 2b LEDA Study informed on the Phase 3 registrational endpoint, the optimal patient population and dose selection for future

studies. We look forward to discussing our findings with global regulatory authorities and continuing our discussions with potential strategic partners.

LEDA Safety and Tolerability Results

The incidence of adverse events was generally comparable across treatment groups: 65.8% placebo, 65.8% GB001 20 mg, 69.5% GB001 40 mg, and 68.0% GB001 60 mg.

Adverse events of interest (liver chemistry elevations leading to study drug discontinuation) occurred more frequently in GB001 60 mg (4.1%, n=5) than placebo (0.8%, n=1), GB001 20 mg (0.8%, n=1), or GB001 40 mg (1.7%, n=2). One adverse event of interest was a serious adverse event of liver chemistry elevations meeting Hy's Law criteria in the GB001 60 mg group. The patient was asymptomatic during the event, which was reversible and resolved without sequelae.

Full results from LEDA will be submitted for future presentation at an upcoming scientific meeting.

TITAN Phase 2a Trial in Chronic Rhinosinusitis with and without Nasal Polyps

The proof-of-concept TITAN trial enrolled 97 patients with chronic rhinosinusitis with and without nasal polyps and assessed treatment with GB001 40 mg vs. placebo over 16 weeks. Neither the primary nor the secondary endpoints of the trial were met. The safety and tolerability of GB001 40 mg was generally consistent with that observed in the LEDA Study. We do not plan to continue further development of GB001 in chronic rhinosinusitis.

Conference Call and Webcast

Gossamer's management team will host a conference call and live audio webcast at 8:00am EDT today, Tuesday, October 13, to discuss its GB001 Phase 2 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: 1333166
Domestic Dial-in Number: (833) 640-7726
International Dial-in Number: (602) 585-9912
Live Webcast: https://edge.media-server.com/mmc/p/6yqpwnxf

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 GB001

GB001 is a potent and highly selective oral antagonist of the DP2 pathway, a potentially important modulator of the inflammatory cascade in asthma. GB001 is an investigational, once-daily tablet being developed as an add-on maintenance treatment for moderate-to-severe uncontrolled asthma.

About the GB001 Phase 2b LEDA Study

LEDA (GB001-2001, NCT03683576) was a 24-week, randomized, double-blind, placebo-controlled, dose-ranging, multi-center Phase 2b trial in patients with moderate-to-severe eosinophilic asthma. The patient population included 480 adult patients, randomized equally to placebo, GB001 20 mg, GB001 40 mg, and GB001 60 mg, who were receiving Global Initiative for Asthma (GINA) Step 4 or 5 standard of care treatment with inhaled medium or high dose corticosteroids and at least one additional asthma controller medication. The objective of the trial was to evaluate the efficacy and safety of GB001 relative to placebo when added to standard of care treatment.

The primary endpoint was the proportion of patients who experienced asthma worsening by Week 24. Asthma worsening was a composite outcome defined as the occurrence of any one of the following at any time by Week 24: deterioration of morning peak expiratory flow, pre-bronchodilator forced expiratory volume in 1 second (FEV1), or asthma control as measured by the Asthma Control Questionnaire 5, relative to baseline; an increase in rescue medication use relative to baseline; or the occurrence of a severe asthma exacerbation, defined as deterioration of asthma that led to the use of systemic corticosteroids for at least 3 days, hospitalization, or an Emergency Department visit.

Secondary endpoints included time to first asthma worsening and the annualized rate of severe asthma exacerbations.

The safety of GB001 was assessed by adverse events, clinical laboratory tests, electrocardiograms, and vital signs.

About the GB001 Phase 2 TITAN Study

TITAN (GB001-2101, NCT03956862) was a 16-week, randomized, double-blind, placebo-controlled, dose-ranging, multi-center Phase 2 trial in patients with chronic rhinosinusitis with and without nasal polyps. The patient population included 97 adult patients, randomized equally to placebo and GB001 40 mg, stratified by nasal polyp status. The objective of the trial was to evaluate the efficacy and safety of GB001 40 mg relative to placebo when added to standard of care treatment of intranasal corticosteroids.

The primary endpoint was the change from baseline to Week 16 in SNOT-22, a patient-reported, quality of life instrument that assesses the impact of chronic rhinosinusitis. A key secondary endpoint in subjects with nasal polyps was the change from baseline to Week 16 in nasal polyp score.

The safety of GB001 was assessed by adverse events, clinical laboratory tests, electrocardiograms, and vital signs.

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 potential for the LEDA Study results to allow for the design of a well-powered Phase 3 program for GB001 and our plans to discuss such results with global regulatory authorities to inform potential partnerships or strategic alternatives; potential plans to advance GB0O1; and the potential of GB001 to serve asthma patients. The inclusion of forward-looking statements should not be regarded as a representation by Gossamer that any of our 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: Gossamer may not proceed into Phase 3 clinical trials for GB001, including because the LEDA Study results may not support continued clinical development of GB001; topline results Gossamer reports is based on preliminary analysis of key efficacy and safety data, and such data may change following a more comprehensive review of the data related to the clinical trial and such topline data may not accurately reflect the complete results of a clinical trial, and the FDA and other regulatory authorities may not agree with Gossamer's interpretation of such results; disruption to our operations from the recent global outbreak of the COVID-19 pandemic, including clinical trial and regulatory meeting delays; the Company's dependence on third parties in connection with product manufacturing, research and preclinical and clinical testing; potential delays in the commencement, enrollment and completion of any future clinical trials of GB001 and the success of any such trials; Gossamer may not be successful in establishing strategic partnerships or collaborations and may not realize the benefits of such arrangements; 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 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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