Gossamer Bio Announces Early Encouraging Safety and Biomarker Data from Phase 1/2 Study of GB1275 at American Society of Clinical Oncology 2020 Virtual Scientific Program

May 29, 2020

SAN DIEGO--(BUSINESS WIRE)--May 29, 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 the presentation of positive safety and biomarker data at the 2020 American Society of Clinical Oncology Virtual Scientific Program (ASCO20) from its ongoing Phase 1/2 study of GB1275 in patients with selected solid tumors.

The KEYNOTE-A36 Phase 1/2 study is currently undergoing dose escalation of GB1275 as a monotherapy and in combination with KEYTRUDA® (pembrolizumab). As of the March 27, 2020 data cutoff, 22 patients had been enrolled in the study. GB1275 has been well tolerated to date, both as monotherapy and in combination with KEYTRUDA. No dose-limiting toxicities have been reported, and dose escalation in both arms continues. Dose-dependent increases in GB1275 plasma concentration have been observed, and the 7-hour elimination half-life of GB1275 supports BID, or twice-daily, dosing.

Consistent with the proposed mechanism of GB1275, decreases in both peripheral monocytic and granulocytic myeloid-derived suppressor cells, or MDSCs, were observed following treatment with GB1275. Preliminary analyses also showed dose-dependent differences in peripheral gene expression profiles and unique transcriptomic expression patterns in patients treated with GB1275 monotherapy or combination with KEYTRUDA.

Early signs of activity were observed in a patient with metastatic castrate-resistant prostate cancer (mCRPC), who had previously experienced disease progression after more than ten lines of therapy, including treatment with atezolizumab, an anti-PDL1 antibody. The patient, enrolled in the lowest dosage cohort of the combination arm, experienced greater than 50% decreases in prostate-specific antigen (PSA) and neutrophil to lymphocyte ratio (NLR), both of which were sustained after four cycles of therapy. This patient was the only mCRPC patient enrolled at the time of data cutoff and remains on study treatment.

“We are encouraged by the early signs of biologic and clinical activity observed as we have been able to safely dose escalate the GB1275 monotherapy and KEYTRUDA combination therapy regimens,” said Sheila Gujrathi, M.D., Co-Founder and Chief Executive Officer of Gossamer. “We hope to build on these promising signals from our initial dose escalation cohorts as the study continues.”

“Despite the advent of checkpoint immunotherapies, a high unmet medical need remains for the vast majority of patients with advanced solid tumors,” said Drew Rasco, M.D., of the START Cancer Center in San Antonio, TX, a principal investigator of the study who also provided a five-minute audio commentary that accompanies the poster on the ASCO20 website. “The preliminary biomarker analyses presented at ASCO20 show GB1275 is having an impact on the immunosuppressive cells which often lead to primary or secondary resistance to checkpoint immunotherapy. I am excited to continue studying GB1275 in the clinic and look forward to future data readouts.”

The poster can be viewed in the “Posters and Presentations” section of the Gossamer Bio website (https://www.gossamerbio.com/pipeline/posters-and-publications/). The poster and a 5-minute audio commentary presented by Dr. Rasco are available on demand on the ASCO20 website. Gossamer expects to present additional data from the KEYNOTE-A36 study in the second half of 2020.

Details for the presentation are as follows:

Session Type: Poster Session
Session Title: Developmental Therapeutics—Immunotherapy
Session Date: Friday, May 29, 2020
Abstract Number: 3085
Poster Number: 149
Poster Title: A Phase 1/2 Study of GB1275, a First-in-Class CD11b Modulator, as Monotherapy and With an Anti-PD-1 Antibody in Specified Advanced Solid Tumors or With Chemotherapy in Metastatic Pancreatic Cancer (KEYNOTE A36)
Presenter Name: Drew Rasco, M.D., of the START Cancer Center in San Antonio, TX

About GB1275 and the KEYNOTE-A36 Trial

GB1275 is an oral CD11b modulator in development for the treatment of selected solid tumors. GB1275 is designed to modulate the activity of immunosuppressive cell types, such as tumor-associated macrophages (TAMs) and MDSCs, by decreasing the trafficking of these cells into the tumor microenvironment (TME) and re-polarizing those cells in the TME to an active state. The KEYNOTE-A36 Phase 1/2 trial is enrolling patients with selected solid tumor indications. The study is currently enrolling dose escalation cohorts of GB1275 monotherapy and combination therapy with KEYTRUDA and will also include dose escalation of GB1275 in combination with chemotherapy in patients with metastatic pancreatic cancer. Merck (known as MSD outside the US and Canada) has agreed to supply KEYTRUDA for the KEYNOTE-A36 trial. KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp, a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA. Gossamer retains worldwide rights to GB1275.

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 clinical benefits of our product candidates. 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: the results of preclinical studies and early clinical trials are not necessarily predictive of future results; 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; 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 comply with its obligations in collaboration agreements with third parties or the agreements under which it licenses intellectual property rights from third parties; 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20200529005079/en/

For Investors and Media:
Bryan Giraudo, Chief Financial Officer
Gossamer Bio Investor Relations
ir@gossamerbio.com

Source: Gossamer Bio, Inc.