Gossamer Bio and Chiesi Group Announce Transformative Global Collaboration to Develop and Commercialize Seralutinib in PAH, PH-ILD & Other Indications

May 6, 2024 at 7:30 AM EDT

- Gossamer to receive $160 million development reimbursement payment and eligible to receive up to $146 million in regulatory and $180 million in sales milestones -

- Gossamer leading US commercialization activities in PAH and PH-ILD;
50 / 50 commercial profit split in US and global development cost sharing arrangement -

- Chiesi, a global leader in the pulmonary and rare disease spaces, obtains exclusive ex-US commercial rights, with Gossamer to receive mid-to-high teens royalties on net sales -

- Gossamer and Chiesi plan to initiate Phase 3 Trial of Seralutinib in PH-ILD in Mid-2025 -

SAN DIEGO, Calif. & PARMA, Italy--(BUSINESS WIRE)--May 6, 2024-- Gossamer Bio, Inc. ("Gossamer") (Nasdaq: GOSS), a clinical-stage biopharmaceutical company focused on the development and commercialization of seralutinib for the treatment of pulmonary hypertension, and Chiesi Farmaceutici S.p.A ("Chiesi Group"), an international, research-focused biopharmaceutical group, today announced that they have entered into a global collaboration and license agreement to develop and commercialize seralutinib.

This global collaboration combines the strengths of both Chiesi and Gossamer to support ongoing work in pulmonary arterial hypertension (PAH) and to accelerate development in pulmonary hypertension associated with interstitial lung disease (PH-ILD), enabling the expansion of the seralutinib franchise to reach more patients with pulmonary hypertension world-wide. Patients will benefit from both Chiesi's expertise in global respiratory, rare disease, and inhaled drug development and commercialization and Gossamer's world-class PAH and PH-ILD development and commercialization teams.

"This partnership with Chiesi allows us to meaningfully deepen and rapidly accelerate our investment in seralutinib as a potential treatment for PAH, PH-ILD, and other indications of high unmet medical need," said Faheem Hasnain, Co-Founder, Chairman and CEO of Gossamer. "We are particularly thrilled that this collaboration enables seralutinib to move directly into a Phase 3 trial in PH-ILD, an indication with a paucity of available treatments, and a disease which we believe seralutinib is specifically designed to address."

"Seralutinib is a potential paradigm shifting therapy in PAH and PH-ILD, and we could not be more excited to partner with Gossamer to develop and bring this therapy to patients world-wide," said Giuseppe Accogli, Group CEO of Chiesi. "Gossamer shares Chiesi's commitment to using innovation to promote the health and well-being of people around the world and we are proud to add this collaboration as a key pillar to our next phase of growth."

Prevalence estimates vary widely, but PAH is believed to affect approximately 30,000 to 50,000 people in the US, with a similar prevalence in Europe. While many approved PAH treatments are available, most are primarily vasodilators and do not impact the progressive course of the disease. Median 5-year overall survival rate for patients with PAH is approximately 57%. In the past, PH-ILD has not been as readily diagnosed as PAH, in part due to a lack of approved treatment options for these patients. Based on prevalence figures for various forms of ILD and reported rates of PH in ILD patient cohorts, we estimate that PH-ILD affects approximately 60,000-100,000 patients in the US. Patients with PH-ILD in the US have access to only one approved therapy, while no therapies to treat PH-ILD are approved outside of the US. Median 5-year overall survival rate for patients with PH-ILD is approximately 23%.

Seralutinib is an inhaled PDGFRα/β, CSF1R, and c-KIT inhibitor designed to be delivered via dry powder inhaler for the potential treatment of pulmonary hypertension. Following the positive readout of the Phase 2 TORREY Study in patients with PAH, Gossamer initiated the Phase 3 PROSERA Study in 2023. Gossamer and Chiesi plan to initiate a global Phase 3 registrational study in PH-ILD in mid-2025 and to evaluate seralutinib in additional indications of high unmet need.

Under the terms of the agreement, Gossamer will continue to lead global development of seralutinib in PAH and PH-ILD, and the companies will evenly split development costs, except with respect to the PROSERA Study, for which Gossamer will remain financially responsible. In the US, the companies will evenly share commercial profits and losses. Gossamer will lead commercialization and book sales for PAH and PH-ILD in the US, with both companies contributing 50 percent of commercial efforts. Chiesi will lead US commercialization in additional indications. Chiesi will have the exclusive right to commercialize seralutinib outside of the US and will pay Gossamer an escalating mid-to-high teens royalty on net sales. Chiesi will pay Gossamer $160 million as a development reimbursement. Additionally, Gossamer will be eligible to receive up to $146 million in regulatory milestones and $180 million in sales milestones.

Conference Call and Webcast

Gossamer's management team will host a conference call and live audio webcast to discuss the partnership today, May 6th, at 8:30 a.m. EDT.

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:

Date / Time: May 6, 8:30am EDT
Domestic Dial-in Number: 1-800-285-6670
Conference Reference: Gossamer Bio Announcement Presentation
Live Webcast: https://edge.media-server.com/mmc/p/5y35ojfx

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 the development and commercialization of seralutinib for the treatment of pulmonary hypertension. Its goal is to be an industry leader in, and to enhance the lives of patients living with, pulmonary hypertension.

About Chiesi Group

Chiesi is a research-oriented international biopharmaceutical group that develops and markets innovative therapeutic solutions in respiratory health, rare diseases, and specialty care. The company’s mission is to improve people’s quality of life and act responsibly towards both the community and the environment.

By changing its legal status to a Benefit Corporation in Italy, the US, and France, Chiesi’s commitment to create shared value for society as a whole is legally binding and central to company-wide decision-making. As a certified B Corp since 2019, we’re part of a global community of businesses that meet high standards of social and environmental impact. The company aims to reach Net-Zero greenhouse gases (GHG) emissions by 2035.

With over 85 years of experience, Chiesi is headquartered in Parma (Italy), with 31 affiliates worldwide, and counts more than 7,000 employees. The Group’s research and development centre in Parma works alongside 6 other important R&D hubs in France, the US, Canada, China, the UK, and Sweden.

For further information please visit www.chiesi.com

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 reimbursement, regulatory and sales milestones payable to Gossamer pursuant to the collaboration and license agreement; the development and commercialization potential of seralutinib; the worldwide expansion of the seralutinib franchise; the anticipated timing of commencing a Phase 3 registrational study in PH-ILD; the ability to develop seralutinib in additional indications; and each of Gossamer’s and Chiesi’s respective obligations under the collaboration and license agreement to lead commercialization efforts and split development costs. 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 expected benefits of, and opportunities related to, the partnership with Chiesi may not be realized by Gossamer or may take longer to realize than anticipated; potential delays in the commencement, enrollment and completion of clinical trials; disruption to our operations from pandemics, 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 seralutinib; regulatory developments in the United States and foreign countries; unexpected adverse side effects or inadequate efficacy of seralutinib that may limit its development, regulatory approval and/or commercialization, or may result in clinical holds, recalls or product liability claims; Gossamer’s ability to obtain and maintain intellectual property protection for seralutinib; 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; unstable market and economic conditions and adverse developments with respect to financial institutions and associated liquidity risk may adversely affect our business and financial condition and the broader economy and biotechnology industry; 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20240506306603/en/

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

For Media Chiesi Group
Carla Arrieta
Head of Global External Communications
Tel:+393408849754
mediarelations@chiesi.com

Gentry Lassier
Sr. Director Communications & Public Affairs US
Office +1 (888) 466-6505 x1549
us.mediarelations@chiesi.com

Source: Gossamer Bio, Inc.