GRAVITAS THERAPEUTICS APPOINTS BILL ENRIGHT, CEO OF VACCITECH, TO ITS BOARD OF DIRECTORS

Gravitas Adds Independent Director in Advance of Securing Series A to Fund Clinical Development of GR-2397, a Novel Therapeutic for Serious Fungal Infections

SAN DIEGO, CALIFORNIA, UNITED STATES, January 4, 2022 /EINPresswire.com/ -- Gravitas Therapeutics, Inc. (“Gravitas”), a clinical-stage biopharmaceutical company engaged in the development of GR-2397 (previously VL-2397, ASP2397), a novel first-in-class antifungal agent for the treatment of immunocompromised patients with serious fungal infections, today announced the appointment of Bill Enright, CEO of Vaccitech, plc (NASDAQ: VACC; “Vaccitech”), as an independent director to its Board of Directors. In December 2021 Gravitas announced the purchase of GR-2397.

> “Gravitas' advantageous position to pursue GR-2397's accelerated development and registration via the Limited Population Pathway for Antifungal Drugs is the result of considerable prior R&D investments”
>
> *Bill Enright, CEO of Vaccitech, plc*

“Bill brings an impressive track record of leading multiple infectious disease-focused biopharmaceutical companies, including raising significant monies in private and public financings,” said Tom Smart, Chairman and CEO of Gravitas. “We believe Bill’s background and leadership skills will aid Gravitas achieving its financing and product development objectives.”

“Gravitas is in an advantageous position to pursue the accelerated development and registration of GR-2397 via the Limited Population Pathway for Antibacterial and Antifungal Drugs. This follows considerable prior research and development investments resulting in the successful completion of single and multiple ascending dose Phase 1 studies,” said Mr. Enright. “I look forward to supporting Gravitas’ expedited, cost-efficient quest to realize GR-2397’s potential to address the significant unmet medical need for better therapeutics to treat severe fungal infections.”

In 2019, Mr. Enright was appointed CEO of Vaccitech, a clinical-stage biopharmaceutical company engaged in the discovery and development of novel immunotherapeutics and vaccines for the treatment and prevention of infectious diseases and cancer. In that role, Mr. Enright has raised

over $250 million, completed an initial public offering, and acquired Avidea Technologies to expand both Vaccitech's product pipeline and scientific leadership. Prior to joining Vaccitech, Mr. Enright served as CEO of Altimmune Inc, a company developing novel immunotherapies and vaccines. He led Altimmune through a significant period of growth including a Series B financing, the acquisition of Immune Targeting Systems – a UK T-cell vaccine company – and taking the company public on NASDAQ through the acquisition of PharmAthene. Mr. Enright's prior experience includes executive and management roles at GenVec (now Intrexon), Biotech Venture Management and Life Technologies Corporation (now ThermoFisher).

About GR-2397

GR-2397 is the first of a new class of antifungal agents being developed for the treatment of serious fungal infections. GR-2397 is differentiated by its novel mechanism of action, rapid ability to kill fungal cells, activity against difficult-to-treat resistant fungal pathogens and low propensity for P450 drug-drug interactions. Gravitas intends to develop GR-2397 initially for the treatment of invasive aspergillosis, which is a significant commercial opportunity within the multi-billion-dollar global market for systemic antifungals. There are currently few treatment options and these therapies are limited by renal and liver toxicity, drug-drug interactions, pharmacokinetic variability resulting in the need for drug monitoring, and emerging drug resistance. Significantly, a high fatality rate (>50%) is still observed in invasive pulmonary aspergillosis among severely immunosuppressed patients, such as neutropenic leukemic and allogeneic hematopoietic stem cell transplant recipients. GR-2397 was discovered and initially developed by Astellas. In 2015, Vical Incorporated ("Vical") in-licensed GR-2397 from Astellas and subsequently completed a randomized, double-blind Phase 1 clinical trial. In 2018, Vical initiated a multicenter, open label randomized Phase 2 clinical study to compare the efficacy and safety of GR-2397 to standard treatment for invasive aspergillosis in immunocompromised adults with acute leukemia and recipients of allogeneic hematopoietic cell transplant. Vical discontinued that study in February 2019 to conserve cash resources while exploring strategic options to enhance shareholder value following the unsuccessful completion of a Phase 3 trial for a separate program unrelated to GR-2397.

About Invasive Aspergillosis

Invasive aspergillosis is a life-threatening infection that typically affects immunocompromised patients, including those with acute leukemia and recipients of allogeneic HCT or lung transplants. Infection typically starts in the lungs and rapidly disseminates to other tissues. More than 200,000 cases of invasive aspergillosis are diagnosed annually worldwide.

About the Limited Population Pathway (LPAD)

Prior to initiating the Phase 2 clinical trial, the U.S. Food and Drug Administration (FDA) advised Vical that GR□2397 would be eligible for accelerated development via the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) with the objective of receiving registration for a Limited Use Indication (LUI). Receiving the LUI registration would require a successful outcome of a single Phase 2 trial for the LUI carried out in accordance with a protocol and statistical analysis plan consistent with the FDA's advice and be subject to a final determination

by the FDA whether the drug is approvable after reviewing all relevant data. LPAD is designed to streamline development programs for antibacterial and antifungal agents intended to treat specific groups of patients with serious or life-threatening infections and limited treatment options. Under this pathway, the drug can be used to treat a limited patient population while additional trials are conducted to establish safety and effectiveness for broader indications. Standards for a new drug application must be met for LUI approval. In the case of GR□2397, the limited population approval would be for treatment of invasive aspergillosis in patients who are unable to receive treatment with one of the currently approved antifungal agents. The LUI is a provision of the Limited Population Pathway established under the 21st Century Cures Act of 2016.

About Additional Designations Granted GR-2397 by the FDA
The FDA granted Qualified Infectious Disease Product (QIDP), Orphan Drug and Fast Track designations to GR-2397 for the treatment of invasive aspergillosis. GR-2397's IND remains open with the FDA.

About Gravitas Therapeutics, Inc.
In December 2021 Gravitas announced the purchase of GR-2397, a clinical-stage novel first-in-class antifungal agent for the treatment of immunocompromised patients with serious fungal infections including patients who are unable to receive one of the currently available antifungal agents due to resistance and/or intolerance. For additional information on Gravitas, please contact us at info@gravitastx.com.

Forward-Looking Statements
This press release contains forward-looking statements subject to risks and uncertainties that could cause actual results to differ materially from those projected.

Tom Smart
Gravitas Therapeutics
+1 858-228-6827
email us here