GRAVITAS THERAPEUTICS ANNOUNCES PURCHASE OF FIRST-IN-CLASS ANTIFUNGAL INTENDED TO TREAT INVASIVE ASPERGILLUS INFECTIONS

GR-2397 to be developed for its potential to become a major advancement in the treatment of serious fungal infections

SAN DIEGO, CALIFORNIA, UNITED STATES, December 7, 2021 /EINPresswire.com/ -- Gravitas Therapeutics, Inc. (“Gravitas”) today announced that it has purchased the rights to the novel first-in-class antifungal, GR-2397 (fka VL-2397), from Brickell Biotech, Inc. ("Brickell").

> “Our goal is to rapidly and efficiently develop GR-2397 for patients with serious fungal infections”
>
> *Tom Smart, CEO, Gravitas Therapeutics*

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 that confers rapid fungicidal activity, low propensity for P450 drug-drug interactions, and activity against difficult-to-treat resistant fungal pathogens. 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. The currently available antifungal agents indicated for treatment of this infection have limited efficacy, as the mortality in allogeneic hematopoietic stem cell transplant recipients with invasive aspergillosis can be as high as 50-60%. Over the past 30 years, only one new class of antifungal agents (echinocandins, which are primarily used for the treatment of fungal infections other than invasive aspergillosis) has been approved for the treatment of serious fungal infections.

“Returning GR-2397 to the clinic is significant because of its potential to become a major advancement in the treatment of serious fungal infections” said Tom Smart, Chairman, CEO and a founder of Gravitas. “We’ve assembled a strong development team with hands-on experience in the development of GR-2397 and other antifungal agents and have the support of major clinical investigators and key opinion leaders in the field.”

Under the terms of the purchase agreement, Brickell received an upfront fee, and is eligible to

receive certain milestone, royalty and other payments from Gravitas. In addition, GR-2397's originator, Astellas Pharma Inc. (TOKYO:4503) ("Astellas"), is eligible to receive certain milestone, royalty and other payments from Gravitas. Financial terms of the purchase agreement were not disclosed.

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 GR-2397

GR-2397 is a novel antifungal compound that was discovered by Astellas. GR-2397 was isolated from a leaf litter fungus collected in a Malaysian national park and represents the first agent in a potential new class of antifungal drugs. 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 patients 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. In September 2019, Brickell, a clinical-stage pharmaceutical company developing therapeutics for the treatment of dermatologic, autoimmune and other debilitating diseases, completed a reverse merger with Vical and in conjunction assumed the rights to GR-2397.

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.
Gravitas was founded to acquire and advance the clinical development of GR-2397, a 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. Forward-looking statements include anticipated developments in clinical programs, the potential benefits of GR-2397 and its commercial opportunity. Risks and uncertainties include whether Gravitas or others will continue development of GR-2397; whether Gravitas will obtain regulatory allowances necessary to proceed with proposed clinical trials or implement anticipated clinical trial designs; whether planned clinical trials will be initiated or completed on the timelines Gravitas currently expects; whether GR-2397 will be shown to be safe and efficacious in clinical trials; whether Gravitas will have access to sufficient capital to fund its planned development activities. Gravitas disclaims, however, any intent or obligation to update these forward-looking statements.

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