Rani Therapeutics Announces Partnership with ProGen on Development of Oral Obesity Treatment

June 24, 2024

~ New RT-114 obesity program combines ProGen's FC Fusion protein conjugated GLP-1/GLP-2 dual agonist, PG-102, with the RaniPill® capsule designed to provide a differentiated oral delivery mechanism with bioavailability comparable to subcutaneous injection ~

~ Rani and ProGen to share responsibilities for the development and commercialization of RT-114, including a 50/50 cost and revenue share arrangement ~

~ Rani to host conference call today at 8:00 a.m. ET/5:00 a.m. PT ~

SAN JOSE, Calif., June 24, 2024 (GLOBE NEWSWIRE) -- Rani Therapeutics Holdings, Inc. ("Rani Therapeutics" or "Rani")(Nasdaq: RANI), a clinical-stage biotherapeutics company focused on the oral delivery of biologics and drugs, today announced that it has entered into a definitive agreement with ProGen Co., Ltd. ("ProGen")(Konex: 296160), a South Korean clinical-stage biotech company developing next generation long-acting, multi-specific fusion protein therapeutics, for the co-development and commercialization of RT-114, an oral RaniPill® capsule containing ProGen's PG-102, a GLP-1/GLP-2 dual agonist, for the treatment of obesity.

"This collaboration with ProGen reinforces Rani's clear commitment to improving the lives of people suffering from chronic conditions, such as obesity, by replacing painful injections with the convenience of a pill," said Talat Imran, Chief Executive Officer of Rani Therapeutics. "We chose to collaborate with ProGen based on the potentially unique pharmacokinetic (PK) and tolerability profile of PG-102 in a RaniPill® capsule. Given the long half-life of PG-102, the parties intend to pursue development of RT-114 as a convenient, weekly oral dose. It also has the potential to improve body composition and nutritional health of patients owing to the unique mechanism of action of GLP-2. We look forward to working with ProGen to advance RT-114 with the goal of creating a truly differentiated oral anti-obesity medicine designed to enhance patients' adherence and maximize therapeutic effects with bioavailability comparable to subcutaneous injections."

"This partnership brings together Rani's oral biologics delivery expertise with ProGen's two decades of experience in Fc-fusion proteins to enable development of a potentially unique oral therapy option for people with obesity," said Dr. Jong-Gyun Kim, Chief Executive Officer of ProGen. "Together, we are focused on pursuing RT-114 as a potential first-in-class, oral dual agonist in the anti-obesity arena."

Under the terms of the collaboration agreement, Rani and ProGen agree to share responsibilities for the development and commercialization of RT-114 worldwide, including a 50/50 cost and revenue share arrangement. Rani has exclusive rights to lead development and commercialization of RT-114 in the United States, Europe, Canada and Australia, and ProGen has exclusive rights to lead development and commercialization in the rest of the world. Each party has certain rights to sublicense in its territories. Rani is designated to lead operationally in conducting preclinical and development activities through the Phase 1 program, which is expected to initiate in 2025. As part of this agreement, there is no upfront payment or financial exchange between the companies.

Rani has developed the RaniPill® capsule, which is a novel, proprietary and patented platform technology, intended to replace subcutaneous injection or intravenous infusion of biologics and drugs with oral dosing. Rani has tested 15 molecules in the RaniPill® platform. The RaniPill® platform has delivered antibodies, peptides and large proteins with high bioavailability. To date, Rani has completed three Phase 1 clinical studies with the RaniPill® capsule. Additionally, ProGen's preclinical studies demonstrated that treatment with PG-102 resulted in greater glycemic control while inducing a similar degree of body weight loss versus semaglutide and tirzepatide.[1]

ProGen recently presented results from its Phase 1 single-ascending dose study of PG-102, a GLP-1/GLP-2 dual agonist, at the 2024 American Diabetes Association conference in which PG-102 showed a favorable safety profile with lower frequencies of gastrointestinal (GI) side effects compared to competitors' trials in similar settings. Additionally, the PK/pharmacodynamic (PD) data from this trial and preclinical studies support potential dosing of RT-114 on a weekly to monthly schedule, which could improve patient compliance.

Conference Call

Rani will host a corresponding conference call and live webcast on June 24, 2024, at 8:00 a.m. ET/5:00 a.m. PT to discuss the ProGen collaboration. Individuals interested in listening to the live conference call may do so by using the webcast link in the "Investors" section of the Company's website at www.ranitherapeutics.com. A webcast replay will be available in the investor relations section on the Company's website for 90 days following the completion of the call.

About Rani Therapeutics

Rani Therapeutics is a clinical-stage biotherapeutics company focused on advancing technologies to enable the development of orally administered biologics and drugs. Rani has developed the RaniPill® capsule, which is a novel, proprietary and patented platform technology, intended to replace subcutaneous injection or intravenous infusion of biologics and drugs with oral dosing. Rani has successfully conducted several preclinical and clinical studies to evaluate safety, tolerability and bioavailability using RaniPill® capsule technology. For more information, visit ranitherapeutics.com.

About ProGen

ProGen is a South Korean clinical-stage biotech company developing next generation long-acting biologics for the treatment of metabolic diseases (obesity, type 2 diabetes, etc.) and immune-mediated diseases (inflammatory diseases and cancer). ProGen harnesses its proprietary technology platform known as Neo Tri-ImmunoGlobulin (NTIG®) that enables multi-targeting and allows drugs to have longer *in vivo* persistence than conventional Fc-fusion proteins. ProGen is currently focusing on the development of its lead product PG-102, a GLP-1/GLP-2-NTIG® fusion protein for the treatment of obesity and type 2 diabetes. PG-102 has shown improvement of body composition and glycemic control compared to tirzepatide in

mouse models of obesity with and without type 2 diabetes.[2] PG-102 is currently being investigated in a Phase 1b multiple ascending dose trial in Korea.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include statements regarding, among other things, the potential for RT-114 to be an oral treatment for obesity, the potential for RT-114 to be dosed weekly or less frequently, the potential for RT-114 to have a unique and differentiated product profile, success of the collaboration with ProGen and related activities, and the potential for Rani to make oral biologics a reality for millions of patients living with chronic conditions. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as “believe,” “design,” “intend,” “look forward,” “could,” “plan,” “goal,” “potential,” “will,” “would” and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Rani’s current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks and uncertainties associated with Rani’s business in general and the other risks described in Rani’s filings with the Securities and Exchange Commission, including Rani’s annual report on Form 10-K for the year ended December 31, 2023, and subsequent filings and reports by Rani. All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management’s assumptions and estimates as of such date. Rani undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

Investor Contact:
investors@ranitherapeutics.com

Media Contact:
media@ranitherapeutics.com

[1] PG-102, Next Generation GLP-1/GLP-2 Dual Agonist for the Treatment of Metabolic Diseases. Presentation at 2024 BIO Korea

[2] Fat-specific weight loss in diet-induced obesity mouse model when treated with bispecific GLP-1R/GLP-2R agonist vs. dual GLP1R/GIPR agonist. Presentation at 59th EASD Annual Meeting