Rani Therapeutics and Celltrion Expand Partnership to Include Adalimumab Biosimilar for RT-105

June 5, 2023

This is the second deal announced between Rani and Celltrion, building upon a previously announced partnership for ustekinumab biosimilar for RT-111

SAN JOSE, Calif., June 05, 2023 (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 expanded its partnership with Celltrion by entering into an agreement for the development of RT-105, an orally administered adalimumab biosimilar. Rani’s first partnership with Celltrion, for the development of RT-111, an orally administered ustekinumab biosimilar, was announced in January of this year.

Under the terms of the new license and supply agreement, Celltrion will exclusively supply to Rani the adalimumab biosimilar drug substance (CT-P17) required for RT-105. Rani is granted an exclusive license to use CT-P17 in the development and commercialization of RT-105, and Celltrion is granted a right of first negotiation to acquire worldwide rights to RT-105 following a Phase 1 study.

“We are delighted to expand our partnership with Celltrion, a world-class pharmaceutical company, a leader in biosimilars and our valued partner,” said Talat Imran, CEO of Rani. “We believe this expansion of the Rani-Celltrion relationship further validates our RaniPill ® platform and offers the potential to deliver great value for both our companies. We look forward to advancing both RT-105 and RT-111 as oral alternatives to painful injections for people with chronic inflammatory conditions.”

Rani has developed an oral delivery technology known as the RaniPill® capsule, which is intended to replace subcutaneous or intravenous injection of biologics and drugs with oral dosing. The RaniPill® capsule is designed to administer biologics and drugs with bioavailability comparable to subcutaneous injection.

The RaniPill® platform is payload-agnostic and has the potential to create an oral option for almost any biologic or drug, regardless of modality or therapeutic area. In this agreement with Celltrion, Rani is applying its oral delivery technology to a TNF- α antibody for the potential treatment of inflammatory diseases.

“We are pleased to build upon our existing partnership with Rani, a company that is pioneering oral drug delivery across a broad range of injectable therapeutics,” said SungHyun Kim, Head of Medical Science Division. "The cooperation between our companies allows each of us to pursue our commitment to delivering effective and convenient medicines, which in time could benefit healthcare systems, providers and patients.”

This is the first announced partnership for a program involving the RaniPill® HC, a high-capacity device that is designed to deliver up to 20mg of payload with high bioavailability and is in preclinical testing.

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 www.ranitherapeutics.com.

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 the partnership with Celltrion to deliver value, the advancement of Rani’s pipeline and RaniPill ® platform technology including the RaniPill® HC, the potential of the RaniPill® platform to deliver almost any biologic or drug, the attractiveness of the RaniPill® platform technology to healthcare providers, drug developers and patients, and Rani’s growth as a company. 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 “could,” “potential,” “believe,” “look forward” 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, 2022 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