Celltrion and Rani Therapeutics Partner on Development of Oral Monoclonal Antibody Treatment

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Celltrion will be Rani's exclusive supplier of ustekinumab biosimilar, CT-P43, for oral RT-111 RaniPill™ program

SAN JOSE, Calif., Jan. 09, 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 partnered with Celltrion for the development of RT-111, an orally administered ustekinumab biosimilar.

Under a license and supply agreement, Celltrion will exclusively supply to Rani the ustekinumab biosimilar drug substance (CT-P43) required for RT-111. Rani is granted an exclusive license to use CT-P43 in the development and commercialization of RT-111, and Celltrion is granted a right of first negotiation to acquire worldwide rights to RT-111 following a Phase 1 clinical trial.

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.

"We are delighted to be partnering with Celltrion, a leader in biosimilars and biologics manufacturing, on RT-111. This agreement is a validation of our RaniPill oral drug delivery technology, which has already performed well in two separate Phase 1 trials of RT-101 and RT-102, respectively," said Talat Imran, CEO of Rani. "We value Celltrion as the exclusive provider of ustekinumab biosimilar for our RT-111 program and look forward to sharing the results of our study in due course, and potentially broadening our partnership with Celltrion."

"Celltrion strives to address unmet needs of patients and partnering with Rani offers the opportunity to replace painful injections with a pill," said SungHyun Kim, Head of Medical Science Division. "Celltrion sees potential for the RaniPill platform to be applicable to other biologics."

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™ capsules, which are 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™ capsules. For more information, visit 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 expected initiation of a Phase 1 trial of RT-111 and the timing of results from such trial, the potential to broaden the partnership with Celltrion, the potential future commercialization of RT-111, the potential for Celltrion to acquire worldwide rights to RT-111, the ability of the RaniPill™ capsule to replace subcutaneous or intravenous injections, or the ability of the RaniPill™ capsule to administer biologics or drugs with bioavailability comparable to subcutaneous injection. 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 "may," "could," "anticipate," "believe," "look forward," "progress," "advance," "potential", "be able to" 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, the impact of the COVID-19 pandemic, and the other risks described in Rani's filings with the Securities and Exchange Commission. 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.

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