Rani Therapeutics Initiates Phase 1 Study of RT-111 (RaniPill® Containing Ustekinumab Biosimilar, CT-P43)

September 18, 2023

- Topline results from this study are expected in early Q1 2024

- Celltrion has a right of first negotiation for RT-111 following positive Phase 1 results

SAN JOSE, Calif., Sept. 18, 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 the initiation of a Phase 1 clinical trial to evaluate the safety and tolerability of RT-111, an orally administered RaniPill®GO capsule containing an ustekinumab biosimilar, CT-P43. Topline results from this study are expected early in the first quarter of 2024.

Ustekinumab is a human IgG1κ monoclonal antibody that binds with specificity to the p40 protein subunit used by both the interleukin-12 and interleukin-23 (IL-12 and IL-23) cytokines, and is marketed in the United States by Janssen as STELARA®. STELARA® is approved by the FDA for the treatment of moderate to severe plaque psoriasis, active psoriatic arthritis, moderate to severe Crohn’s disease, and moderate to severe ulcerative colitis, all of which have large unmet medical needs for oral treatment. Sales for STELARA® were approximately $6.4 billion in the United States and approximately $9.7 billion worldwide in 2022.

Currently, ustekinumab is available only as a subcutaneous injection. In preclinical testing of RT-111 in animal models, the RaniPill® delivered ustekinumab biosimilar orally with bioavailability comparable to subcutaneous injection.

“We are thrilled to announce the advancement of RT-111 into the clinic, an important milestone for Rani which brings us one step closer to our goal of making oral biologics a reality for patients with autoimmune diseases,” said Talat Imran, Chief Executive Officer of Rani. “Psoriasis, psoriatic arthritis and other autoimmune conditions are chronic diseases that can require regular, painful injections that are burdensome for patients. RT-111 is a convenient, oral delivery of ustekinumab via the RaniPill® capsule. Moreover, because the RaniPill® capsule technology is a drug-agnostic delivery platform, RT-111 also represents a broader opportunity to potentially replace other injectable-only monoclonal antibodies and large molecules with an oral alternative.”

The first subject has been administered RT-111 in the single-center, open-label Phase 1 study, which is being conducted in Australia. The study will evaluate the pharmacokinetics, safety and tolerability of RT-111 administered in up to 55 healthy human participants. The trial will consist of three cohorts, with two cohorts evaluating RT-111 at a dose of 0.5mg or 0.75mg, administered as a RaniPill® capsule containing ustekinumab. The third cohort, as the control group, will receive Stelara® (ustekinumab) 0.5mg via subcutaneous injection.

The ustekinumab biosimilar used in RT-111 is manufactured and supplied by Celltrion, Inc. (“Celltrion”) under Rani’s License and Supply Agreement with Celltrion announced in January 2023. Under that agreement, Celltrion exclusively supplies 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 that meets its primary endpoint(s).

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 is progressing two RaniPill® capsules, the RaniPill®GO and the RaniPill®HC. 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.

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 timing of topline results from the RT-111 Phase 1 study in Q1 2024, the potential for Celltrion to exercise its right of first negotiation or for Rani to derive value from its partnership with Celltrion, the potential for RT-111 and the RaniPill® capsule technology to represent a broader opportunity to potentially replace injectable-only monoclonal antibodies and large molecules with an oral alternative, market opportunity for RT-111, customer acceptance of the RaniPill® capsule technology, and the potential benefits of the RaniPill® capsule technology. 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 “expected,” “potential,” “anticipate,” “opportunity” 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.

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