Rani Therapeutics Announces Successful Oral Delivery of Monoclonal Antibody via High-Capacity Pill in Preclinical Study

October 19, 2023

- RaniPill® HC achieved 4/4 successful drug delivery of orally administered Humira® (adalimumab) -

- RaniPill® HC has achieved a cumulative >90% success rate across multiple preclinical studies –

- RaniPill® HC shortlisted as a finalist by Fierce Life Sciences Innovation Awards –

SAN JOSE, Calif., Oct. 19, 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 successful oral delivery of a monoclonal antibody, Humira® (adalimumab), via its high-capacity capsule, the RaniPill® HC, in a preclinical study.

“The preclinical results we are sharing today show the potential of the RaniPill® platform to orally deliver large molecules, such as antibodies, at high volume, which could enable the replacement of many injectable drugs with an oral pill,” said Mir Hashim, PhD, Chief Scientific Officer for Rani Therapeutics. “The high-capacity version, the RaniPill® HC, is capable of delivering up to a 500%-plus higher drug payload than Rani’s existing oral biologics capsule and has achieved a cumulative >90% success rate for delivery across multiple preclinical studies. The data generated to date with the RaniPill® HC give us confidence as we progress the high-capacity device towards clinical readiness.”

Data Highlights

Rani conducted a preclinical study tracking the serum concentrations of adalimumab, following the oral administration of the enteric-coated, RaniPill® HC capsule containing 11mg of Humira® (adalimumab) to four canine models. The RaniPill® HC successfully delivered adalimumab in all of the subjects. All device remnants were excreted normally without sequelae.

Rani has orally administered the RaniPill® HC in multiple preclinical studies, including with teriparatide and adalimumab, and has achieved a greater than 90% drug delivery success rate across such studies.

Fierce Life Sciences Innovation Awards 2023

Rani Therapeutics has been shortlisted as a finalist in the 2023 Fierce Life Sciences Innovation Awards in the ”Drug Delivery Technology” category. Winners will be announced on November 29, 2023.

The shortlist recognizes the RaniPill® HC, Rani Therapeutics’ high-capacity, drug-agnostic capsule designed to enable oral delivery of biologic medicines that are otherwise only available as injections. Rani’s mission is to alleviate the burden of painful injections for patients suffering from chronic diseases.

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 potential for the RaniPill® HC to orally deliver large molecules at a high volume, the ability of the RaniPill® capsule to replace injectable drugs with an oral pill, the ability of Rani to continue to progress the RaniPill® HC towards clinical readiness, the ability of the RaniPill® to alleviate the burden of painful injections, 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 “capable of,” “potential,” “could,” “confidence,” “designed 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 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