The RaniPill® Capsule, Rani Therapeutics' Oral Delivery Platform, was Well-Tolerated in 60-Day, Repeat-Administration, GLP Safety Study

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– Daily administration for 60 days was well-tolerated with no treatment-related adverse events –

– Preclinical data support the safety and tolerability of RaniPill® capsule for subsequent clinical studies –

SAN JOSE, Calif., Oct. 25, 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 preclinical data supporting the safety and tolerability of the RaniPill® drug delivery platform following 60-day repeat administration. In the 60-day good laboratory practices ("GLP") study in healthy animals, the RaniPill® capsule was well-tolerated with no treatment-related adverse events.

"The preclinical data announced today are highly encouraging and we believe these data further validate the safety and tolerability of our RaniPill® drug delivery platform," said Mir Hashim, PhD, Chief Scientific Officer of Rani. "Our platform has the potential to offer an oral delivery option for drugs otherwise only available as injections and is drug-agnostic with the opportunity for application across a wide range of biologics. The data from this 60-day GLP study further bolster the safety database supporting the RaniPill® capsule and enable the launch of longer-term clinical trials of Rani's pipeline programs, including our Phase II study of RT-102 for osteoporosis which we plan to initiate in 2023."

Data Highlights

The preclinical GLP study evaluated the safety and tolerability of the RaniPill® drug delivery platform, following 60-day repeat oral administration of the test article, RT-100. RT-100 is an enteric-coated capsule identical to RT-102, but instead of teriparatide contains the pharmaceutical excipient mannitol. The control group received a capsule (Mock-RP) of similar weight to RT-100 but filled with potato starch.

The study included males and females (1:1) divided into two groups that were administered orally either a Mock-RP (N=12) or RT-100 (N=24) once daily for 60 consecutive days with half the animals completing an additional 14-day clinical observation and safety evaluation period. RT-100 was well-tolerated with no treatment-related adverse events and all animals remained clinically healthy throughout the study.

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 planned initiation of the RT-102 Phase II study in 2023, the potential for the data from the 60-day GLP study to validate the safety and tolerability of the RaniPill® drug delivery platform, the potential for the RaniPill® capsule technology to have application across a wide range of biologics, the ability of the data from the 60-day GLP study to bolster the safety database supporting the RaniPill® capsule and Rani's pipeline programs, 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 "believe," "potential," "plan," "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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