Rani Therapeutics Announces Successful Drug Delivery of High-Capacity Pill in Preclinical Studies

September 7, 2023

- Two preclinical studies of RaniPill® HC achieved 18/20 successful drug delivery of orally administered teriparatide resulting in a cumulative 90% success rate

- Rani will continue preclinical testing to confirm preliminary reliability rate and optimize device performance

- Increased payload of up to 20mg enables potential delivery of 90+ additional drug candidates -

SAN JOSE, Calif., Sept. 07, 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 three new positive preclinical studies which support the development of a high-capacity oral biologics device known as the RaniPill® HC, a version of the RaniPill® capsule that is capable of delivering up to a 500%-plus higher drug payload than Rani’s existing oral biologics capsule.

“We are delighted to share that the orally administered RaniPill® HC was able to demonstrate successful drug delivery and high reliability across multiple preclinical studies, further supporting our development of the RaniPill® HC,” said Talat Imran, Chief Executive Officer of Rani. “The RaniPill® HC is designed to enable the potential delivery of 90+ additional drug candidates, opening up a significant market opportunity for Rani Therapeutics. We are excited about the difference the RaniPill® HC could make to alleviate the burden of painful injections for patients and provide a new solution for providers, and look forward to bringing the technology into the clinic through the initiation of a Phase 1 study of adalimumab RT-105.”

Preliminary Data Highlights:

Teriparatide Canine Studies

Rani conducted two preclinical studies of the RaniPill® HC containing 40ug of teriparatide. In the first study, two RaniPill® HC capsules were orally administered to 5 awake canine subjects sequentially, with a second RaniPill® HC capsule administered after the deployment of the previous device was confirmed. In the second study, a single RaniPill® HC capsule was administered to 10 awake canines.

- RaniPill® HC achieved 18/20 successful drug delivery of teriparatide in the two studies, resulting in a cumulative 90% success rate.
- Successful drug delivery was confirmed by positive drug signal for teriparatide in serum.
- Devices used in these studies were separate iterations, and may not comprise all the same components expected in a final version.
- Preliminary preclinical testing supports the potential for RaniPill® HC to have high reliability.

Fe57 Canine Study

Rani also conducted an additional preclinical study of RaniPill® HC containing Fe57 (iron) in 2 canine subjects.

- The RaniPill® HC containing Fe57 showed a positive drug signal comparable to subcutaneous injection.
- Initial analysis of drug delivery via the RaniPill® HC shows a potential for mimicking parenteral (subcutaneous) administration.

Anticipated Next Steps & Milestones:

- Continue preclinical testing of the RaniPill® HC to confirm the preliminary reliability rate and optimize device performance.
- Introduce RaniPill® HC into the clinic with the initiation of a Phase 1 trial of RT-105 containing adalimumab.

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 initiation of a Phase 1 trial of RT-105, Rani’s development and advancement of its RaniPill® HC and RaniPill® GO capsule technology, the ability to confirm reliability and optimize performance of the RaniPill® HC, the market opportunity for Rani utilizing the RaniPill® HC including the potential to

enable Rani to address 90+ additional product candidates, customer acceptance of the RaniPill® capsule technology, the potential benefits of the RaniPill® capsule technology, 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," "look forward," "potential," "enables," "designed to," "continue," "anticipated," "expected" 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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