Rani Therapeutics Announces Preclinical Pharmacodynamic Data on Transenteric Delivery of GLP-1 Incretin Triagonist

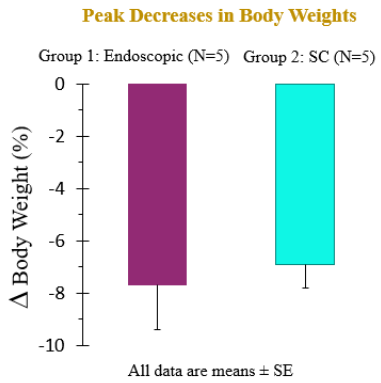
December 14, 2023

- Transenteric delivery of incretin triagonist of GLP-1, GIP, glucagon receptors elicits rapid weight loss in animal study –

- Preclinical data support the potential for the RaniPill platform to enable oral delivery of multiple obesity treatments -

SAN JOSE, Calif., Dec. 14, 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 pharmacodynamic data of an incretin triagonist of the GLP-1, GIP, and glucagon receptors delivered transenterically, which mimics the RaniPill route of administration. This follows Rani’s prior study demonstrating oral delivery of a GLP-1 receptor agonist with high bioavailability via the RaniPill capsule.

Peak Decreases in Body Weights



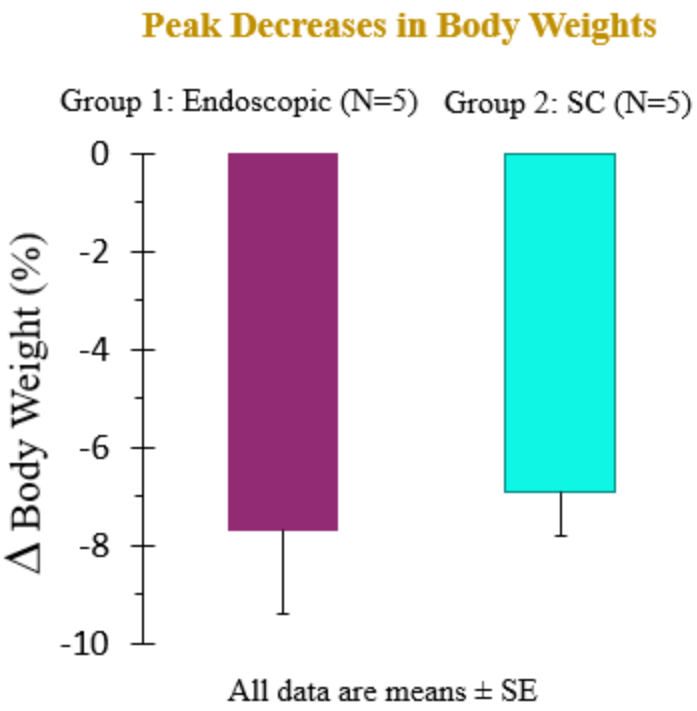
All data are means ± SE

“The preclinical data announced today are highly encouraging, as the data highlights that transenteric delivery mimicking the RaniPill’s route of drug administration results in pharmacodynamics comparable to subcutaneous injection for an incretin triagonist,” said Talat Imran, Chief Executive Officer of Rani Therapeutics. “In a previous preclinical study, Rani showed that the RaniPill capsule can orally deliver a GLP-1 receptor agonist with bioavailability and pharmacokinetics comparable to a subcutaneous injection. In the recent study of an incretin triagonist, Rani obtained pharmacodynamic data showing weight loss and reduction in serum lipids comparable to that observed via the subcutaneous injection route. We believe these data are reflective of the potential contributions our RaniPill capsule can make to the GLP-1 receptor agonist space and the broader obesity market. With the RaniPill platform, we have the potential to create oral alternatives for single and multiagonist drugs with differentiated dosing flexibility. We are evaluating our options with an intention to move forward with one or more products in this space.”

Data Highlights

The recent preclinical study evaluated the pharmacokinetic (PK) and pharmacodynamic (PD) profiles of an incretin triagonist (GLP-1, GIP, glucagon receptors) when delivered via an endoscope-guided transenteric administration to mimic the RaniPill route of administration, versus the traditional administration route of subcutaneous (SC) injection. The study was conducted in canines separated into two groups. In Group 1 (N=5), 0.12 mg/kg of drug was administered via transenteric delivery by endoscope. In Group 2 (N=5), 0.12 mg/kg of drug was administered by subcutaneous injection. Blood samples were collected over 2 weeks for analysis of serum drug concentrations and various PD and safety biomarkers.

A single dose of drug delivered via either transenteric or SC routes elicited rapid decreases in body weight and serum lipids. Weight loss is believed to be due to early satiety leading to reduced caloric intake. The drug was well tolerated in both groups with no serious adverse events (SAEs) observed or changes in safety markers examined.



Near-Term Milestone Expectations:

- Initiation of Phase 2 clinical trial of RT-102, a RaniPill GO containing teriparatide for osteoporosis, expected in 2024.
- Topline results of Phase 1 clinical trial of RT-111, a RaniPill GO containing ustekinumab biosimilar CT-P43, expected in the first quarter of 2024.
- Development of RaniPill HC to be ready for potential Phase 1 clinical trials in the second half of 2024.

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 initiation of a Phase 2 clinical trial of RT-102 in 2024, the potential opportunity for the RaniPill platform to support oral delivery of multiple obesity drug products, the expected timing of topline results from the RT-111 Phase 1 clinical trial in the first quarter of 2024, the expected readiness of the RaniPill HC for clinical development in the second half of 2024, the potential for the transenteric delivery via endoscope of an incretin triagonist to mimic the RaniPill route of delivery, the likelihood that weight loss in the preclinical study of the incretin triagonist was caused by early satiety leading to reduced caloric intake, the belief that the preclinical data are reflective of the potential contributions the RaniPill capsule can make to the GLP-1 receptor agonist space and the broader obesity market, and the potential for Rani to use the RaniPill platform to create oral alternatives for single and multiagonist drugs with differentiated dosing flexibility. 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 “potential,” “expected,” “believed” 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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A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/fabfe920-addc-4e80-ad31-cdb2716763c2