



Rani Therapeutics Announces Positive Initial Phase 1a Data for RT-114 for the Treatment of Obesity, with Oral Bioavailability Exceeding Matched Subcutaneous Dosing

July 15, 2026

- *RT-114 achieved systemic exposure greater than 150% relative to a matched 12mg subcutaneous dose of PG-102*
- *No adverse events attributed to RaniPill® Capsule; treatment-related adverse events were mild and consistent with the GLP-1/GLP-2 agonist class of therapeutics*
- *Phase 1a study expanded with an additional cohort to further define the oral-to-subcutaneous pharmacokinetic relationship ahead of a planned Phase 1b repeat-dose study in patients with obesity*

SAN JOSE, Calif., July 15, 2026 (GLOBE NEWSWIRE) -- Rani Therapeutics Holdings, Inc. (Nasdaq: RANI), a clinical-stage biotherapeutics company focused on oral delivery of biologics, today reported positive initial data from the ongoing Phase 1 study of RT-114, an orally administered RaniPill® Capsule delivering PG-102, a GLP-1/GLP-2 dual agonist being developed by ProGen Co., Ltd. ("ProGen"). The initial data demonstrated that oral RT-114 achieved systemic exposure exceeding that of matched subcutaneous administration, with a safety and tolerability profile consistent with the GLP-1/GLP-2 agonist class of therapeutics.

"The safety and bioavailability findings reported today exceeded our expectations and represent an important milestone for the RaniPill® platform," said Talat Imran, Chief Executive Officer of Rani. "We have previously demonstrated that the RaniPill® can orally deliver a broad range of biologics across multiple therapeutic areas. With RT-114, we have now extended that capability into obesity and metabolic disease while achieving systemic exposure well above that of the matched subcutaneous dose. At a time when many oral biologic delivery technologies continue to produce only a small fraction of subcutaneous exposure, these data reinforce the unique potential of the RaniPill® platform."

Phase 1a Study Design and Results

The ongoing Phase 1a study is evaluating the safety, tolerability, bioavailability, pharmacokinetics and pharmacodynamics of RT-114 relative to subcutaneous PG-102. In the single-dose, open-label Phase 1a portion of the study, 30 healthy volunteers were randomized to receive an identical 12 mg dose of PG-102, delivered either orally via RT-114 or by subcutaneous injection.

Key Findings:

- No serious adverse events were reported in either arm, and no adverse events were attributed to the RaniPill® Capsule itself.
- Treatment-related adverse events, including nausea, vomiting and diarrhea, were mild, transient and consistent with the known profile of GLP-1/GLP-2 dual agonists.
- Oral RT-114 achieved bioavailability greater than 150% relative to a matched subcutaneous dose of 12 mg PG-102.
- Elimination half-life was similar between arms: 5.6 days for oral RT-114 versus 5.3 days for subcutaneous PG-102.

Study Expansion and Next Steps

Rani is expanding the Phase 1a study to include an additional cohort to further characterize the oral-to-subcutaneous pharmacokinetic relationship before advancing to the Phase 1b portion of the study. In this cohort, 15 healthy volunteers will each receive two separate 12 mg doses of PG-102 via the RaniPill® (24 mg total administered dose).

The data from this cohort are expected to inform dose selection for the planned Phase 1b portion of the study, which will assess the safety, tolerability and pharmacodynamic effect of eight weeks of repeat dosing with RT-114 in patients with obesity. The Phase 1b study is expected to begin in 2026, with data anticipated in 2027.

"The magnitude of exposure achieved with oral RT-114 relative to subcutaneous administration may give us greater flexibility to explore a higher range of serum concentrations using fewer and more practical oral doses than we had previously anticipated," Imran added. "We are therefore expanding the Phase 1a study with an additional cohort to help inform dose selection for the repeat-dose Phase 1b study."

About RT-114

RT-114 is an investigational RaniPill® Capsule designed for oral delivery of PG-102, a GLP-1/GLP-2 dual agonist in development by ProGen for the treatment of obesity. RT-114 is being developed by Rani Therapeutics in collaboration with ProGen.

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, a novel, proprietary and patented platform technology, intended to replace subcutaneous injection or intravenous infusion of biologics and drugs with oral dosing. Rani has successfully conducted several preclinical and clinical studies to evaluate safety, tolerability and bioavailability using RaniPill® Capsule technology.

About RT-114 Collaboration

RT-114 is the subject of a Collaboration Agreement between Rani and ProGen entered into in June 2024. Under the Collaboration Agreement, Rani and ProGen will collaborate to manufacture, develop, seek regulatory approvals for and, if approved, commercialize RT-114 in the field of weight management (including without limitation obesity, weight reduction and weight maintenance) in humans. Under the Collaboration Agreement, development costs, as well as operating profits and losses from the commercialization of RT-114, will be equally shared by Rani and ProGen. The parties share responsibility for the development of RT-114 worldwide, with Rani leading such development for preclinical activities through Phase 1 clinical trials. After initiation of the first Phase 2 clinical trial, Rani will lead development and commercialization of RT-114 in the United States, Canada, Europe (including the United Kingdom) and Australia, and ProGen will lead development and commercialization in all other countries.

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. Forward-looking statements include, without limitation, statements regarding: the planned expansion of the Phase 1a study with one additional cohort; anticipated data from the expanded cohort informing dose selection for the planned Phase 1b study; timing of the expected initiation of and data readout from the planned Phase 1b study; potential success of the collaboration between Rani and ProGen; the potential of oral RT-114 to offer greater flexibility in dose selection relative to subcutaneous administration; the potential of RT-114 and the RaniPill® platform in the obesity and metabolic disease field; and the potential of Rani's RaniPill® platform to replace subcutaneous injection or intravenous infusion of biologics and drugs with oral therapies. 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 "anticipate," "intend," "potential," "expect," "will," 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, 2025, 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