Rani Therapeutics Announces Repeat-Dose Topline Results from RT-102 Phase 1 Study

December 6, 2022

- RT-102 achieved all of its endpoints in the repeat-dose Part 2 of the Phase 1 Study -

- Repeat doses of RT-102 were generally well tolerated, with no serious adverse events -

- RaniPill™ GO delivered PTH to subjects with a 91% success rate and demonstrated high bioavailability -

- Data from Part 1 and Part 2 of the Phase 1 study of RT-102 support advancement to a Phase 2 study –

- Company to host conference call today at 4:30 pm ET / 1:30 pm PT -

SAN JOSE, Calif., Dec. 06, 2022 (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 topline results from Part 2 (repeat-dose portion) of the Phase 1 study of RT-102, the RaniPill™ GO capsule containing a proprietary formulation of human parathyroid hormone (1-34) analog (PTH) being developed for the treatment of osteoporosis. The study achieved all of its endpoints, with repeat doses of RT-102 being generally well tolerated and delivering drug with high reliability to participants via the RaniPill™ GO.

“The data are highly encouraging and reinforce the tolerability and high bioavailability of RT-102 that was observed in Part 1 of the study,” said Mir Hashim, PhD, Chief Scientific Officer of Rani. “The RaniPill™ GO capsule continues to deliver drug payloads to subjects at success rates exceeding 90%. Importantly, we believe the safety, reliability, and pharmacokinetic data that we collected through both parts of the Phase 1 study support the initiation of a Phase 2 trial of RT-102 in osteoporosis, which we anticipate beginning in the second half of 2023.”

With these data, in total, 185 RaniPill™ GO capsules have now been administered to more than 90 participants in clinical studies, in addition to over 1,700 RaniPill™ capsules administered to animals in preclinical studies. In the clinical studies, the RaniPill™ capsule has been well tolerated and delivered its drug payload with high reliability and with bioavailability comparable to or better than subcutaneous injection.

“The repeat-dose data contribute to our growing body of preclinical and clinical data that we believe support the viability of the RaniPill™ platform to orally deliver biologics and drugs to treat chronic diseases,” said Talat Imran, Chief Executive Officer of Rani. “These data give us confidence to move forward with multiple programs in parallel, including our ustekinumab biosimilar and adalimumab biosimilar programs, and to expand manufacturing scale-up. We can see a future where millions of patients no longer carry the burden of regular injections.”

Study Design

Part 2 is a continuation of Rani’s single-center, open-label Phase 1 study of RT-102 conducted in Australia. The study evaluated the safety and tolerability of once-daily administration of RT-102 containing 20µg of PTH given repeatedly for seven consecutive days in 10 healthy female volunteers (5 of whom were post-menopausal). Complete pharmacokinetic profiles of PTH were obtained for each subject on Day 7.

Topline Results

Safety and Tolerability

- RT-102 was generally well tolerated, with no serious adverse events (SAEs) noted during the study
  - None of the participants withdrew from the repeat-dose study due to any adverse event related to the RaniPill™ capsule or due to difficulty swallowing the capsule
  - Two subjects had transient, mild-to-moderate adverse events which resolved without any intervention
- Device remnants were excreted without sequelae in all subjects

Device Performance

- In all 10 participants who completed seven days of daily, consecutive dosing, the RaniPill™ GO capsule demonstrated an overall drug delivery success rate of 91% over the seven days (drug sampling was done at three, six and nine hours after capsule swallowing on Days 1-6)
- On Day 7, with more frequent, serial drug sampling after capsule swallowing on that day, the drug delivery success rate was 100%
- On Days 1 through 6, participants ate food three hours after administration of the RaniPill™ GO capsule. The number of successful deployments was comparable before and after food was consumed

Pharmacokinetics

- RT-102 delivered 20µg of PTH with high bioavailability (relative to 20µg subcutaneous Forteo® (teriparatide) in Part 1 of the study), confirming the high bioavailability of PTH delivered via the RaniPill™ capsule observed during Part 1 of the Phase 1 study

- These data indicate that PTH delivered via RT-102 (RaniPill™ GO capsule) may be efficacious at doses lower than 20µg

Conference Call and Webcast

Rani will host a conference call and live webcast at 4:30 pm ET / 1:30 pm PT on December 6, 2022 to discuss the topline results from the Phase 1 Part 2 repeat dose study of RT-102. Individuals interested in listening to the conference will need to register for the event here or through the link provided in the investor relations section on the company's website. The webcast will be available for replay for approximately 180 days.

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™ capsules, which are 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™ capsules. 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 filing of an investigational new drug application and initiation of a Phase 2 trial of RT-102 in 2023, the expected initiation of additional Phase 1 trials of other product candidates in 2023, the prospects for RT-102 being efficacious at doses lower than 20µg, the ability of the data from the Phase 1 study of RT-102 to support progressing to a Phase 2 trial of RT-102, the viability of the RaniPill™ platform to be an oral delivery solution for treating chronic diseases, Rani's advancement of its preclinical and clinical programs and timing of results, Rani's development and advancement of its RaniPill™ capsule technology, the impact of its technology on medical treatment, the potential benefits of the RaniPill™ capsule technology, patient and physician acceptance of the RaniPill™ technology, and the ability of Rani to expand manufacturing scale-up. 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 "may," "could," "anticipate," "believe," "look forward," "progress," "advance," "potential", "be able 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, the impact of the COVID-19 pandemic, and the other risks described in Rani's filings with the Securities and Exchange Commission. 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