Rani Therapeutics Receives Feedback from Pre-IND Meeting with FDA; Provides Pipeline Update

January 5, 2023

- Preliminary feedback from FDA on RT-102 development plans; 505(b)(2) pathway for RT-102 could be suitable -

- Multiple anticipated clinical milestones expected in 2023, including initiation of Phase 2 study of RT-102 in osteoporosis -

SAN JOSE, Calif., Jan. 05, 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 that it completed a pre-Investigational New Drug (IND) meeting with the U.S. Food and Drug Administration ("FDA") with respect to RT-102, the RaniPill™ GO containing a proprietary formulation of human parathyroid hormone (1-34) analog (PTH) for the potential treatment of osteoporosis, and provided a corporate update.

Pipeline Updates:

- **Preliminary feedback received from the FDA on future development of RT-102.** Following feedback from a pre-IND meeting with the FDA, Rani believes that a 505(b)(2) pathway is suitable for the development of RT-102 in the U.S. In addition, Rani obtained guidance from the FDA on its preclinical and clinical development plans for RT-102, including the Phase 2 clinical trial which is expected to initiate in the second half of 2023.
- **Announced topline results from Phase 1 study of RT-102.** In December 2022, Rani announced positive topline results from Part 2 (repeat-dose portion) of the Phase 1 study of RT-102. RT-102 is 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.

"We thank FDA for its feedback and helping us chart the path forward for RT-102. As we enter 2023, Rani has multiple upcoming clinical milestones that we believe could be transformative for the company, including the initiation of a Phase 2 trial for RT-102 - our first Phase 2 trial - and the initiation of three additional Phase 1 studies, including two antibody programs," said Talat Imran, Chief Executive Officer of Rani. "We are delighted by the recent results from our RT-102 program, with positive Phase 1 single and repeat-dose data reinforcing the potential of the RaniPill platform as an oral delivery solution for biologics. We plan to carry this momentum forward, and I look forward to providing further updates in coming months."

Near-Term Milestone Expectations:

- RT-102 – Phase 2 initiation in the second half of 2023
- Initiation of three additional Phase 1 studies in 2023 with pipeline molecules:
  - RT-105 containing an adalimumab biosimilar
  - RT-110 containing PTH for hypo-parathyroidism
  - RT-111 containing an ustekinumab biosimilar for psoriatic arthritis, ulcerative colitis, Crohn's disease and psoriasis

Preliminary Unaudited Cash Position:

- Rani has approximately $99 million in cash, cash equivalents, restricted cash equivalents and marketable securities as of December 31, 2022. This estimate of the Company's cash, cash equivalents, restricted cash equivalents and marketable securities as of December 31, 2022 is preliminary, unaudited and is subject to change upon completion of the Company's financial statement closing procedures and the audit of the Company's consolidated financial statements.

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 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 impact achievement of upcoming clinical milestones could have on the business of the Company, the potential suitability of the 505(b)(2) pathway for RT-102 or other Rani programs, the ability of the data from the Phase 1 study of RT-102 to support progressing to a Phase 2 trial of RT-102, and the preliminary cash position of the 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 "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.

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