



Rani Therapeutics Announces Initiation of Phase 1 Study of RT-102 Oral PTH for Osteoporosis

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SAN JOSE, Calif., March 23, 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, today announced the initiation of a Phase 1 study of RT-102, an oral formulation of the human parathyroid hormone analog PTH(1-34) for the treatment of osteoporosis, delivered via RaniPill™ capsule.

Osteoporosis is a bone loss disease that affects approximately 10 million Americans annually. While there are several medications available for the prevention or treatment of osteoporosis, PTH is one of the few anabolic (bone-building) treatments. Current forms of PTH(1-34) require daily self-injections, a treatment course characterized by poor adherence compared with oral medications. RT-102 is an optimized formulation of PTH(1-34) for oral delivery by the RaniPill capsule to the small intestine. In preclinical studies, RT-102 demonstrated a pharmacokinetic profile comparable to published data of PTH(1-34) injections for the treatment of osteoporosis.

"At Rani, our goal is to make oral biologics a reality. Today represents another step towards this goal with the progression of RT-102 into the clinic, an important milestone for Rani as we begin to evaluate PTH(1-34) delivered by the RaniPill capsule in human subjects," said Talat Imran, Chief Executive Officer of Rani Therapeutics. "Osteoporosis is a chronic and undertreated disease that often requires frequent and painful injections. We believe that RT-102 has the potential to advance treatment of osteoporosis and reach more patients by offering a convenient, oral option."

The first subject has been administered RT-102 in the single-center, open label, Phase 1 study, which is being conducted in Australia. The study will evaluate the pharmacokinetics (PK), safety, and tolerability of RT-102 administered in healthy adult women volunteers. RT-102 will be ingested orally, administering a single dose of parathyroid hormone. Doses will range from 20 to 80 µg.

Rani Therapeutics

Rani Therapeutics is a clinical stage biotherapeutics company focused on advancing technologies to enable the development of orally administered biologics. Rani has developed the RaniPill™ capsule technology, which is a novel, proprietary and patented platform technology, intended to replace subcutaneous injection of biologics with oral dosing. Rani has successfully conducted several preclinical and clinical studies to evaluate safety, tolerability and bioavailability using the RaniPill™ capsule.

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, Rani's advancement of its RaniPill™ capsule technology, the impact of its technology on medical treatment, Rani's advancement of its preclinical and clinical programs, customer acceptance of the RaniPill™ capsule technology, Rani's ability to attract and retain talent, Rani's prospects for entering into strategic partnerships or transactions, 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 "may," "could," "believe," "potential," "look forward," "progress" 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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