



Rani Therapeutics Announces Acceptance into U.S. FDA's Emerging Technology Program (ETP)

October 5, 2026

~ Acceptance into ETP enables early FDA engagement to support development of the RaniPill® platform technology ~

SAN JOSE, Calif., Oct. 05, 2026 (GLOBE NEWSWIRE) -- Rani Therapeutics Holdings, Inc. (Nasdaq: RANI), a clinical-stage biotherapeutics company focused on oral delivery of biologics, today announced that the RaniPill® Capsule™ platform technology has been accepted into the U.S. Food and Drug Administration (FDA) Emerging Technology Program (ETP).

The FDA's Emerging Technology Program, administered within the Agency's Center for Drug Evaluation and Research (CDER), is designed to support the development and implementation of innovative approaches to pharmaceutical product design and manufacturing. Technologies accepted into the program must demonstrate the potential to improve pharmaceutical product quality and incorporate novel elements for which the FDA has limited review or inspection experience. Participation provides Rani with early, direct engagement with the FDA's Emerging Technology Team to address technical and regulatory considerations related to the RaniPill platform, including through pre-submission meetings and potential site visits. Importantly, these interactions can address the broader applicability of the underlying technology rather than being limited to individual drug products.

"Our acceptance into the FDA's Emerging Technology Program reflects the Agency's recognition of the RaniPill® platform as a novel and innovative approach to the oral delivery of biologics," said Talat Imran, Chief Executive Officer of Rani Therapeutics. "This program enables direct, collaborative access to the FDA on a technology as novel as Rani's, and we expect that engagement to be especially valuable as we work to automate our vertically integrated manufacturing process in anticipation of broader clinical use. Combined with our rare disease, immunology, and obesity focused partnerships with Chugai, ProGen and PegBio, this milestone reflects our continued confidence in the RaniPill platform's potential as an alternative to injectable biologics. We look forward to working closely with the FDA as we continue to advance the platform."

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.

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 potential of Rani's RaniPill® platform to convert injectable biologics into oral therapies, and to address unmet needs in the treatment of patients requiring injectable biologics, the anticipated value of Rani's engagement with the FDA under the Emerging Technology Program, Rani's plans to automate its vertically integrated manufacturing process in anticipation of broader clinical use, Rani's expectations regarding its partnerships with Chugai, ProGen and PegBio and the continued development of the RaniPill platform. 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 "continue," "intend," "look forward to," "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