Recursion Announces Completion of Phase 1 Study for REC-3964 for Clostridioides Difficile Infection

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REC-3964 has been well tolerated in healthy volunteers with no reported serious adverse events. Recursion to explore initiating a Phase 2 proof-of-concept study in patients with recurrent Clostridioides difficile infection in 2024.

SALT LAKE CITY, Sept. 05, 2023 (GLOBE NEWSWIRE) -- Recursion (NASDAQ: RXRX), a leading clinical stage TechBio company decoding biology to industrialize drug discovery, today announced it has completed the Phase 1 study for REC-3964 in healthy volunteers. The study achieved its primary objectives of assessing the safety, tolerability and pharmacokinetic profile of REC-3964. REC-3964 has been well tolerated with no serious adverse events (SAEs) reported.

“This is an important step in our efforts to rapidly translate our first new chemical entity into a safe and effective therapy that has the potential to address a significant unmet need,” said David Mauro, M.D., Ph.D., Chief Medical Officer of Recursion. “We are encouraged by the strong safety and tolerability profile and are actively exploring the most expeditious path to advance this program to patients.”

REC-3964 is a novel non-antibiotic small molecule inhibitor of C. difficile toxins that is being developed for the potential treatment of Clostridioides difficile (C. diff) infection, a bacterial disease that impacts more than 730,000 people in the US and EU5 every year. REC-3964 is Recursion’s first and most advanced new chemical entity, demonstrating the power of Recursion’s platform to rapidly identify, validate, optimize and translate novel insights into clinical candidates.

REC-3964 represents a novel small molecule approach designed to selectively inhibit the toxin produced by Clostridioides difficile in the gastrointestinal tract. This molecule has the potential, when used as part of a treatment regimen, to prevent recurrent disease and/or other forms of C. diff infection, which is a leading cause of antibiotic-induced diarrhea sometimes leading to significant morbidity and mortality. More than 29,000 patients die in the US every year from C. diff infection.

About the Trial

The Phase 1 study was designed as a first-in-human protocol evaluating single and multiple doses of orally administered REC-3964 in healthy volunteers. The study assessed the safety, tolerability and pharmacokinetic (PK) profile of REC-3964 and consisted of two parts: single ascending dose (SAD) and multiple ascending dose (MAD). Dosing levels for MAD were 100 mg (Cohort 1), 300 mg (Cohort 2), 500 mg (Cohort 3), and 900 mg (Cohort 4). In Cohort 1, 12 participants were randomized to receive either REC-3964 (N=10) or placebo (N=2) and in each Cohorts 2 through 4, 10 participants were randomized to receive either REC-3964 (N=8) or placebo (N=2) for a total of 42 participants for the MAD study. Participants were dosed with REC-3964 for 14 days.

PK analysis demonstrated that exposures (AUC) increased approximately dose-proportionally across the dose ranges tested and the half-life ranged from approximately 7 to 10 hours. As a result, twice-daily (BID) dosing is expected to reach targeted trough concentrations. Overall, REC-3964 was very well tolerated. Four participants (11.8%, N=34) experienced treatment-related adverse events, which were mild. Additionally, no treatment-related SAEs were observed, and there were no discontinuations due to a treatment-related adverse event. Based on these data, a Phase 2 proof-of-concept trial is expected to initiate in 2024 to further study the attributes of this molecule.

About Recursion

Recursion (NASDAQ: RXRX) is a clinical stage TechBio company leading the space by decoding biology to industrialize drug discovery. Enabling its mission is the Recursion OS, a platform built across diverse technologies that continuously expands one of the world’s largest proprietary biological and chemical datasets. Recursion leverages sophisticated machine-learning algorithms to distill from its dataset a collection of trillions of searchable relationships across biology and chemistry unconstrained by human bias. By commanding massive experimental scale — up to millions of wet lab experiments weekly — and massive computational scale — owning and operating one of the most powerful supercomputers in the world, Recursion is uniting technology, biology, and chemistry to advance the future of medicine.

Recursion is headquartered in Salt Lake City, where it is a founding member of BioHive, the Utah life sciences industry collective. Recursion also has offices in Toronto, Montréal and the San Francisco Bay Area. Learn more at www.Recursion.com, or connect on Twitter and LinkedIn.

Forward-Looking Statements

This document contains information that includes or is based upon "forward-looking statements" within the meaning of the Securities Litigation Reform Act of 1995, including, without limitation, those regarding REC-3964 and other early and late stage discovery, preclinical, and clinical programs; licenses and collaborations; prospective products and their potential future indications and market opportunities; the Recursion OS and other technologies; business and financial plans and performance; and all other statements that are not historical facts. Forward-looking statements may or may not include identifying words such as "plan," "will," "expect," "anticipate," "intend," "believe," "potential," "continue," and similar terms. These statements are subject to known or unknown risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statements, including but not limited to: challenges inherent in pharmaceutical research and development, including the timing and results of preclinical and clinical programs, where the risk of failure is high and failure can occur at any stage prior to or after regulatory approval due to lack of sufficient efficacy, safety considerations, or other factors; our ability to leverage and enhance our drug discovery platform; our ability to obtain financing for development activities and other corporate purposes; the success of our collaboration activities; our ability to obtain regulatory approval of, and ultimately commercialize, drug candidates; our ability to obtain, maintain, and enforce intellectual property protections; cyberattacks or other disruptions to our technology systems; our ability to attract, motivate, and retain key employees and manage our growth; and other risks and uncertainties such as those described under the heading "Risk Factors" in our filings with the U.S. Securities and Exchange Commission, including our most recent Quarterly Report on Form 10-Q and our Annual Report on Form 10-K. All forward-looking statements are based on management's current

estimates, projections, and assumptions, and Recursion undertakes no obligation to correct or update any such statements, whether as a result of new information, future developments, or otherwise, except to the extent required by applicable law.

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