Recursion Announces First Patient Dosed in Phase 1 Clinical Study of REC-3565, a Selective MALT1 Inhibitor for Relapsed or Refractory B-cell Lymphomas

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REC-3565 is a potential best-in-class MALT1 inhibitor for multiple hematology indications, designed to reduce the risk of hyperbilirubinemia, a common side effect of other MALT1 inhibitors

Salt Lake City, UT, April 08, 2025 (GLOBE NEWSWIRE) -- Recursion (Nasdaq: RXRX), a leading clinical stage TechBio company decoding biology to radically improve lives, today announced that the first patient has been dosed in the Phase 1 EXCELERIZE clinical study evaluating REC-3565 for the treatment of relapsed or refractory B-cell lymphomas.

"REC-3565 showed durable tumor regressions in preclinical studies, both as a monotherapy and in combination with a BTK inhibitor. Leveraging our AI-powered Recursion OS platform, which combines physics-based modeling with molecular dynamics and hotspot analysis, we delivered a lead candidate in just 15 months," said Najat Khan, Chief R&D Officer and Chief Commercial Officer at Recursion. "Its allosteric design enhances potency, selectivity, and safety, potentially reducing hyperbilirubinemia risks associated with UGT1A1 inhibition seen in other MALT1 inhibitors. This is particularly promising for patients with B-cell malignancies, where unmet needs remain high."

EXCELERIZE, the Phase 1, open-label, multicenter dose-escalation study will assess the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary efficacy of REC-3565 in two parts. Part A will assess monotherapy dosing to identify a recommended dose for combination in Part B, which will evaluate combination regimens to inform future studies in B-cell cancers.

“We’re advancing REC-3565, a potential best-in-class MALT1 inhibitor, to improve outcomes for patients with B-cell malignancies with limited treatment options,” said David Mauro, Chief Medical Officer at Recursion. “This milestone reflects our unwavering commitment to advancing patient-centric solutions and recruitment with AI-driven innovation.”

About REC-3565
REC-3565 is a mucosa-associated lymphoid tissue lymphoma translocation protein 1 (MALT1) inhibitor designed using Recursion’s AI-driven multi-parameter optimization approach. MALT1, a key protease in the NF-kB pathway, drives malignant B-cell proliferation in hematological cancers. While current therapies (e.g., BTK inhibitors) have advanced treatment, resistance remains a significant challenge. REC-3565 targets MALT1 to potentially overcome resistance and improve outcomes, either as a monotherapy or in combination with BTK and BCL2 inhibitors. Unlike other MALT1 inhibitors, REC-3565 significantly minimizes UGT1A1 inhibition, reducing the risk of drug-drug interactions and hyperbilirubinemia, potentially enabling safer dose escalation and higher target engagement for better clinical efficacy. Approximately 41,000 relapsed and/or refractory (R/R) patients with CLL and B-cell lymphomas in the U.S. and EU5 are eligible for treatment each year.

About Recursion
Recursion (NASDAQ: RXRX) is a clinical stage TechBio company 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, New York, London, Oxford area, and the San Francisco Bay area. Learn more at www.Recursion.com, or connect on X (formerly 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 the potential efficacy of REC-3565, including the potential to be a best-in-class treatment; timing of and outcomes of the EXCELERIZE clinical trial; the effects of our partnerships and our platform on trial outcomes, efficiency, or enrollment; the potential size of the market opportunity for our drug candidates; the relevance of pre-clinical data; early and late stage discovery, preclinical, and clinical programs; licenses and collaborations; prospective products and their potential future indications; 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; inflation and other macroeconomic issues; 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 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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