# Recursion is Granted Orphan Drug Designation for REC-4881 for the Potential Treatment of Familial Adenomatous Polyposis

September 29, 2021

SALT LAKE CITY, Sept. 29, 2021 /PRNewswire/ -- Recursion (NASDAQ: RXRX), a clinical-stage biotechnology company decoding biology by integrating technological innovations across biology, chemistry, automation, machine learning and engineering, today announced that the U.S. Food and Drug Administration (FDA) has granted the company orphan drug designation for REC-4881 for the potential treatment of familial adenomatous polyposis (FAP). REC-4881 is an orally bioavailable, non-ATP-competitive allosteric small molecule inhibitor of MEK1 and MEK2 being developed to reduce tumor size in FAP patients.

The FDA designates orphan products to support the development and evaluation of new treatments for rare diseases. The designation qualifies the sponsor for incentives including tax credits for qualified clinical trials, exemption from user fees and potentially seven years of market exclusivity if the medicine is approved.

"The orphan drug designation for REC-4881 is an important addition to our work to develop this medicine to treat patients with FAP, for which there is significant unmet need," said Ramona Doyle, M.D. chief medical officer of Recursion. "I am pleased that the team continues to advance this medicine towards a Phase 2, randomized, double-blind, placebo-controlled study to evaluate safety, pharmacokinetics and efficacy in FAP patients, for which we expect to begin enrolling patients within the next three quarters."

FAP is a rare tumor syndrome with no approved therapies. In the US, France, Germany, Italy, Spain and the UK alone the disease affects approximately 50,000 patients. FAP is caused by autosomal dominant inactivating mutations in the tumor suppressor gene *APC*. FAP patients develop polyps and adenomas in the gastrointestinal tract throughout life. These growths have a high risk of malignant transformation and can give rise to invasive cancers of the colon, stomach, duodenum and rectal tissues. Standard of care for patients with FAP is colectomy, and without surgical intervention, affected patients will progress to colorectal cancer in adulthood. Post-colectomy, patients receive endoscopic surveillance every 6-12 months to monitor disease progression. While surgical management and surveillance have improved the prognosis for FAP patients, duodenal and desmoid tumors remain a major cause of death in patients with FAP following colectomy.

Learn more about Recursion and view its pipeline at Recursion.com/pipeline.

**About Recursion**

Recursion is a clinical-stage biotechnology company decoding biology by integrating technological innovations across biology, chemistry, automation, machine learning and engineering. Our goal is to radically improve the lives of patients and industrialize drug discovery. Central to our mission is the Recursion Operating System, which combines an advanced infrastructure layer to generate what we believe is one of the world's largest and fastest-growing proprietary biological and chemical datasets. We combine that with the Recursion Map, a suite of custom software, algorithms and machine learning tools that we use to explore foundational biology unconstrained by human bias and navigate to new biological insights. Learn more at www.Recursion.com, or connect on Twitter and LinkedIn.

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**Forward-Looking Statements**

This press release contains information that includes or is based upon "forward-looking statements" within the meaning of the Securities Litigation Reform Act of 1995. Forward-looking statements provide our expectations or forecasts regarding future events. You can identify these statements by the fact they do not relate strictly to historical or current facts. They may use words such as "anticipate," "estimate," "expect," "project," "intend," "plan," "believe," and other terms of similar meaning in connection with a discussion of future operating or financial performance. In particular, forward-looking statements include statements relating to intended future actions; plans with respect to clinical trials and preclinical activities; prospective products or product approvals; future performance or results of anticipated products or technology; expenses; our ability to obtain, maintain and enforce intellectual property protections and financial results; in addition to other topics. Any or all of our forward-looking statements here or elsewhere may turn out to be wrong. They can be affected by inaccurate assumptions or by known or unknown risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statements and from expected or historical results. Many such factors will be important in determining our actual future results. Consequently, no forward-looking statement can be guaranteed. In particular, you should read the discussion in the "Risk Factors" section in our Prospectus filed with the U.S. Securities and Exchange Commission (SEC) on April 16, 2021 and in our periodic filings with the SEC. Other factors besides those listed could also adversely affect the company. We undertake no obligation to correct or update any forward-looking statements, whether as a result of new information, future developments or otherwise, except to the extent required by applicable law. These forward-looking statements (except as may be otherwise noted) speak only as of the date of this press release. Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. You are advised to consult any further disclosures we make on related subjects in our reports to the SEC.

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