

Recursion is Granted Fast Track Designation for REC-4881 for the Potential Treatment of Familial Adenomatous Polyposis

SALT LAKE CITY, April 11, 2022 /PRNewswire/ -- [Recursion](#) (NASDAQ: RXXR), the clinical-stage biotechnology company industrializing drug discovery by decoding biology, today announced that the U.S. Food and Drug Administration (FDA) has granted the company Fast Track designation for REC-4881 for the potential treatment of familial adenomatous polyposis (FAP) in patients who have previously undergone a colectomy/proctocolectomy. REC-4881 is an orally bioavailable, non-ATP-competitive allosteric small molecule inhibitor of MEK1 and MEK2 being developed to reduce polyp burden and progression to adenocarcinoma in FAP patients.

"The Fast Track designation for REC-4881 is an important addition to our work to rapidly develop this potential medicine to treat patients with FAP, for which there is significant unmet need," said Recursion Chief Medical Officer Ramona Doyle, M.D. "I am pleased that the team continues to advance this drug candidate towards a Phase 2 study to evaluate safety, pharmacokinetics and efficacy in FAP patients, for which we expect to begin enrolling patients in the third quarter of this year."

The FDA's Fast Track designation was established to expedite the review of investigational drugs to treat serious conditions and address unmet medical needs by enabling important drugs to get to patients earlier if approved. Fast Track designation can lead to more frequent interactions with the FDA, as well as Accelerated Approval and/or Priority Review eligibility if certain criteria are met.

Learn more about Recursion and view its pipeline at [Recursion.com/pipeline](https://www.recursion.com/pipeline).

About REC-4881

REC-4881 is an orally bioavailable, non-ATP-competitive allosteric small molecule inhibitor of MEK1 and MEK2 being developed to reduce polyp burden and progression to adenocarcinoma in FAP patients. REC-4881 has been well tolerated in prior clinical studies, consistent with the intended use, and has a gut-localized PK-profile that may be advantageous for FAP, and potentially other APC-driven gastrointestinal tumors. REC-4881 has been granted Orphan Drug designation for FAP by the FDA. We expect to enroll the first patient in a Phase 2, double-blind, randomized, placebo-controlled basket trial in the third quarter of 2022.

About Familial Adenomatous Polyposis

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 in the gastrointestinal tract throughout their lives. These growths have a high risk of malignant transformation and can give rise to invasive cancers of the colon, stomach, duodenum, rectum, and other tissues. Standard of care for patients with FAP is colectomy, and without surgical intervention, affected patients will progress to colorectal cancer in adulthood. Even after 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 major causes of death following colectomy in patients with FAP.

About Recursion

[Recursion](#) is the clinical-stage biotechnology company industrializing drug discovery by decoding biology. Enabling its mission is the Recursion Operating System, a platform built across diverse technologies that continuously expands one of the world's largest proprietary biological and chemical datasets, the Recursion Data Universe. Recursion leverages sophisticated machine-learning algorithms to distill from its dataset the Recursion Map, a collection of hundreds of billions 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.

The Company is proudly 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](https://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 and 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 as well as in our Form 10-K filed with the SEC on March 23, 2022 and our other 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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