



Recursion Initiates Two Additional Clinical Trials For a Total of Four in 2022

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- Recursion initiates TUPELO, a Phase 2 trial of REC-4881 for the potential treatment of Familial Adenomatous Polyposis (FAP)
- Recursion initiates a Phase 1 trial for the potential treatment of Clostridium difficile (C. diff) Colitis with Recursion's first new chemical entity to enter the clinic

SALT LAKE CITY, Sept. 13, 2022 /PRNewswire/ -- [Recursion](#) (NASDAQ: RXRX), the clinical-stage biotechnology company industrializing drug discovery by decoding biology, today announced the initiation of **two** additional clinical trials including its first in-house generated new chemical entity to enter the clinic. Recursion has now initiated a total of four clinical trials in 2022; three Phase 2 or 2/3 proof-of-concept studies and one Phase 1 study.

"In a challenging year for the biotech industry, Recursion has continued to deliver on its goals and mission to decode biology to radically improve lives," said Chris Gibson, Ph.D., CEO and Co-Founder of Recursion. "Our teams have worked tirelessly to advance our first new chemical entity into a first-in-human study and deliver on our goals, initiating four new clinical trials this year. These include initiating a Phase 2 trial for cerebral cavernous malformation (CCM) in March, a Phase 2/3 trial for neurofibromatosis type 2 (NF2)-mutated meningiomas in June, and now our Phase 2 trial for FAP and Phase 1 trial for C. diff."

About the Phase 2 Trial of REC-4881 for FAP

The Phase 2 TUPELO clinical trial is evaluating 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 people living with FAP. It has been granted Fast Track and Orphan Drug designations for the potential treatment of FAP by the U.S. Food and Drug Administration as well as Orphan Drug designation by the European Commission.

There are currently no FDA-approved therapies for the treatment of FAP, a rare tumor predisposition syndrome affecting approximately 50,000 people in the US, France, Germany, Italy, Spain and the UK. Recursion discovered REC-4881 as a potential candidate for treatment of FAP by leveraging its proprietary AI-powered drug discovery platform, the Recursion OS, against cellular models of loss of function of the APC gene. Mutations in the APC gene lead to FAP. The company believes its approach, in which machine learning is used to identify relationships between biological contexts and chemical entities, enables Recursion to accelerate the drug discovery process and expand the scope of potential therapeutic candidates for numerous diseases.

"Despite progress with surgical management, the need for effective therapies for FAP remains high due to continued risk of tumors post-surgery," said Niloy Jewel Samadder, M.D., Professor of Medicine at Mayo Clinic, Enterprise Co-Director, Office of Individualized/Precision Medicine, Mayo Clinic Comprehensive Cancer Center. "The initiation of the TUPELO trial is an important step toward potential treatment options to reduce or eliminate the burden of this devastating disease."

The TUPELO Phase 2 trial is a multicenter, randomized, double-blind, placebo-controlled two-part clinical trial to evaluate efficacy, safety, and pharmacokinetics of REC-4881 in patients with FAP.

About the Phase 1 Trial of REC-3964 for Clostridium Difficile Infection

Recursion today announced the initiation of its Phase 1 clinical trial evaluating REC-3964 in healthy volunteers. REC-3964 is a novel non-antibiotic small molecule inhibitor of *C. difficile* toxins which is being developed for the potential treatment of Clostridium difficile infection, a bacterial disease that impacts more than 730,000 people in the US and EU5 every year. It is the first new chemical entity discovered by the Recursion OS to enter clinical trials.

Recursion discovered REC-3964 using its proprietary AI-powered drug discovery platform, the Recursion OS, in which machine learning is used to identify relationships between biological contexts and chemical entities. REC-3964 represents a novel small molecule approach designed to selectively inhibit the toxin produced by Clostridium 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.

"Initiating this trial is a significant milestone for Recursion, as it represents the progression and maturation of our clinical pipeline to include new chemical entities – illustrating the power of our Recursion OS platform to not only uncover novel biological insights, but also help optimize and test novel chemical compounds for potential use as therapeutics," said Shafique Virani, Chief Business Officer and Interim Chief Medical Officer at Recursion. "We are encouraged by the preclinical data from this program and look forward to advancing it rapidly through clinical studies."

The Phase 1 study is a first-in-human protocol evaluating single and multiple doses of REC-3964 in healthy volunteers. The study will assess the safety, tolerability and pharmacokinetic profile of REC-3964 and will provide the basis for establishing the therapeutic potential of this novel C. difficile antitoxin agent.

For more information about enrollment in these trials, please contact clinicaltrials@recursion.com.

About Recursion

[Recursion](#) is a clinical-stage biotechnology company industrializing drug discovery by decoding biology. 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, Montreal and the San Francisco Bay Area. Learn more at www.Recursion.com, or connect on [Twitter](#) and [LinkedIn](#).

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