Recursion Receives FDA Clearance of Investigational New Drug Application to Initiate First Clinical Trial of REC-994 in Cerebral Cavernous Malformation

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SALT LAKE CITY, July 10, 2018 /PRNewswire/ -- Recursion, a biotechnology company that combines artificial intelligence (AI), experimental biology, and automation to discover drugs at scale, today announced that the U.S. Food and Drug Administration (FDA) has cleared an investigational new drug (IND) application for a Phase 1 clinical trial of REC-994 in the treatment of cerebral cavernous malformation (CCM). REC-994 is a well-characterized, small molecule that has been granted orphan designation by the U.S. FDA for the treatment of symptomatic CCM and by the European Medicines Agency for the treatment of familial CCM. Later this year, Recursion plans to initiate the company's first clinical trial to evaluate the safety and pharmacokinetics of REC-994 as an oral treatment for CCM. REC-994 is a potent, selective superoxide dismutase mimetic, a mechanism of action that has preclinical proof of concept to impact lesion development in a mouse model of CCM.1

Chris Gibson, Ph.D., Co-founder and CEO of Recursion said, "REC-994 was discovered using a basic machine learning system that was the seed for Recursion's AI-powered drug discovery platform. As we embark on this important milestone of initiating our first clinical trial, we are further emboldened in our goal of building a fully integrated drug discovery and development organization that leverages computational tools to accelerate every step in the process of bringing new medicines to patients. As we enter the clinic with our first program, we will continue to build tools to accelerate and scale the discovery of both repurposed and novel drugs, to advance important new therapies for rare genetic diseases, as well as unlock therapeutic targets in multifactorial diseases in inflammation and immunology."

CCM is a genetic disease present in up to 1.5 million individuals in the United States, according to Angioma Alliance, a patient advocacy organization for patients with the disease. Cerebral cavernous malformations (CCMs) are collections of small blood vessels in the brain that are enlarged and irregular in structure which lead to altered blood flow. While these malformations can occur anywhere in the body, for approximately 60,000 patients in the United States, CCMs occur in the brain and cause severe symptoms, including seizures, vision and hearing loss, paralysis, other focal neurologic deficits and/or hemorrhagic stroke.

"A non-surgical treatment for cerebral cavernous malformation could have a significant impact on patients' lives," said Angioma Alliance President Dr. Connie Lee. "We are excited about this important milestone and our continued work with Recursion to advance a novel oral treatment into clinical trials."

1Gibson et. al. (2014) *Circulation* 134(8)

About Recursion

Recursion is a clinical-stage biotechnology company combining experimental biology and automation with artificial intelligence methods in a massively parallel system to efficiently discover potential drugs for diverse indications, including genetic disease, inflammation, immunology, and infectious disease. Recursion applies causative perturbations to human cells to generate disease models and associated biological image data. Recursion's rich, relatable database of more than a petabyte of biological images generated in-house on the company's robotics platform enables advanced machine learning approaches to reveal drug candidates, mechanisms of action, and potential toxicity, with the eventual goal of decoding biology and advancing new therapeutics to radically improve lives. Recursion is headquartered in Salt Lake City. Learn more at www.recursionpharma.com, or connect on Twitter, Facebook, and LinkedIn.

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