Anagram Therapeutics Completes Dosing Study of ANG003, a Broad-Spectrum Oral Enzyme Replacement Therapy, in People with Cystic Fibrosis

ANG003 is a Novel Non-Porcine Enzyme Replacement for Exocrine Pancreatic Insufficiency

Data to be Presented at North American Cystic Fibrosis Conference in September

FRAMINGHAM, Mass., July 30, 2024— Anagram Therapeutics Inc., a clinical-stage biopharmaceutical company dedicated to improving the lives of people with cystic fibrosis (CF) and other rare diseases, today announced the completion of a dose ranging clinical study of ANG003, a novel broad-spectrum orally delivered non-porcine enzyme replacement therapy, in people with CF who have exocrine pancreatic insufficiency (EPI). People with EPI do not produce enough pancreatic (digestive) enzymes to break down foods and absorb nutrients, which can lead to malnutrition, fatty acid abnormalities, profound gastrointestinal symptoms, a significant decrease in quality of life and reduced life expectancy.

A total of fifty-one (51) CF patients completed dosing at one of the Cystic Fibrosis Therapeutics Development Network centers in the U.S., the largest CF clinical trials network in the world. The primary objective of this multicenter, randomized, parallel study was to evaluate the safety and dose ranging of orally administered ANG003 in adult subjects with CF-related EPI. Data from the ANG003-22-101 study will be presented at the upcoming North American Cystic Fibrosis Conference to be held in September in Boston, MA.

"We are grateful to the cystic fibrosis patient community and CF clinical teams, whose high level of interest enabled us to advance this important clinical research," said Robert Gallotto, president and CEO, Anagram. “The completion of this clinical study is a significant milestone as we take one step closer in advancing a new class of oral enzyme therapy that is not of porcine origin, creating a potential alternative treatment option for the many patients suffering from EPI."

ANG003-22-101 Clinical Trial

Patients were randomized to one of four possible combinations of orally delivered lipase, protease, and amylase, administered with a standard high fat meal, to identify recommended doses for further clinical development in people with EPI. ANG003 was generally well tolerated with no serious adverse events reported. Additionally, the study was conducted to demonstrate absorption of the byproducts of digestion (fat, protein, and carbohydrates) in plasma using sensitive biomarkers of absorption. A series of robust preclinical studies suggested ANG003 would improve absorption of the most beneficial fats and other key macronutrients in a dose dependent manner.

“We are thrilled with our continued progress advancing ANG003 and a portfolio of other orally delivered enzymes,” continued Mr. Gallotto. "Anagram is well positioned to deliver on its mission to improve the lives of people with malabsorption and nutrient metabolism disorders and deliver first-in-class products that can have a meaningful long-term benefit."

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About ANG003, Malabsorption Syndromes and Nutrient Metabolism Disorders

Anagram aims to create a new class of orally delivered enzyme replacement therapy (ERT) based on a deep knowledge of gastrointestinal disease pathology, advances in enzyme engineering and formulation technologies, with an experienced team that has previously built successful enzyme-based biotech companies. ANG003, Anagram's lead product for the treatment of malabsorption and exocrine pancreatic insufficiency (EPI), is a new class of broad-spectrum digestive enzyme replacement therapy, targeting some of the most challenging diseases in infants, children, and adults. ANG003 contains lipase for fat malabsorption, protease for protein malabsorption, and amylase for carbohydrate malabsorption. ANG003 was engineered to be stable and immediately active in the gastrointestinal tract to maximize digestion.

People with EPI are currently treated with pancreatic enzyme replacement therapies (PERT) derived from porcine pancreas extract. The current PERT market is approximately $2 billion annually in the U.S. PERT treatment rarely eliminates maldigestion and in spite of the high treatment burden, requiring 15-40 capsules per day, patients still have chronic gastrointestinal symptoms. Malabsorption syndromes and nutrient metabolism disorders are a group of conditions caused by enzyme deficiencies or genetic disorders that prevent the body from properly processing or absorbing certain fats, sugars, proteins, vitamins or other key nutrients.

About Anagram Therapeutics

Anagram Therapeutics Inc. is a clinical stage biopharmaceutical company developing novel, orally delivered enzyme therapeutics for the treatment of serious diseases caused by malabsorption syndromes and nutrient metabolism disorders that prevent the body from properly processing or absorbing certain fats, sugars, proteins, vitamins or other key nutrients. The company is leveraging proprietary enzyme technologies and expertise in gastrointestinal diseases to solve complex problems and advance a pipeline of products that can make a life-changing impact for people and their families living with cystic fibrosis and other rare diseases. ANG003, Anagram's lead product for the treatment of malabsorption and exocrine pancreatic insufficiency, is a new class of broad-spectrum digestive enzyme replacement therapy in clinical trials in people with cystic fibrosis. Anagram is a privately held company headquartered in Framingham, MA. To learn more, visit www.anagramtx.com or follow us on LinkedIn and Twitter.

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