FOR IMMEDIATE RELEASE

Anagram Therapeutics Announces Enrollment Initiation in Clinical Study of ANG003 for People with Exocrine Pancreatic Insufficiency (EPI) Due to Cystic Fibrosis (CF)

EPI Remains a Persistent Cause of Severe Gastrointestinal Issues in CF Children and Adults

Sean Harper, MD, Joining Anagram Therapeutics Board of Directors

NATICK, Mass., May 27, 2026 — Anagram Therapeutics ("Anagram"), a clinical-stage private biopharmaceutical company dedicated to improving the lives of people living with rare and life-threatening diseases, today announced that the first participants have been enrolled in its global Phase 2 clinical study of ANG003 for the treatment of exocrine pancreatic insufficiency ("EPI") due to cystic fibrosis ("CF"). ANG003 is a novel orally delivered recombinant enzyme therapy that has the potential to be the first non-porcine product approved for EPI due to CF, pancreatic cancer, chronic pancreatitis, and related disorders.

The ANG003 clinical trial is a global, randomized, study that will evaluate the safety, tolerability, and effectiveness of ANG003 in children and adults 12 years of age and older with EPI due to CF who are on a modulator as well as those not on a modulator. The trial will be conducted at up to 45 clinical sites in the United States, United Kingdom, Europe, Israel, and Canada. The trial expects to enroll approximately 100 participants and will evaluate ANG003 over a prolonged treatment period compared to existing porcine pancrelipase treatment.

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, severe gastrointestinal symptoms, a significant decrease in quality of life, and reduced life expectancy. EPI is currently treated with pancreatic enzyme replacement therapies (PERT) from pig pancreas extract that requires enteric plastic coating to prevent it from being inactivated in the stomach. Pig-derived enzymes have a high treatment burden, requiring people to take up to 40 capsules per day while also experiencing global supply shortages due to the animal source.

"Gastrointestinal complications are rated as the most burdensome concern for the vast majority of people living with CF so EPI remains an important unmet medical need," said Robert Gallotto, President and CEO of Anagram Therapeutics. "ANG003 represents an entirely new treatment modality which we believe has the potential to be a transformative solution for patients with EPI due to CF and other EPI related conditions, their families, and healthcare providers globally. "

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ANG003 demonstrated positive clinical data in a dose-ranging study in people with EPI due to CF with results presented at the North American Cystic Fibrosis Conference. ANG003 was safe and well tolerated, with no serious adverse events observed. ANG003 significantly improved fat absorption in a dose dependent manner while protease and amylase activity suggested that doses lower than those in current porcine-derived PERTs may be efficacious.

“The initiation of the clinical trial with ANG003 marks an important milestone for patients, physicians, and Anagram as we work together to advance new solutions for people with EPI due to CF,” said Evan Bailey, MD, Chief Medical Officer of Anagram. "This Phase 2 study will provide crucial insights into the safety, tolerability, and therapeutic activity of our innovative approach for ANG003 that utilizes stable engineered recombinant enzymes. We are optimistic that improving plasma absorption will ultimately tie to long-term outcomes in patients as well as historical endpoints used in similar studies. This should enable us to assess a more physiological dose ratio that can’t be accomplished with existing porcine extract products. Modulators, for those eligible, have been a remarkable advance for CF lung disease, however there is still a need to improve clinical outcomes associated with gastrointestinal complications and the treatment burden with PERT dosing. We are pleased to continue our work with the CF patient and clinical community.”

Dr. Sean Harper Joins Anagram Board

Anagram recently announced a $250 million investment from Blackstone Life Sciences that will help fund the further development, approval, and launch of ANG003. As part of this financing, Sean Harper, MD, will be joining the Anagram Therapeutics Board of Directors. Dr. Harper is a highly accomplished biotechnology development expert with an extensive list of achievements as Amgen’s Executive Vice President of R&D as well as his role as co-founding managing director at Westlake Village BioPartners. Dr. Harper has helped bring over a dozen novel therapies to patients during his career. Dr. Harper attended medical school at the University of California at San Francisco, completed internal medicine and gastroenterology training at Massachusetts General Hospital, and was a postdoctoral fellow in the laboratory of Nobel Laurette Phillip A. Sharp at the Massachusetts Institute of Technology.

How to Access the ANG003 Clinical Trial in People with Cystic Fibrosis

For more information about the trial, visit the Cystic Fibrosis Clinical Trial Finder https://apps.cff.org/Trials/Finder/details/755/Study-to-evaluate-ANG003-in-people-with-CF-ages-12-and-older or clinicaltrials.gov and use study identifier NCT07450547.

About ANG003 and Exocrine Pancreatic Insufficiency

ANG003 is Anagram’s lead product for the treatment of exocrine pancreatic insufficiency (EPI) due to cystic fibrosis, pancreatic cancer, and other related disorders. ANG003 is a new class of broad-spectrum recombinant digestive enzyme replacement therapy, targeting some of the most challenging diseases in infants, children, and adults. ANG003 was engineered to be stable and immediately active in the gastrointestinal tract to maximize digestion and absorption.

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ANG003 contains lipase for fat malabsorption, protease for protein malabsorption, and amylase for carbohydrate malabsorption. 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. Gastrointestinal issues remain as one of the most burdensome challenges faced by people with CF. EPI is currently treated with pancreatic enzyme replacement therapies (PERT) from pig pancreas glands that have a high treatment burden, requiring people to take up to 40 capsules per day. Pig-derived PERT require a significant amount of plastic coating to prevent it from being degraded in the stomach. PERT derived from pig pancreas glands continue to experience global product shortages. The current U.S. PERT market is approximately $2 billion annually.

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, 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. The company is leveraging proprietary enzyme technologies and expertise in gastrointestinal diseases to solve complex problems and advance a pipeline of products that can have 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 exocrine pancreatic insufficiency due to cystic fibrosis. Anagram is a privately held company headquartered in Natick, MA. To learn more, visit https://anagramtx.com/ or follow us on LinkedIn and X/Twitter. Anagram Therapeutics® is a registered trademark of Anagram Therapeutics, Inc.

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