ANG003-22-101: A Phase 1, Open-Label, Multicenter Study to Assess the Safety and Efficacy of ANG003 in Patients with Exocrine Pancreatic Insufficiency Due to Cystic Fibrosis

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: 18 years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- confirmed diagnosis of cystic fibrosis (CF) - clinically controlled Exocrine Pancreatic Insufficiency (EPI) with minimal symptoms - adequate nutritional status measured by body mass index of at least 20kg/m2

Exclusion Criteria:

- diagnosis of diabetes mellitus who are unable to refrain from short-acting and rapid-acting insulin on Days 1 and 5 for a daily total of 6 hours - involuntary loss of 10% or more of usual body weight within last 6 months or involuntary loss of more than 5% of body weight within 1 month - eequires use of naso-gastric, J-tube, G-tube, and/or enteral feeding - CF pulmonary exacerbation within last 30 days - additional criteria (study staff will review)

Conditions & Interventions

Conditions:
Rare Diseases
Keywords:
CF, Cystic Fibrosis, EPI, Exocrine Pancreatic Insufficiency

More Information

Description: This experimental drug is being studied as a possible treatment for Exocrine Pancreatic Insufficiency (EPI) caused by Cystic Fibrosis (CF). EPI is the inability to properly release pancreatic enzymes that help digest and absorb the food you eat so that your body can use it. During this study, participants will receive one dose of ANG003 with a provided test meal. Participation in this study will last approximately 30 days and will include approximately six study visits; and three telemedicine calls.
Study Contact: Brooke Noren - boer0039@umn.edu
Principal Investigator: Elissa Downs
IRB Number: SITE00001965