A Research Study to Advance the CF Therapeutics Pipeline for People Without Modulators

Status: RECRUITING

Eligibility Criteria

Age: 12 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Consent A. Written informed consent (and assent when applicable) obtained from participant or participant's legal guardian B. Is willing and able to adhere to the study visit schedule and other protocol requirements Demographics A. ≥ 12 years of age at Visit 1 Medical History A. For persons of child-bearing potential: must not be pregnant at Visit 1 or plan to get pregnant during the 12-month study period Disease History A. Documentation of a CF diagnosis as evidenced by one or more clinical features consistent with the CF phenotype and one or more of the following criteria: * Sweat chloride ≥ 60 mEq/liter by quantitative pilocarpine iontophoresis test (QPIT) * Two well-characterized disease-causing pathogenic variants in the CFTR gene or * One well-characterized disease-causing mutation and a second CFTR variant (with variable or uncharacterized disease-causing potential) and sweat ≥ 30 mmol/liter with permission of the study sponsor-investigators B. Clinically stable with no significant changes in health status within the 28 days prior to and including Visit 1 C. Does not have a history of lung transplantation Concomitant Medications A. Not genetically eligible for a CFTR modulator according to product label indications and/or No use of CFTR modulator for 28 days prior to Visit 1 with no intent to start or restart during the study period B. No use of an investigational drug within 90 days prior to and including Visit 1 C. Not currently participating in an interventional drug or device trial. Participation in long-term safety follow-up studies (without redosing) and/or behavioral intervention trials is allowed. D. No initiation of new chronic therapy (e.g., ibuprofen, azithromycin, inhaled tobramycin, Cayston®) within 28 days prior to and including Visit 1 E. No acute use of antibiotics (oral, inhaled or IV) or acute use of systemic corticosteroids for respiratory tract symptoms within 28 days prior to and including Visit 1

Conditions & Interventions

Conditions:

Cystic Fibrosis

Keywords:

ineligible and/or not taking CFTR modulators, People with CF

More Information

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Principal Investigator:

Phase:

IRB

Number:

System ID: NCT06504589
