Study to Evaluate Adverse Events and Change in Disease Activity With Oral Capsules of Galicaftor/Navocaftor/ABBV-119 or Galicaftor/Navocaftor/ABBV-576 Combination Therapies in Adult Participants With Cystic Fibrosis

Status: Recruiting

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

• Confirmed clinical diagnosis of cystic fibrosis (CF).

• Arm 1 participants with genotype homozygous for the F508del CF transmembrane conductance regulator (CFTR) mutation and not receiving elexacaftor/tezacaftor/ivacaftor (ETI) treatment .

• Arm 2 and 3 participants with genotype heterozygous for the F508del CFTR mutation and a minimal function and not receiving ETI treatment.

• Arm 4 participants with genotype either homozygous or heterozygous for the F508del mutation. Participants must be receiving stable (ETI) treatment.

• Percent predicted forced expiratory volume in 1 second (ppFEV1) >= 40% and <=90% of predicted normal for age, gender and height at screening.

• For arms 1 and 2: sweat chloride (SwCl) >= 60 mmol/L at screening. For participants who participated in Study M19-530, it is acceptable to use a SwCl value that the central lab provided in Study M19-530 to establish eligibility.

• Weight >= 35 kg at screening and Day -28 for arm 1 or day 1 for arms 2 to 4.

Exclusion Criteria:

•Clinically significant laboratory values at screening that would pose undue risk for the participant or interfere with safety assessments (per the investigator).

Conditions & Interventions

Interventions:
Drug: ABBV-576, Drug: Galicaftor, Drug: Placebo, Drug: Navocaftor, Drug: ABBV-119
Conditions:
Cystic Fibrosis (CF)
Keywords:
Cystic Fibrosis (CF), Galicaftor, Navocaftor, ABBV-119, ABBV-576

More Information

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IRB
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