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FDLCombo

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This is a Four-Part, Phase 1-2, Drug-Drug Interaction Study to Assess the Safety, Tolerability, and Pharmacokinetic (PK) Profile of concomitant FDL176 (a potentiator) and FDL169 (a 1st site corrector) in Healthy subjects (Parts 1-3) and Cystic Fibrosis (CF) Subjects (Part 4).

Part 1 dosing included FDL169 for 4 weeks with the 3rd and 4th week following a single dose FDL176. Part 2 dosing included FDL176 for 3 weeks with the 3rd week following concomitant FDL169 for a total of seven doses. Part 3 dosing included 28 days of concomitant FDL169 and FDL176. Part 4 is a randomized, double-blind, placebo-controlled, 28-day concomitant dosing of FDL169 and FDL 176 in CF subjects.

Enrollment for Part 4 of this study is currently ongoing in the U.K. For more information please refer to the Celerion website and clinicaltrials.gov.

Requirements for participation in the study

Healthy Subjects:

- Body mass index (BMI) between 19 and 30 kg/m^2
- Healthy as determined by the PI or delegate, based upon a medical evaluation including medical history, physical examination, laboratory tests and ECG.

Cystic Fibrosis Subjects:

- Males and females aged 18 years and older
- A diagnosis of cystic fibrosis
- Be 18 years of age or older
- Have an FEV_1 40 – 90% predicted
- No respiratory tract infection, pulmonary exacerbation, or changes in therapy for pulmonary disease 4 weeks prior to dosing
- No treatment with ivacaftor or lumacaftor 4 weeks prior to dosing

Additional information on this trial is available at www.clinicaltrials.gov

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