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FDL176 a CFTR Potentiator

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FDL176 First-in-Human Study

FDL176-2016-01 study is a five part Phase 1 Study to Assess the Safety, Tolerability and Pharmacokinetic (PK) Profile of Single and Repeat Oral Doses of FDL176 in Healthy and

Cystic Fibrosis (CF) Participants

Part 1 is a randomized, double-blind, placebo-controlled, dose escalation study in healthy male participants. Part 2 is a single dose, open-label study in healthy male participants.

Part 3 is a single dose, double-blind, placebo-controlled study in healthy female participants. Part 4 is a randomized, double-blind, placebo-controlled, dose-escalation study in healthy male and female participants. Part 5 is a single dose, open-label study in male and female participants with CF.

Enrollment is planned to occur at approximately 2 sites. Approximately 102 healthy adult males and females and up to 10 adults with CF will be enrolled in the study.

Participation in this study will take up to 6 weeks.

Requirements for participation in the study

Part 1 to Part 4:

- Body mass index (BMI) between 19 and 30 kg/m²
- Healthy as determined by the PI or delegate, based upon a medical evaluation including medical history, physical examination, laboratory tests and ECG.

Part 5:

Males and females aged 18 years and older.

- A diagnosis of cystic fibrosis
- Be 18 years of age or older
- Be pancreatic insufficient
- Have an FEV1 \geq 40% 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 2 weeks prior to dosing

Additional information is available at www.clinicaltrials.gov

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We'd love to hear it!

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