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FDL169 a CFTR Corrector

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FDL169 Phase 1b Study

FDL169-2016-04 Study is a randomized, double-blind, placebo-controlled, parallel study to evaluate safety, pharmacokinetics (PK) and pharmacodynamics(PD) of FDL169 in cystic

fibrosis subjects homozygous for the F508del-CFTR mutation.

Enrollment is planned to occur at approximately 14 global sites. Approximately 24 adults with CF will be enrolled in the study. Participation in this study will take approximately 9 weeks.

Requirements for participation in the study:

- A diagnosis of cystic fibrosis
- Have 2 copies of the F508del-CFTR mutation
- Be 18 years of age or older
- Have a weight ≥40 kg
- Have an FEV1 ≥ 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 4 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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