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A Study to Test How Well BI 1291583 is Tolerated by People With Cystic Fibrosis Bronchiectasis (Clairafly[®]) - Phase 2 - Not yet recruiting

Code: NCT05865886

Year: 2023 **Date:** October 16, 2023

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Study design (if review, criteria of inclusion for studies)

Interventional - Allocation: Randomized|Intervention Model: Parallel Assignment|Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)|Primary Purpose: Treatment

Participants

Cystic Fibrosis|Bronchiectasis - 18 Years and older (Adult, Older Adult)

Interventions

Drug: BI 1291583|Drug: Placebo

Outcome measures

Occurrence of Treatment emergent Adverse Events (TEAEs) up to 16 weeks from first drug administration|Relative change from baseline in neutrophil elastase (NE) activity in sputum at week 8 after first drug administration|Area under the concentration-time curve of the analyte in plasma over a uniform dosing interval (AUC_{0-24}) for the first dose|Maximum measured concentration of the analyte in plasma (C_{max}) for the first dose|Area under the concentration-time curve of the analyte in plasma at steady state over a uniform dosing interval ($AUC_{0-24,ss}$)|Maximum measured concentration of the analyte in plasma (C_{max}) at steady state ($C_{max,ss}$)

<https://ClinicalTrials.gov/show/NCT05865886>

Keywords

BI 129158; Clairafly; Cathepsin C Inhibitor; Anti-Inflammatory Agents - excl Steroids; pharmacological_intervention;