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A Study To Evaluate The Safety Of CMTX-101 In People With Cystic Fibrosis - Phase 1|Phase 2 - Not yet recruiting

Code: NCT06159725 Year: 2023 Date: December 2023 Author: Clarametyx Biosciences, Inc.

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

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

Interventions

Drug: CMTX-101|Drug: Placebo

Outcome measures

ss the AUCO-â°ž Area under the concentration time curve from zero to infinite time following a single IV infusion of CMTX-101|Assess the Terminal phase elimination rate determined by ELISA following a single IV infusion of CMTX-101|Assess the Terminal elimination half- determined by ELISA following a single IV infusion of CMTX-101|Assess the Apparent total body clearance (CL/F) determined by ELISA following a single IV infusion of CMTX-101|Assess the Apparent volume distribution (Vx/F) determined by ELISA following a single IV infusion of CMTX-101|Evaluate the immunogenicity of CMTX-101 as measured by anti-drug antibodies (ADA) determined by the electrochemiluminescence assay following a single IV infustion of CMTX-101|Assess the apparent reduction in pulmonary P. auriginosa burden as measured by quantitative microbial culture of sputum

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Keywords

CMTX-101; monoclonal antibodies; Anti-Bacterial Agents; pharmacological_intervention;