ongoing trials - trial from www.clinicaltrials.gov

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

Number and % of participants experiencing adverse events following a single IV infusion of CMTX-101|Number and % of participants experiencing serious adverse events following a single IV infusion of CMTX-101|Assess the CMax - observed maximum plasma concentration determined by ELISA following a single IV infustion of CMTX-101|Assess the TMax - time to reach maximum concentration curve following a single IV infusion of CMTX-101|Assess the AUC0-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 infustion 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

https://ClinicalTrials.gov/show/NCT06159725

Keywords

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