ongoing trials - trial from other registries

A Phase 2a, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate Safety, Tolerability, and Effect of Inhaled SNSP113 in Adult Subjects with Cystic Fibrosis

Code: EUCTR2019-003178-25 **Year:** 2019 **Date:** 2019 **Author:**

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

Controlled: Yes.1 Randomised: Yes.2 Open: No.3 Single blind: No.4 Double blind: Yes.5 Parallel group: Yes.6 Cross over: No

Participants

Principal inclusion criteria: 1. Male and female subjects 18 to 65 years of age (inclusive), on the day of signing informed consent; Stable pulmonary symptoms associated with CF for 28 days prior to Screening

Interventions

multiple ascending doses (MAD) of inhaled SNSP113 administered once-daily for 28 days to adult Cystic Fibrosis (CF) subjects.

Outcome measures

Primary end point(s): â€¢ Vital signs (blood pressure, heart rate, respiratory rate) â€¢ Clinical laboratory evaluations (hematology included complete blood cell count (CBC) with differential and platelet count, serum biochemistry including blood urea nitrogen and creatinine, liver function tests, coagulation profile, and urinalysis) â€¢ ECG parameters â€¢ Pulmonary function assessed by spirometry, pulse oximetry â€¢ PE

https://www.clinicaltrialsregister.eu/ctr-search/trial/2019-003178-25/HU/

Keywords

SSP113; Synspira; Anti-bacterial agents; pharmacological_intervention; Pseudomonas; Pseudomonas aeruginosa; Respiratory Tract Infections; Respiratory Tract Diseases; Infection; Bacterial Infections;