

ongoing trials - trial from other registries

# **A Phase 3 Double-blind, Randomized, Placebo-controlled Study Evaluating the Efficacy and Safety of ELX/TEZ/IVA in Cystic Fibrosis Subjects 6 Years of Age and Older With a Non-F508del ELX/TEZ/IVA-responsive CFTR Mutation**

**Code:** EudraCT Number: 2021-005320-38 **Year:** 2021 **Date:** 2021

**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: No.6 Cross over: No

## **Participants**

Subjects aged 12 years or older, on the date of informed consent; Confirmed diagnosis of CF as determined by the investigator. Subject has one of the following genotypes: 1) homozygous for F508del; 2) heterozygous for F508del and a gating (F/G) mutation; 3) heterozygous for F508del and a residual function (F/RF) mutation; at least 1 other TCR CFTR mutation identified as responsive to ELX/TEZ/IVA and no F508del mutation. For subjects currently receiving Vertex CFTR modulator therapy, FEV1 value  $\geq 40\%$  and  $\geq 90\%$  of predicted mean for age, sex, and height at the Screening Visit. All subjects not currently receiving Vertex CFTR modulator therapy must have an FEV1 value  $\geq 40\%$  and  $\geq 80\%$  of predicted mean. Stable CF disease as judged by the investigator.

## **Interventions**

VX-121/TEZ/D-IVA

## **Outcome measures**

Primary end point(s): Absolute change from baseline in percent predicted forced expiratory volume in 1 second (ppFEV1) through Week 24.

<https://www.clinicaltrialsregister.eu/ctr-search/trial/2021-005320-38/ES/>

## **Keywords**

CFTR Modulators; Genetic Predisposition to Disease; pharmacological\_intervention; placebo; VX-770; VX-121; ivacaftor; Aminophenols; tezacaftor; VX-661; vanzacaftor;