ongoing trials - trial from other registries

A Phase 3b Open-label Study Evaluating the Safety of Elexacaftor/Tezacaftor/Ivacaftor Combination Therapy in Subjects With Cystic Fibrosis

Code: EUCTR2020-004885-21 **Year:** 2020 **Date:** 2020 **Author:**

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

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

Participants

Principal inclusion criteria: at least 1 of the following criteria: â€¢ Completed study drug treatment in a parent study. â€¢ Had study drug interruption(s) in a parent study, but did not permanently discontinue study drug, and completed study visits up to the last scheduled visit of the Treatment Period of a parent study. For subjects being considered for resumption of participation in this study after enrolling in another Vertex study of investigational CFTR modulators (referred to as â€œanother qualified Vertex studyâ€•): Completed the ETT visit in another qualified Vertex study before or on the same day as the Returning Visit in this study. If more than 30 days have elapsed since the ETT visit in the other qualified Vertex study, approval of the medical monitor is required. Willing to remain on a stable CF treatment regimenthrough completion of study participation.

Interventions

Elexacaftor (ELX)/Tezacaftor (TEZ)/Ivacaftor (IVA) in subjects with Cystic Fibrosis (CF).

Outcome measures

Primary end point(s): Safety and tolerability of ELX/TEZ/IVA based on adverse events (AEs), clinical laboratory values, ECGs, vital signs, and pulse oximetry.

https://www.clinicaltrialsregister.eu/ctr-search/trial/2020-004885-21/BE/

Keywords

Adult; Aged; CFTR Modulators; Genetic Predisposition to Disease; pharmacological_intervention; placebo; VX-770; VX-661; ivacaftor; Aminophenols; tezacaftor; VX-445; elexacaftor; Trikafta;