primary studies - published RCT

Cannabinoid receptor 2 agonist, lenabasum, for the treatment of pulmonary exacerbations in cystic fibrosis.

Code: PM40425421 **Year:** 2025 **Date:** **Author:** West NE

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

Randomized, double-blind, placebo-controlled Phase 2b trial.

Participants

PwCF were â‰¥12 years old with 2-3 pulmonary exacerbations (PEx) treated with intravenous (IV) antibiotics (or 1 PEx treated with IV and â‰¥1 PEx treated with oral antibiotics) in the past year. 447 subjects from 21 countries, mean age was 26.9 (10.3 SD) years, 53.6% were female, 45.2% homozygous for F508del, and 24.9% received CFTR modulators.

Interventions

Subjects were randomized 2:1:2 to lenabasum 20 mg BID, lenabasum 5 mg BID, or placebo BID.

Outcome measures

Primary endpoint was rate of Pex

Main results

PEx incidence over 28 weeks was 0.84 for placebo, 0.75 for lenabasum 5 mg BID, and 0.91 for lenabasum 20 mg BID; rates were not lower relative to placebo in the 5 mg (incidence rate ratio (IRR)=0.89, 95% CI 0.66 to 1.19, p = 0.44) or the 20 mg group (IRR 1.08, 95% CI 0.86 to 1.37, p = 0.51). PEx occurred less frequently in participants from Eastern Europe, but there was no evidence of regional variation in treatment efficacy. Lenabasum was well tolerated, without safety signals.

Authors' conclusions

Lenabasum did not improve key clinical outcomes in this Phase 2b study in pwCF.

http://dx.doi.org/10.1016/j.jcf.2025.03.015

See also

J Cyst Fibros. 2025 May 26:S1569-1993(25)00111-0. doi: 10.1016/j.jcf.2025.03.015.

Keywords

Lenabasum; Cannabinoid receptor agonist; Anti-Inflammatory Agents - excl Steroids; pharmacological_intervention; Bacterial Infections; Respiratory Tract Infections; Respiratory Tract Diseases; Infection; Exacerbation;