

primary studies - published RCT

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

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

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

Participants

PwCF were ≥ 12 years old with 2-3 pulmonary exacerbations (PE_x) treated with intravenous (IV) antibiotics (or 1 PE_x treated with IV and ≥ 1 PE_x 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

PE_x 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, $p = 0.51$). PE_x 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.

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See also

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Keywords

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