

Abstract Preview - Step 3/4

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Topic: 5. Clinical Trials / New Therapies

Title: Patient demographics and baseline disease characteristics in a multicenter, randomized, double-blind, placebo-controlled phase 2b study of lenabasum, a selective cannabinoid receptor type 2 agonist, in cystic fibrosis

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Text: **Objectives:** We report the baseline characteristics of a large cohort of Cystic Fibrosis (CF) participants enrolled in a Phase 2b trial of lenabasum, a selective cannabinoid receptor type 2 agonist. Treatment with lenabasum was safe and well-tolerated in a prior Phase 2a study in adults with CF and was associated with fewer pulmonary exacerbations (PEX). **Methods:** This study was designed with input from study investigators, CF experts and regulatory authorities. An important intent of the design was to have eligibility criteria that enriched for subjects at increased risk of PEX in the next 6 months. The study is ongoing and remains blinded. **Results:** Primary efficacy outcome is the rate of PEX (expanded Fuchs criteria) at 28 weeks, comparing lenabasum 20 mg BID to placebo. Key inclusion criteria are subjects with new PEX treated with antibiotics within the past 12 months (2 - 3 with IV only OR 1 with IV and ≥ 1 with oral antibiotics), ≥ 12 years of age with CF who are on stable standard of care medicines, FEV1% predicted ≥ 40%. CFTR modulators are allowed. The study enrolled 426 subjects over 19 months who received ≥ 1 dose of study drug in 21 countries with 105 sites (34 in North America and 71 in Europe), with last subject first visit on NOV 14, 2019. Baseline characteristics are shown in Table 1. **Conclusion:** This is the first Phase 2b study to use rate of PEX as the primary efficacy outcome in a patient population with any CF mutation, bacterial profile, who maintained their current standard of care and who are at higher risk of PEX in the next 6 months.

	2 - 3 PEX past 12 mo Requiring IV antibiotics	1 PEX past 12 mo Requiring IV antibiotics	Overall
Mean ± SD or %	N = 220 (51.6%)	N = 198 (46.5%)	N = 426
Years of age	28.1 ± 10.10	25.9 ± 10.50	27.0 ± 10.29
Female	57.7 %	49.0 %	53.5 %
CFTR modulators	29.5 %	22.2 %	25.8 %
FEV1% Predicted	55.9 ± 16.25	64.7 ± 18.15	60.4 ± 17.81
CFQ-R Respiratory (Children 12 & 13)	83.3 ± 6.80	76.0 ± 6.95	78.5 ± 7.50
CFQ-R Respiratory (Teen/Adult)	62.8 ± 18.9	65.5 ± 18.6	63.9 ± 18.64

[Table 1. Baseline Demographics and Disease Characteristics (Blinded)]

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