Clinical Trials Information #48

Principal Investigator	Mona Al Mukaddam, MD, MS
Study Title:	A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Tolerability of INCB000928 in Participants With Fibrodysplasia Ossificans Progressiva (PROGRESS)

Purpose:
Treatment

Brief Description
This Phase 2, Randomized, Double-Blind, Placebo-Controlled Study is intended to evaluate the Efficacy, Safety, and Tolerability and PK of INCB000928 administered to participants with a clinical diagnosis of fibrodysplasia ossificans progressiva (FOP).

Eligibility
Inclusion Criteria:
Female and male adults and adolescents ≥ 12 years of age with a diagnosis of FOP.
Willingness to avoid pregnancy or fathering children based on the criteria below.
Willing and able to undergo low-dose WBCT (excluding the head) imaging without requiring intubation.
Further inclusion criteria apply.

Exclusion Criteria:
Pregnant or breast-feeding.
CAJIS score ≥ 24.
FOP disease severity that in the investigator's opinion precludes participation.
Any clinically significant medical condition other than FOP that would, in the investigator's judgment, interfere with full participation in the study, pose a significant risk to the participant, or interfere with interpretation of study data.
Chronic or current active infectious disease requiring systemic antibiotic, antifungal, or antiviral treatment.
HIV, HBV, or HCV infection. Note:
Further exclusion criteria apply.

Which section would you like the trial listed under?	FOP Clinical Trials
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