Phase II Extension Study

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DESCRIPTION

Open-label, Phase II extension study evaluating the safety and efficacy of palovarotene on new bone formation during and after a flare-up

- All participants experiencing a flare-up will receive palovarotene
- All adult participants and teenagers who are nearly grown (have achieved 90% skeletal maturity - called the adult cohort) will also receive a daily dose of palovarotene between flare-ups

ELIGIBILITY CRITERIA

The study is open to everyone who participated in and completed the Phase II double-blind, placebo-controlled study (PVO-1A-201)

Additionally, the study will accept new participants who:

- Reside in the US, Canada, UK, or France due to regulatory requirements
- Have had at least two self-reported flare-ups in the last two years but cannot have had flare-up symptoms in the last four weeks at time of enrollment
- Have achieved 90% skeletal maturity (if under age 18) as measured by height assessments and by X-rays of the hands/wrists and knees at enrollment screening, which is the standard measurement for bone growth maturity
- Have some movement limitations in joints but not complete locking of most joints as determined by the site principal investigator using a standardized assessment
- Have the most common mutation, R206H, associated with FOP as confirmed by genetic testing performed at enrollment screening
- Meet all other enrollment criteria

DESIGN

Up to 60 participants will be enrolled:

- Up to 40 participants who completed the Phase II study (PVO-1A-201)
- Up to 20 new adult cohort participants who did not participate in PVO-1A-201

Between eligible flare-ups (adult cohort):

- All participants are treated with low chronic dose of palovarotene daily
- Site visits at enrollment screening and at months 12 and 24
- Telephone/home contact every three months

For eligible flare-ups (all subjects):

- All participants are treated with palovarotene for 12 weeks at an acute dose (to be determined by weight)
- Site visits at the onset of an eligible flare-up and at the end of treatment
- Telephone/home contact every two weeks
- No placebo will be administered

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TRIAL ID NUMBER	PVO-1A-202 PVO-1A-204 (France only)
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