

Date: Tuesday, 23 June 2020

REF: NL67312.028.18 & MEC No. P1849

RE: Clementia Palovarotene DSUR 28-Apr-2019 to 27-Apr-2020

Protocol	Title	IND #/ EudraCT #
PVO-1A-202	A Phase 2 Open-Label Extension, Efficacy and Safety Study of a RARy-Specific Agonist (Palovarotene) in the Treatment of Proseous Flare-ups in Subjects with Fibrodysplasia Ossificans Progressiva (FOP)	IND# 120181 EudraCT: 2014-002496-28
PVO-1A-204	A Phase 2, Open-Label, Efficacy and Safety Study of an RARy-Specific Agonist (Palovarotene) to Prevent Heterotopic Ossification in Subjects with Fibrodysplasia Ossificans Progressiva (FOP)	IND# 120181 EudraCT: 2016-002526-36
PVO-1A-301	Maintain Optimal MoVement Efficacy (MOVE) Trial: A Phase 3, Efficacy and Safety Study of Oral Palovarotene for the Treatment of Fibrodysplasia Ossificans Progressiva (FOP)	IND# 120181 EudraCT: 2017-002541-29
PVO-2A-201	A Phase 2/3, Randomized, Double-Blind, Placebo-Controlled Efficacy and Safety Study of Palovarotene in Subjects with Multiple Osteochondromas	IND# 135403 EudraCT: 2017-002751-28
Manufacturer: Clementia		

Dear Sir/Madam,

Please find enclosed the DSUR for Clementia Palovarotene covering the period of 28-Apr-2019 to 27-Apr-2020.

If you require any further information, please do not hesitate to contact us.

Yours sincerely

PPD PVG Central Safety Reporting Team, on behalf of Clementia Pharmaceuticals, Inc

Enc: DSUR 28-Apr-2019 to 27-Apr-2020 (312 pages)