PPD

Centrale Commissie Mensgebonden Onderzoek
Parnassusplein 5
2511VX
The Hague
The Netherlands

Bennekom, *18 May 2021*

Concerns:	**Notification – CSR Delay**
Our reference:	**NT – (KP)**
Protocol number:	**PVO-2A-201**
EudraCT number:	**2017-002751-28**
NL number:	**NL67312.028.18**

Dear Members of the CCMO,

On behalf of the Sponsor, Clementia Pharmaceuticals Inc. (an Ipsen company), we would like to notify you regarding the delay of Clinical Study Report (CSR) submission for the Phase 2 palovarotene trial (PVO-2A-201) for Multiple Osteochondromas (MO). Registered with NL-number NL67312.028.18

The date of the Last Patient Last Visit (LPLV) globally for the PVO-2A-201 trial was on 30 October 2020. The LPLV in The Netherlands was conducted on 02 July 2020. This has been communicated to the competent authority and ethics committee on 26 August 2020.

Due to the premature termination of the clinical program for MO prior to the conclusion of the primary efficacy endpoint, as well as delays on the delivery of the outputs for this study, the CSR is delayed and is planned to be submitted within the third quarter of 2021.

A summary of the study results will be posted to EudraCT as soon as the CSR is available in accordance with the Commission guidance and submitted where required.

Please find the list of enclosed documents supporting this application in the Table of Contents below.

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We hope that we have informed you sufficiently and would appreciate receiving a confirmation of receipt for this notification.

Yours sincerely,

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Table of contents