



Central Committee on research Involving Human Subjects (CCMO)
Attn. Competent Authority
Parnassusplein 5
2511 VX Den Haag

Bennekom, 31 Augustus 2021

Re: Submission of Clinical Study Report Synopsis
Protocol number: PVO-2A-201
EudraCT number: 2017-002751-28
NL number: NL67312.028.18

Dear members of the Central Committee on Research Involving Human Subjects,

On behalf of our client, Clementia Pharmaceuticals Inc. (an Ipsen company), please find enclosed the Clinical Study Report Synopsis dated 19Jul2021 for the study entitled '*A Phase 2, Randomized, Double-Blind, Placebo-Controlled Efficacy and Safety Study of Palovarotene in Subjects with Multiple Osteochondromas*' registered under NL67312.028.18.

The Global End of Trial (EoT) notification for the above-mentioned clinical trial took place on 30 October 2020 and was notified to the Central Ethics Committee and Competent Authority on 11Dec2020.

The structure and content of the Clinical Study Report is in line with the ICH guidance (CPMP/ICH/137/95).

I would like to inform you that the clinical trial results will be posted in EudraCT according to Directive 2001/20/EC. A publication or summary of the results will be uploaded to ToetsingOnline once available.

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

With this submission we declare that all relevant documents from the above-mentioned research dossier are signed by the authorised people.

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The signed documents are/will be submitted for review to the responsible review committee specified in question I1 of the general assessment and registration form (ABR form).

We would appreciate a confirmation of receipt and hope to have informed you sufficiently this way. Should you have any questions regarding this submission, please do not hesitate to contact us.

Yours sincerely,

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A1.	Cover Letter CA NL67312.028.18 dd 31Aug2021
M3.	Clinical Study Report Synopsis dd 19Jul2021