



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

Bennekom, 11 Dec 2020

**Re:** Digital submission of Global End of Trial  
**Protocol:** PVO-2A-201  
**EudraCT number:** 2017-002751-28  
**NL number:** NL67312.028.18

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

With this letter we would like to notify the Competent Authority (Central Committee on Research Involving Human Subjects) that the study entitled '*A Phase 2, Randomized, Double-Blind, Placebo-Controlled Efficacy and Safety Study of Palovarotene in Subjects with Multiple Osteochondromas*', registered under number NL67312.028.18, has ended globally.

As communicated to the Competent Authority (Central Committee on Research Involving Human Subjects) on 07Apr2020, the Investigators were contacted on 24-March-2020 to inform all subjects and their legal guardians of the study termination and to return unused quantities of drug to their sites. At that moment, no subjects in study PVO-2A-201 were on treatment due to previous partial clinical hold communicated to investigators on 05-Dec-2019.

According to the protocol, date of the last subject last visit (LSLV) is considered the end of the trial and it should be scheduled 6 months after end of treatment.

The date of the LSLV globally for the whole trial was on 30 October 2020 and therefore, the trial is now completed. The committee was informed on 26Aug2020 that the LSLV in The Netherlands was conducted on 02Jul2020. Please update the EudraCT web page accordingly.

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The Clinical Study Report (CSR) will be submitted to you within six months from the global study end date.

A summary of the study results will be posted to EudraCT within the applicable deadlines in accordance with the Commission guidance and submitted where required.

With this amendment, we also submit a change in sponsor contact person as listed in the updated EudraCT – Application form.

Enclosed to this email you will find the relevant documents for submission of the above-mentioned research for review:

- A1. Cover letter Cover letter NL67312.028.18 dd 11Dec2020
- B3. EudraCT Application Form dd 11Dec2020
- B7. EudraCT End Of Trial dd 11Dec2020

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

Yours sincerely,

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