

**Declaration of the End of Trial Form (cf. Section 4.2.1 of the *Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial*<sup>1</sup>)**

**NOTIFICATION OF THE END OF A CLINICAL TRIAL OF A MEDICINE FOR HUMAN USE TO THE COMPETENT AUTHORITY AND THE ETHICS COMMITTEE**

*For official use*

Date of receipt :	Competent authority registration number : Ethics committee registration number:
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**To be filled in by the applicant**

**A MEMBER STATE IN WHICH THE DECLARATION IS BEING MADE : *The Netherlands***

**B TRIAL IDENTIFICATION**

<b>B.1 EudraCT number :</b>	2017-002751-28
<b>B.2 Sponsor's protocol code number:</b>	PVO-2A-201
<b>B.3 Full title of the trial :</b>	A Phase 2, Randomized, Double-Blind, Placebo-Controlled Efficacy and Safety Study of Palovarotene in Subjects with Multiple Osteochondromas

**C APPLICANT IDENTIFICATION (please tick the appropriate box)**

<b>C.1 DECLARATION FOR THE COMPETENT AUTHORITY</b>	<b>X</b>
C.1.1 Sponsor	<input type="checkbox"/>
C.1.2 Legal representative of the sponsor	<input type="checkbox"/>
C.1.3 Person or organisation authorised by the sponsor to make the application.	<b>X</b>
C.1.4 <b>Complete below:</b>	
C.1.4.1 Organisation : PPD Netherlands BV	
C.1.4.2 Name of person to contact : <b>s.1.2.e</b>	
C.1.4.3 Address : Bornweg 12C, 6721 AH Bennekom, the Netherlands	
C.1.4.4 Telephone number : +31 (0)318 65 <b>s.1.2.e</b>	
C.1.4.5 Fax number : +31 (0)318 65 <b>s.1.2.e</b>	
C.1.4.6 E-mail: ppdnl@ppdi.com	

<b>C.2 DECLARATION FOR THE ETHICS COMMITTEE</b>	<input type="checkbox"/>
C.2.1 Sponsor	<input type="checkbox"/>
C.2.2 Legal representative of the sponsor	<input type="checkbox"/>
C.2.3 Person or organisation authorised by the sponsor to make the application.	<input type="checkbox"/>
C.2.4 Investigator in charge of the application if applicable <sup>2</sup> :	
• Co-ordinating investigator (for multicentre trial):	<input type="checkbox"/>
• Principal investigator (for single centre trial):	<input type="checkbox"/>
C.2.5 <b>Complete below :</b>	
C.2.5.1 Organisation:	
C.2.5.2 Name :	
C.2.5.3 Address :	
C.2.5.4 Telephone number :	
C.2.5.5 Fax number :	
C.2.5.6 E-mail :	

**D END OF TRIAL**

<b>D.1 Date of the end of the trial in this Member State ?</b>	yes <b>X</b> no <input type="checkbox"/>
D.1.1. (YYYY/MM/DD): <b>2020/07/02</b>	

<b>D.2 Date of the end of the complete trial in all countries concerned by the trial?</b>	yes <b>X</b> no <input type="checkbox"/>
D.2.1 (YYYY/MM/DD): <b>2020/10/30</b>	

<sup>1</sup> OJ, C82, 30.3.2010, p. 1; hereinafter referred to as 'detailed guidance CT-1'.

<sup>2</sup> According to national legislation.

<b>D.3</b>	<b>Is it an early termination?<sup>3</sup></b>	yes <input type="checkbox"/> no <input checked="" type="checkbox"/>
D.3.1	If yes, give date (YYYY/MM/DD):	
D.3.2	Briefly describe in an annex (free text):	
D.3.2.1	The justification for early termination of the trial;	
D.3.2.2	Number of patients still receiving treatment at time of early termination in the MS concerned by the declaration and their proposed management;	
D.3.2.3	The consequences of early termination for the evaluation of the results and for overall risk benefit assessment of the investigational medicinal product.	

**E SIGNATURE OF THE APPLICANT IN THE MEMBER STATE**

<b>E.1</b>	I hereby <del>confirm that</del> /confirm on behalf of the sponsor that (delete which is not applicable):
	<ul style="list-style-type: none"> <li>• The above information given on this declaration is correct; and</li> <li>• That the clinical trial summary report will be submitted within the applicable deadlines in accordance with the applicable guidance by the Commission.<sup>4</sup></li> </ul>

<b>E.2</b>	<b>APPLICANT TO THE COMPETENT AUTHORITY</b> (as stated in C.1)	X
E.2.1	Date : 11Dec2020	
E.2.2	Signature :	
E.2.3	Print name: : 5.1.2.e	

<b>E.3</b>	<b>APPLICANT TO THE ETHICS COMMITTEE</b> (as stated in C.2) :	<input type="checkbox"/>
E.3.1	Date :	
E.3.2	Signature :	
E.3.3	Print name	

<sup>3</sup> Cf. Section 4.2. of the detailed guidance CT-1.

<sup>4</sup> Section 4.3. of the detailed guidance CT-1.