

**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:

*To be filled in by the applicant*

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

**B TRIAL IDENTIFICATION**

**B.1 EudraCT number :** (2016-002389-29)

**B.2 Sponsor's protocol code number:** (PULSE-COPD-007)

**B.3 Full title of the trial :**

**An Exploratory, Two-part, Clinical Study to Assess the Effect of Pulsed, Inhaled Nitric Oxide (iNO) on Functional Pulmonary Imaging Parameters in Subjects with World Health organization (WHO) Group 3 Pulmonary Hypertension (PH) Associated with Chronic Obstructive Pulmonary Disease (COPD) on Long Term Oxygen Therapy (LTOT).**

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

|  |                                     |
|--|-------------------------------------|
| <b>C.1 DECLARATION FOR THE COMPETENT AUTHORITY</b>                                     | <input type="checkbox"/>            |
| C.1.1 Sponsor  | <input type="checkbox"/>            |
| C.1.2 Legal representative of the sponsor  | <input checked="" type="checkbox"/> |
| C.1.3 Person or organisation authorised by the sponsor to make the application.        | <input type="checkbox"/>            |
| C.1.4 <b>Complete below:</b>   |                                     |
| C.1.4.1 Organisation : FLUIDDA nv  |                                     |
| C.1.4.2 Name of person to contact : Jan De Backer                                      |                                     |
| C.1.4.3 Address : Groeningenlei 132 2550 Kontich                                       |                                     |
| C.1.4.4 Telephone number : 0032 3 450 87 20  |                                     |
| C.1.4.5 Fax number :   |                                     |
| C.1.4.6 E-mail: <a href="mailto:jan.debacker@fluidda.com">jan.debacker@fluidda.com</a> |                                     |

|   |                                     |
|---|-------------------------------------|
| <b>C.2 DECLARATION FOR THE ETHICS COMMITTEE</b>   | <input checked="" 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 checked="" type="checkbox"/> |
| C.2.5 <b>Complete below :</b>   |                                     |
| C.2.5.1 Organisation: Antwerp University Hospital   |                                     |
| C.2.5.2 Name : Wilfried De Backer   |                                     |
| C.2.5.3 Address : Wilrijkstraat 10<br>2560 Edegem, Belgium  |                                     |
| C.2.5.4 Telephone number : 0032 3 821 47 13   |                                     |
| C.2.5.5 Fax number :  |                                     |
| C.2.5.6 E-mail : <a href="mailto:Wilfried.debacker@uantwerpen.be">Wilfried.debacker@uantwerpen.be</a> |                                     |

<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.

## D END OF TRIAL

**D.1 Date of the end of the complete trial in all countries concerned by the trial?**

D.1.1 (2017/08/31):

**D.2 Is it an early termination?<sup>3</sup>**

yes ☒ no ☐

D.2.1 If yes, give date (2017/08/31):

D.2.2 Briefly describe in an annex (free text):

D.2.2.1 The justification for early termination of the trial;

*The trial was terminated early, because the sponsor had collected enough data that indicated the sponsor should proceed to a larger Phase IIb blinded randomized-controlled trial.*

D.2.2.2 Number of patients still receiving treatment at time of early termination in the MS concerned by the declaration and their proposed management;

*There were no patients still receiving treatment at the time of early termination.*

D.2.2.3 The consequences of early termination for the evaluation of the results and for overall risk benefit assessment of the investigational medicinal product.

*There is no impact of early termination of the evaluation of the results and for overall risk benefit assessment of the investigational medicinal product. The evaluation of the results and the overall risk benefit assessment will continue in the next Phase IIb trial.*

## E SIGNATURE OF THE APPLICANT IN THE MEMBER STATE

**E.1** I hereby confirm that/confirm on behalf of the sponsor that (delete which is not applicable):

- The above information given on this declaration is correct; and
- 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>

**E.2 APPLICANT TO THE COMPETENT AUTHORITY (as stated in C.1)**

☐

E.2.1 Date :

E.2.2 Signature :

E.2.3 Print name:

**E.3 APPLICANT TO THE ETHICS COMMITTEE (as stated in C.2) :**

☒

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.