

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 :**

**B TRIAL IDENTIFICATION**

**B.1 EudraCT number :** (..) 2018-004750-28

**B.2 Sponsor's protocol code number:** (..) protocol

**B.3 Full title of the trial :** Electrocardiographic & clinical effects of Target-controlled infusion of propofol in adults with Brugada syndrome.

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

**C.1 DECLARATION FOR THE COMPETENT AUTHORITY**

C.1.1 Sponsor

C.1.2 Legal representative of the sponsor

C.1.3 Person or organisation authorised by the sponsor to make the application.

C.1.4 **Complete below:**

C.1.4.1 Organisation: UZ Brussel

C.1.4.2 Name of person to contact: paragiotis flamee

C.1.4.3 Address: Laarbeeklaan 101; 1050 Brussel

C.1.4.4 Telephone number: +32 2 477 60 01

C.1.4.5 Fax number:

C.1.4.6 E-mail: paragiotis.flamee@uzbrussel.be

**C.2 DECLARATION FOR THE ETHICS COMMITTEE**

C.2.1 Sponsor

C.2.2 Legal representative of the sponsor

C.2.3 Person or organisation authorised by the sponsor to make the application.

C.2.4 Investigator in charge of the application if applicable<sup>2</sup>:

• Co-ordinating investigator (for multicentre trial):

• Principal investigator (for single centre trial):

C.2.5 **Complete below :**

C.2.5.1 Organisation: UZ Brussel

C.2.5.2 Name: Paragiotis Flamee

C.2.5.3 Address: Laarbeeklaan 101; 1050 Brussel

C.2.5.4 Telephone number: +32 2 477 60 01

C.2.5.5 Fax number:

C.2.5.6 E-mail: paragiotis.flamee@uzbrussel.be

**D END OF TRIAL**

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

D.1.1 (YYYY/MM/DD): 16 SEP 2024

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

yes ☒ no ☐

<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.

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


- D.2.1 If yes, give date (YYYY/MM/DD): 16 SEP 2024
- D.2.2 Briefly describe in an annex (free text):
- D.2.2.1 The justification for early termination of the trial; not enough staff present to complete the 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; 0
- 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. lot enough patients were included to have results.

#### 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 : 16 SEP 2024

E.2.2 Signature : 

E.2.3 Print name: Virgini Van Buggenhout IOR PI

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

E.3.1 Date : 16 SEP 2024

E.3.2 Signature : 

E.3.3 Print name: Virgini Van Buggenhout IOR PI