

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*¹)

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 :

B TRIAL IDENTIFICATION

B.1 EudraCT number :	2019-000831-26
B.2 Sponsor's protocol code number:	RDN-929-103
B.3 Full title of the trial :	<i>A two-part parallel group study to assess the safety, tolerability and pharmacokinetic (PK) profile of multiple oral doses of RDN-929 in healthy older adults and subjects with early symptomatic Alzheimer's Disease".</i>

C APPLICANT IDENTIFICATION (please tick the appropriate box)

C.1 DECLARATION FOR THE COMPETENT AUTHORITY	X
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.	X
C.1.4 Complete below:	
C.1.4.1 Organisation : QPS Netherlands B.V.	
C.1.4.2 Name of person to contact :	5.1.2.e
C.1.4.3 Address : Petrus Campersingel 123, 9713 AG Groningen, The Netherlands	
C.1.4.4 Telephone number : +31 50 304	5.1.2.e
C.1.4.5 Fax number : +31 50 304	5.1.2.e
C.1.4.6 E-mail:	5.1.2.e @qps.com

C.2 DECLARATION FOR THE ETHICS COMMITTEE	<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 ² :	
• Co-ordinating investigator (for multicentre trial):	<input type="checkbox"/>
• Principal investigator (for single centre trial):	<input type="checkbox"/>
C.2.5 Complete below :	
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

D.1 Date of the end of the complete trial in all countries concerned by the trial?
D.1.1 (YYYY/MM/DD): 2020/01/22

D.2 Is it an early termination?³	yes X no <input type="checkbox"/>
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¹ OJ, C82, 30.3.2010, p. 1; hereinafter referred to as 'detailed guidance CT-1'.

² According to national legislation.

- D.2.1 If yes, give date (YYYY/MM/DD): 2020/01/22
- D.2.2 Briefly describe in an annex (free text):
- D.2.2.1 The justification for early termination of the trial; Medically Significant Elevated Serum Transaminases
- 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 (zero)
- 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.

Although early termination of the study reduced the total number of subjects enrolled and the total number of subjects who completed the study, enough of a safety signal had been observed from the available data to justify the early termination. Given the occurrence of [REDACTED] 5.1.1.d

[REDACTED] the decision was made to permanently terminate the study. Ultimately, the data demonstrate that the risks of the trial outweigh the benefits and the safety of the clinical trial subjects may be adversely affected.

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.⁴

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

E.2.1 Date : 29 January 2020

E.2.2 Signature [REDACTED] 5.1.2.e

[REDACTED] 5.1.2.e

E.2.3 Print name [REDACTED] 5.1.2.e

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:

³ Cf. Section 4.2. of the detailed guidance CT-1.

⁴ Section 4.3. of the detailed guidance CT-1.