



Stichting Beoordeling Ethiek
Biomedisch Onderzoek

LETTER OF APPROVAL

APPENDIX XI

On 16 May 2019 the Independent Ethics Committee (Medisch Ethische ToetsingsCommissie) of the Foundation 'Evaluation of Ethics in Biomedical Research' (Stichting BEBO), Assen, the Netherlands, approved the dossier with the study code 190006-CS0317 (see Appendices I, III, IV, V, VI, VII, VIII, IX, and X), and protocol entitled:

'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'

From the information provided by the investigator on 14 October 2019, and on 15 October 2019 it became apparent that the following documents have been made to above-mentioned Protocol after the original date of approval:

- A1 Cover letters, dated 14 October 2019, and 15 October 2019
- B1 ABR Form version 05, for CCMO dossier NL69548.056.19, dated 14 October 2019
- B3 EudraCT Application Form, dated 14 October 2019
- B5 Substantial Amendment Notification Form, dated 14 October 2019
- C1 Clinical Study Protocol and Appendices, Amendment 2, dated 11 October 2019
- E1/2 Informed Consent including Statement of Willingness for Part 2 (in Dutch), version 4, dated 14 October 2019

The Committee feels that this Amendment does not affect the safety of the participants, nor does it affect the adequacy of the Protocol.

Therefore, the Committee does not see any reason to reconsider its previous approval.

However, please note that the Committee assessed and approved only the Dutch versions of the subject information. The responsibility for the certified translation lies with the party concerned.

This appendix is an integral part of the original Letter of Approval and the same conditions and timelines apply for filing a notice of objection.

Assen, 24 October 2019

5.1.2.e

(chairman)