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Central Committee on Research Involving Human Subjects
PO Box 16302
2500 BH The Hague

Groningen, 29 January 2020

Subject: Notification premature termination of research dossier NL69548.056.19

Dear members of the CCMO,

Herewith QPS Netherlands B.V. sends the premature termination documentation of the study *"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"* to the CCMO for notification.

On 07 January 2020, we submitted a substantial amendment requesting a temporarily halt to the study.

During this hold period, we evaluated all of the data from the latest case (subject 5.1.2.e); the extended hepatic lab panel and hepatic/biliary ultrasound assessments did not demonstrate other reasons for the liver transaminase elevations. Given the available data, including the occurrence of the three cases with similar patterns of liver transaminase elevations and probable relation to study drug, the decision was made to permanently terminate the study effective 22 January 2020. 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.

The date of last subject last visit was 21 January 2020.

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The following documents are enclosed:

- A1 – Cover letter applicant CCMO, dated 29 January 2020
- B7 – EudraCT form End of Trial CCMO, dated 29 January 2020

With kind regards,

5.1.2.e

QPS Netherlands BV