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The Netherlands

Bucharest, 13-Dec-2019

Subject: **Digital submission of Investigator Notification following the 11 July 2019 Urgent Safety Measure and Follow-Up Investigator Notification dated 01 August 2019**

- **Investigator letter notification 3 (Follow-up#2) for Generation Program CNP520 discontinuation 12 December 2019**

ToetsingOnline:	NL61015.029.17
EudraCT no.:	2016-002976-28
Protocol code:	CCNP520A2202J
Protocol title:	A randomized, double-blind, placebo-controlled, parallel group study to evaluate the efficacy and safety of CNP520 in participants at risk for the onset of clinical symptoms of Alzheimer's Disease (AD)
Sponsor:	Novartis Pharma AG, Lichtstrasse 35, Basel, 4056, Switzerland
EU Legal Rep:	Novartis Pharma Arzneimittel GmbH, Roonstrasse 25, Nürnberg, 90429, Germany

Dear Madam, dear Sir,

On behalf of the Sponsor, Novartis Pharma AG, Parexel International Romania s.r.l. herewith submits the Investigator letter 3 (Follow-up#2) for Generation Program CNP520 discontinuation dated 12 December 2019.

Following our Urgent Safety Measure (USM) communication sent to you on 15 July 2019 detailing the decision to terminate study CCNP520A2202J (which included a Participants Follow-Up plan as part of the Investigator's Notification) as well as our communication to you on 05 August 2019 providing clarifications to the Participant Follow-up Plan, Novartis in collaboration with its partners at 5.1.1.c to issue a 2nd Investigator Notification to further streamline assessments in the Participant Follow-up Plan post discontinuation of CNP520 treatment.

At this time, Novartis is notifying the respective competent authorities regarding changes to the USM Participant Follow-Up Plan (see Investigator Notification attached for details) at the same time that it is communicated to all participating Investigators and Ethics Committees.

Based on changes to the Participant Follow-up Plan from the three Investigator Notifications (submitted to health authorities and ethic committees) in July, August, and now December, Novartis will be amending both study protocols in January 2020 to administratively reflect the early study terminations and the complete modifications to

the Participant Follow-Up Plan implemented as part of the USM. In January 2020, Novartis will submit the amended protocols as an administrative update for completeness of documentation.

The final study reports will be available for submission to HAs within 12 month after the LPLV from the Participant Follow-up phase. Novartis remains committed to advancing science in Alzheimer's disease and to presenting and sharing the program data when available within a final study report.

Please find attached to this e-mail the following study documents supporting this notification:

Numbering	Document	Version /Date
A.	**Letter**	
A1	Cover Letter	13-Dec-2019
K.	**Other Relevant Documents**	
K6	Investigator letter 3 (Follow-up#2) for Generation Program CNP520 discontinuation	12-Dec-2019

With this submission, we declare that all relevant documents of the present submission dossier are signed by the persons authorised for this task.

We trust that the information provided in the application is sufficient, however if you require any further information, please contact us.

Yours faithfully,

5.1.2.e

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