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**PER E-MAIL TO BI@CCMO.NL**
**CCMO**
Attn. Competent Authority
Parnassusplein 5
2511 VX Den Haag,
The Netherlands

Bucharest, 18-Mar-2020

| | |
|---|---|
| **Subject:** | **Declaration of the Local and Global end of trial - Early termination** |
| **ToetsingOnline dossier no.:** | 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/Sir,

On behalf of the Sponsor, **Novartis Pharma AG**, Parexel International Romania s.r.l. as the applicant herewith notifies the local and global end of the above-mentioned clinical trial.

The Last Patient Last Visit (LPLV) for the study CCNP520A2202J was achieved globally on 13-Mar-2020. The end of trial in The Netherlands was achieved on 10-Mar-2020.

The Sponsor's decision to terminate early study CCNP520A2202J under an Urgent Safety Measure (USM) was made on 8-Jul-2019 and followed the assessment of unblinded data of the BACE1 inhibitor, CNP520, by the independent Data Monitoring Committee (DMC), during a planned data review on 26-Jun-2019 that identified consistent mild worsening was observed in some measures of cognitive function among participants in the CNP 520 groups versus placebo.

Following initial Urgent Safety Measure (USM) communication sent to CCMO on 15-Jul-2019 detailing the decision to terminate study CCNP520A2202J (which included a Participants Follow-Up plan as part of the Investigator's Notification), Novartis in communication with its partners at 5.1.1.c and 5.1.1.c issued 2 additional follow-up communications (on August and December 2019) providing further clarifications to the Participant Follow-up Plan post discontinuation of CNP520 treatment. Both of these communications were sent to Investigators and submitted to HAs.

On 13-Mar-2020 the last patient completed the safety follow-up visit and as per regulations we are submitting the early termination -global end of the trial.

For Netherlands, the results of this clinical trial will be submitted within the applicable timeline as a separate submission of the clinical trial report (summary) to fulfill national reporting obligations.

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

| CCMO numbering | Document | Version/Date |
|---|---|---|
| A1 | Cover letter | 18-Mar-2020 |
| B7 | Declaration of the End of Trial Form –Annex III | 18-Mar-2020 |

We trust that this notification fulfils your requirements; however, in the event of any queries, please do not hesitate to contact us.

Yours faithfully,

**Parexel International Romania s.r.l.**
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