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CCMO
Attn. Competent Authority
Parnassusplein 5
2511 VX Den Haag
The Netherlands

Bucharest, 24-Mar-2021

Subject:	**Digital submission of the synopsis of the Clinical Study Report and Final AFSR-CNP520**
EudraCT no.:	**2016-002976-28**
Sponsor study no.:	**251717**
PAREXEL study no.:	**CCNP520A2202J**
ToetsingOnline dossier no.:	**NL61015.029.17**
Study 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)**

Dear Madam, dear Sir,

On behalf of the Sponsor, **Novartis Pharma AG**, PAREXEL International Romania SRL herewith submits the synopsis of the Clinical Study Report and Final report of 104-Week Oral Gavage Rat Carcinogenicity study with CNP520 for the above-mentioned clinical trial to the CCMO as the Competent Authority in the Netherlands.

On behalf of Novartis, PAREXEL International Romania s.r.l. also notifies the final report for study No. 1470014, a 104-Week Oral Gavage Carcinogenicity Study with CNP520 in Rats. The interim report for this study, including 89 weeks of treatment, was previously submitted on 11-Jun-2019. The study has now been completed and final study data with 104 weeks of treatment are now available. There were no relevant new findings and previous conclusions remain valid.

Please find below the list of documents attached to this notification:

CCMO numbering	Document	Version/Date
A1	Cover Letter to CA NL61015.029.17 CSR Synopsis Notification	24-Mar-2021
M3.1	Clinical Study Report Synopsis NL61015.029.17	19-Feb-2021
M3.2	Final report 104-Week Oral Gavage Rat Carcinogenicity study NL61015.029.17	04-Nov-2020

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

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