

Parexel International Romania s.r.l.

Metropolis Center - Str. Grigore Alexandrescu, Nr.89-97, Sector 1, 010624 Bucharest, Romania

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PER E-MAIL TO BI@CCMO.NL

CCMO

Attn. Competent Authority

Parnassusplein 5

2511 VX Den Haag

The Netherlands

11-Jun-2019

Aggregate Finding Safety Report (AFSR): Preliminary preclinical safety finding from an ongoing 104-week oral (gavage) rat carcinogenicity study with CNP520

Investigational Medicinal Product Code: CNP520

Dear Madam/Sir,

On behalf of Novartis, PAREXEL International Romania s.r.l. herewith notifies an Aggregate Finding Safety Report for CNP520.

Reference is made to studies **buiten reikwijdte verzoek** and CCNP520A2202J (EudraCT No. **buiten reikwijdte verzoek** and 2016-002976-28) for compound CNP520 (umibecestat) which is being developed to delay the onset of symptoms of Alzheimer's disease (AD) in a population at an increased risk of developing symptoms of AD. As part of the non-clinical safety profiling of CNP520, Novartis is performing a 26-week carcinogenicity study in mice (study 1470013) and a 104-week carcinogenicity study in Charles River Wistar rats (study 1470014).

Please note that only CCNP520A2202J study is submitted to the attention of CCMO.

Preclinical safety finding:

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[REDACTED]

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[REDACTED]

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Clinical safety data:

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Sponsor Assessment:

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Investigators will be notified of these preclinical safety findings in parallel to this HA notification.

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

Yours faithfully,

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PAREXEL International Romania SRL

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Attachments

No.	Document	Date of document
A1	Cover Letter to CA NL61015.029.17 AFSR CNP520	11-Jun-2019
K6a	AFSR CNP520 Preclinical assessment report NL61015.029.17	03-Jun-2019
K6b	AFSR CNP520 Generation Program Letter to investigators NL61015.029.17	07-Jun-2019