

To: ccmo_frontoffice[frontoffice@ccmo.nl]
From: ccmo_bi
Sent: Fri 14-6-2019 9:13:06
Subject: FW: Aggregate Finding Safety Report (AFSR): Preliminary preclinical safety finding from an ongoing 104-week oral (gavage) rat carcinogenicity study with CNP520 NL61015.029.17
Received: Fri 14-6-2019 9:13:08
[A1 Cover Letter to CA NL61015.029.17 AFSR CNP520 20190611.pdf](#)
[K6a AFSR CNP520 Preclinical assessment report NL61015.029.17 20190603.pdf](#)
[K6b AFSR CNP520 Generation Program Letter to investigators NL61015.029.17 20190607.pdf](#)

Overige veiligheidsinformatie, alleen verwerken voor NL61015.029.17.

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Van: [redacted]@novartis.com> Namens [redacted]

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11 juni 2019 14:10

Aan: ccmo_bi <bi@ccmo.nl>

CC: [redacted]@novartis.com>

Onderwerp: Aggregate Finding Safety Report (AFSR): Preliminary preclinical safety finding from an ongoing 104-week oral (gavage) rat carcinogenicity study with CNP520 NL61015.029.17

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 [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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Clinical safety data:

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Sponsor Assessment:

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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

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

Yours faithfully,

PAREXEL International Romania SRL

5.1.2.e

Metropolis Center, Str. Grigore Alexandrescu, No. 89-97
Bucharest, Sector 1, Romania, 010624

Correspondence address: CP166, OP 63, Ghiseu 2,
Sos Stefan cel Mare nr.2
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Fax: +40 0372 5.1.2.e

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Parexel International Romania s.r.l.

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Phone: +4031 5.1.2.e / Fax: +4031 5.1.2.e / www.parexel.com

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2511 VX Den Haag

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11-Jun-2019

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

Preclinical safety finding:

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Clinical safety data:

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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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Metropolis Center, Str. Grigore Alexandrescu, No. 89-97
Bucharest, Sector 1, Romania, 010624

Correspondence address: CP166, OP 63, Ghiseu 2,

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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

Preclinical Safety

IND 124050

CNP520

Study no. 1470014

104-week oral gavage carcinogenicity study with CNP520 in rats

Document type: Preclinical assessment report

Document status: Final

Release date: 03-Jun-2019

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Signature Page

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7 June 2019

Dear Generation Program Investigators,

Novartis would like to inform you on interim findings from an ongoing 104-week rat carcinogenicity study with CNP520 (umibecestat). **The benefit-risk profile for CNP520 remains positive, and currently, no changes are recommended for the ongoing clinical trials** (buiten reikwijdte verzoek and CCNP520A2202J).

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Clinical safety data:

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Sponsor Assessment:

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