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Onderwerp: Doorsturen veiligheidsinformatie naar METC
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Geachte METC,

De CCMO heeft als Bevoegde Instantie een bericht ontvangen vanuit de CTFG over de BACE inhibitor, CNP520. Mogelijk heeft dit bericht u al via andere kanalen bereikt. Volgens onze gegevens heeft uw METC een van de volgende onderzoeksdossiers beoordeeld.

buiten reikwijdte verzoek

2016-002976-28, NL61015.029.17, lopend volgens TOL (METC VUMC)

buiten reikwijdte verzoek

BfArM got informed of USM and temporary halt of EudraCT 20016-002976-28 by Novartis:

*Novartis, in consultation with its collaboration partners 5.1.1.c, has decided to **immediately discontinue assessment of CNP520 in the two Phase 2/3 studies in the Alzheimer's Prevention Initiative Generation Program**. The Sponsors' decision follows the assessment of unblinded data of the BACE1 inhibitor, CNP520, by the independent Data Monitoring Committee (DMC), during a planned data review on 26 June 2019.*

Key findings from this data review of CNP520 were as follows:

Consistent mild worsening was observed in some measures of cognitive function. Worse performance on RBANS was observed for CNP520 15 mg and CNP520 50 mg compared to placebo at both Week 13 and 26 in both studies. Increased decline in RBANS of more than 7 points and more than 14 points was detected in the CNP 520 groups versus placebo. A consistent trend in worsening was also observed for CDRSOB in the CNP520 groups compared to placebo.

Volumetric MRI (whole brain and hippocampal volume) indicated increased volume loss on active treatment compared to placebo.

Greater mean weight loss was observed at 26 weeks on CNP520 for both 15 mg and 50 mg doses vs placebo.

The early worsening in some cognitive measures observed with CNP520 appears similar to data reported for other BACE inhibitors.

Met vriendelijke groet, 5.1.2.e

5.1.2.e

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