



CHDR  
Centre for Human Drug Research

Centrale Commissie Mensgebonden Onderzoek (CCMO)  
tav bevoegde instantie (BI)  
Parnassusplein 5  
2511 VX Den Haag

Leiden, 07-May-2021

Ref.: Temporary halt for research dossier CHDR1822 / NL71107.056.19

Dear members of the CCMO,

With this letter I would like to inform the Competent Authority on behalf of the Sponsor, that the study titled "A first-in-human, randomized, subject-blinded, placebo controlled, single ascending dose study to investigate the safety, tolerability and pharmacokinetics of MHS552 in healthy volunteers", (CHDR1822) registered under number NL71107.056.19 is temporarily put on hold due to two subjects who experienced hypersensitivity-like reactions which were assessed as CTCAE AEs grade 2 or higher. As both events were considered drug-related, study-stopping rules were met as agreed by both the Investigator and Sponsor and enrollment is placed on hold while a full safety review will be conducted.

A Substantial Amendment form will follow directly from the Sponsor.

Kind regards,

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