famhp
federal agency for medicines and health products

Federal Agency for Medicines and Health Products
Eurostation II - Place Victor Horta 40/40
1060 BRUSSELS
www.fagg.be - www.afmps.be

DG PRE / R&D Division

Benedicte Nuyttens
Tel. : +32 (0)2 528 44 54
Fax : +32 (0)2 528 40 01
e-mail : benedicte.nuyttens@fagg-afmps.be

Medpace Belgium BVBA
Lore Bussé
Technologielaan 11
3001 Leuven

Your letter from	Your reference	Our reference	Annex	Date
		FAGG/DGPRE/R&D/BEN 1134570		

Dossier GMO : B/BE/18/BVW7 (2017-004305-40): Phase III, open-label, single-dose, multi-center multinational trial investigating a serotype 5 adeno-associated viral vector containing the Padua variant of a codon-optimized human factor IX gene (AAV5-hFIXco-Padua, AMT-061) administered to adult subjects with severe or moderately severe hemophilia B

Geachte Mevrouw Bussé,

Hierbij informeren wij u dat de vergunningsplicht krachtens het Koninklijk besluit van 21 februari 2005 tot reglementering van de doelbewuste introductie in het leefmilieu evenals van het in de handel brengen van genetisch gemodificeerde organismen of van producten die er bevatten u wordt toegekend op basis van het gunstig advies van de Adviesraad voor Bioveiligheid daterend van 11 december 2018 en dit volgens de voorwaarden hernomen in de conclusie van bovenvermeld advies, dat wil zeggen:

"The notifier and the investigators must strictly apply the clinical trial protocol, and all the safety instructions as described in the dossier.

- *Any protocol amendment has to be previously approved by the Competent Authority.*
- *The notifier is responsible to verify that each study centre has qualified personnel experienced in handling infectious material and that the investigator has the required authorizations to perform the clinical trial activities inside the hospital (laboratory, pharmacy, hospital room, consultation room...) according to the Regional Decrees transposing Directive 2009/41/EC on Contained use of genetically modified micro-organisms.*
- *The Biosafety Advisory Council should be informed within two weeks when the first patient starts the treatment and the last patient receives the last treatment.*
- *At the latest six months after the last visit of the last patient included in the trial, the notifier must send to the competent authority at the attention of the Biosafety Advisory Council a report with details concerning the biosafety aspects of the project. This report will at least contain:*
    - *The total number of patients included in the trial and the number of patients included in Belgium;*

- *A summary of all adverse events marked by the investigators as probably or definitely related to the study medication;*
- *A report on the accidental releases, if any, of AMT-061."*

Met hoogachting,

Maggie De Block

Minister van Sociale Zaken, Volksgezondheid, Asiel en Migratie

Marie Christine Marghem

Minister van Energie, Leefmilieu en Duurzame Ontwikkeling

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1060 Bruxelles
www.afmps.be

DG PRE authorisation / RD Division (human)

Benedicte Nuyttens
Tel. : + 32 (0)2 528 44 54
Fax : + 32 (0)2 528 40 01
e-mail : Benedicte.Nuyttens@fagg-afmps.be

Medpace Belgium BVBA
Lore Bussé
Technologielaan 11
3001 Leuven

Your letter from	Your reference	Our reference	Annex	Date
		FAGG/R&D/BEN/ben		

Onderwerp Goedkeuring van een klinische proef op 18 januari 2019.
Titre de l'objet Approbation d'un essai clinique le 18 janvier 2019.
Subject Authorisation of a clinical trial dated 18 January 2019.

Phase III, open-label, single-dose, multi-center multinational trial investigating a serotype 5 adeno-associated viral vector containing the Padua variant of a codon-optimized human factor IX gene (AAV5-hFIXco-Padua, AMT-061) administered to adult subjects with severe or moderately severe hemophilia B,

EudraCT : 2017-004305-40

Chère Madame, Cher Monsieur,

Conformément à l'article 12 de la Loi du 7 mai 2004 relative aux expérimentations sur la personne humaine, j'ai décidé d'autoriser l'essai clinique ci-dessus mentionné.

Salutations sincères,

Pour la Ministre des Affaires sociales, de la Santé publique, de l' Asile et de la Migration

Geachte Mevrouw, Geachte Heer,

In overeenstemming met artikel 12 van de wet van 7 mei 2004 inzake experimenten op de menselijke persoon, heb ik besloten de hierboven vermelde klinische proef goed te keuren.

Met de meeste hoogachting,

Voor de Minister van Sociale zaken, volksgezondheid, Asiel en Migratie

Dr. Greet Musch

Unofficial translation:

In accordance with article 12 of the Law of 7 May 2004 concerning experiments on the human person, I have decided to authorise the above mentioned clinical trial.