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

Onderwerp
Titre de l'objet
Subject

Goedkeuring van een klinische proef op 29/01/2018
Approbation d'un essai clinique le 29/01/2018
Authorisation of a clinical trial dated 29/01/2018

Trial Title: Dossier OGM : B/BE/17/BVW2 : A Phase 1b Study of Talimogene Laherparepvec in Combination With Atezolizumab in Subjects With Triple Negative Breast and Colorectal Cancer With Liver Metastases

EudraCT: 2015-005480-16

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 mentionné ci-dessus.

Nous vous prions d'agréer l'expression de nos sentiments les meilleurs,

Pour la Ministre des Affaires sociales et de la Santé publique

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 proef goed te keuren.

Met de meeste hoogachting,

Voor de Minister van Sociale Zaken en Volksgezondheid

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. However, the points as mentioned in annex are to be followed up.

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10 ans

DG Pré/R&D

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Votre lettre du	Vos références	Nos références	Annexe(s)	Date
		AFMPS/DGPRE/R&D/LSA		

Dossier OGM : B/BE/17/BVW2 (2015-005480-16): A Phase 1b Study of Talimogene Laherparepvec in Combination With Atezolizumab in Subjects With Triple Negative Breast and Colorectal Cancer With Liver Metastases

Geachte Mevr. Houben,

Hierbij informeren wij u dat de vergunning 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 13 december 2016 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 as described in the current dossier and all the safety instructions as described in the notification B/BE/16/BVW1.

- Any protocol amendment has to be previously approved by the Competent Authority.

- The notifier is responsible to verify that each study center has qualified personnel experienced in handling infectious material and that the investigator has the required authorisations 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 the contained use of genetically modified micro-organisms.

- For the transport of the IMP the notifier should conform to the transportation rules regarding transport of GMO's.

  The Biosafety Advisory Council should be informed within 2 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 for the attention of the Biosafety Advisory Council a report with details concerning the biosafety aspects of the project. This report shall contain at least:
    - 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 the recombinant HSV-1.

Met hoogachting,

Maggie De Block
Ministre des Affaires Sociales
et de la Santé publique

Marie Christine Marghem
Ministre de l'Energie, de l'Environnement et du Développement durable