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Your letter from	Your reference	Our reference	Annex	Date
		FAGG/R&D/LSA 188413		27 AVR. 2015

Onderwerp
Titre de l'objet
Subject

Goedkeuring van een klinische proef op
Approbation d'un essai clinique le 20/04/2015
Authorisation of a clinical trial dated

Dossier OGM : B/BE/14/BVW1 : A Phase 2, Multicenter, Open-label, Single-arm Trial to Evaluate theCorrelation Between Objective Response Rate and Baseline Immunoprofile Intratumoral CD8+ Cell Density in Subjects With Unresected Stage IIIB toIVM1c Melanoma Treated with Talimogene Laherparepvec

EudraCT: 2013-005552-15

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.

Cependant, un suivi doit être apporté aux points mentionnés en annexe.

Salutations sincères,

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.

Niettemin moet er gevolg gegeven worden aan de opmerkingen vermeld in bijlage.

Met de meeste hoogachting,

Voor de Minister van Sociale Zaken en Volksgezondheid

Dr. Greet Musch

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.

Annex

QUALITY

All grounds for non-acceptance were addressed appropriately. Therefore, we have no objections against the start of the Clinical Trial.

However, the sponsor is recommended to take into consideration the following points (i.e. recommendations) given in annexe during further development of the product. They may be readdressed at the time of assessment of future applications related to this investigational medicinal product.

Drug product:

- Although mycoplasma testing are performed at the bulk harvest stage, the applicant is recommended to include this testing as a specification to release the drug product.

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Votre lettre du	Vos références	Nos références	Annexe(s)	Date
		AFMPS/DGPRE/R&D/LSA 188425		27 AVR. 2015

Dossier OGM : B/BE/14/BVW1 : A Phase 2, Multicenter, Open-label, Single-arm Trial to Evaluate the Correlation Between Objective Response Rate and Baseline Immunoprofile Intratumoral CD8+ Cell Density in Subjects With Unresected Stage IIIB toIVM1c Melanoma Treated with Talimogene Laherparepvec (EudraCT n°: 2013-005552-15)

Geachte Mevrouw De Paepe,

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 24 februari 2015 en dit volgens de voorwaarden hernomen in de conclusie van bovenvermeld advies, dat wil zeggen:

- The notifier and the investigators must strictly apply the trial protocol, and all safety instructions as described in the dossier also taking into account the suggestions from the Biosafety Advisory Council for improvement of the personnel instructions.

- 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 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.

- 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 subject 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 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 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