Agence fédérale des médicaments et des produits de santé
Eurostation II - Place Victor Horta 40/40
1060 Bruxelles
www.afmps.be

afmps
agence fédérale des médicaments et des produits de santé

DG Pré/R&D

Anne Lenaers
Tél. : 02/528.41.03
Fax : 02/528 40 01
e-mail : anne.lenaers@afmps.be

Mr Luc Van Driessche

Amgen NV/SA

Avenue Ariane, 5

1200 Bruxelles

Votre lettre du	Vos références	Nos références	Annexe(s)	Date
		AFMPS/DGPRE/R&D/LSA		4/12/2015

Dossier OGM : B/BE/15/BVW1 : A Phase 1b/3, Multicenter, Open-label Trial of Talimogene Laherparepvec in Combination With Pembrolizumab (MK-3475) for Treatment of Unresected, Stage IIIB to IVM1c Melanoma (EudraCT n°: 2014-000185-22)

Geachte Mr Van Driessche,

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 12 oktober 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.

- 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.

.be

- 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