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| Your letter from | Your reference | Our reference | Annex | Date |
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**Onderwerp / Titre de l'objet / Subject**
Goedkeuring van een klinische proef op 15/10/2018
Approbation d'un essai clinique le 15/10/2018
Authorisation of a clinical trial dated 15/10/2018

A Phase 2, multi-center, randomized, double-blind, placebo-controlled study to assess the safety and efficacy of topically-applied AG013 for the attenuation of oral mucositis in subjects with cancers of the head and neck receiving concomitant chemoradiation therapy

EudraCT: 2016-004161-68

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.

Sincères salutations,

Pour la Ministre des Affaires sociales et de la Santé publique

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

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.

# Annex

# Safety

**Recommendation**

In view of the update of the CTFG - Q&A document on RSI, published on: http://www.hma.eu/fileadmin/dateien/Human_Medicines/01-About_HMA/Working_Groups/CTFG/2017_11_CTFG_Question_and_Answer_on_Reference_Safety_Information_2017.pdf, the sponsor is highly recommended comply with the Q&A during the IB updates that follow this publication.

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Dossier OGM : B/BE/18/BVW3 (2016-004161-68): A Phase 2, multi-center, randomized, double-blind, placebo-controlled study to assess the safety and efficacy of topically-applied AG013 for the attenuation of oral mucositis in subjects with cancers of the head and neck receiving concomitant chemoradiation therapy

Cher Monsieur Graham,

Par la présente, nous vous informons que l'autorisation imposée en vertu de l'arrêté royal du 21 février 2005 règlementant la dissémination volontaire dans l'environnement ainsi que la mise sur le marché d'organismes génétiquement modifiés ou de produits en contenant vous est accordée sur base de l'avis favorable du Conseil de Biosécurité daté du 11 septembre 2018, et ce, aux conditions reprises dans la conclusion de l'avis précité, c'est-à-dire :

*"The notifier and the investigators must strictly apply the clinical trial protocol, and all the safety instructions as described in the dossier also taking into account the recommendations from the Biosafety Advisory Council for waste treatment.*

- *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 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 AG013."*

Salutations sincères,

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