Federal Agency for Medicines and Health Products

Research and Development

Quintiles Belgium NV/SA
Mr Jordi Hulsmans
32 Medialaan
1800 Volvoorde

REF : FAGG/R&D/LSA
DATUM / DATE
ANNEX / ANNEXE

CONTACT ANNE LENAERS
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FAX + 32 (0) 2 524 80 01
E-MAIL Anne.lenaers@fagg-afmps.be

Titel van de proef : **Titre de l'essai :** **Title of the trial :**	**A Phase IIb/III randomized, double-blind, placebo-controlled study comparing first-line therapy with or without TG4010 immunotherapy product in patients with stage IV non-small cell lung cancer (NSCLC).**
Betreffende : **Concernant :** **Concerning :**	**Goedkeuring van een klinische proef op 21/11/2011** **Approbation d'un essai clinique le 21/11/2011** Autorisation of clinical trial dated 21/11/2011
EudraCT :	**2011-001468-23**

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 ci-dessus mentionné.

Salutations sincères,

Pour la Vice-Première Ministre et 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 Vice-Eerste Minister en Minister van Sociale Zaken en Volksgezondheid

Dr. Greet Musch

Unofficial translation

Conform article 12 of the Law of 7 May 2004 concerning experiments on the human person, I have decided to authorize the above mentioned clinical trial.

Agence Fédérale des Médicaments
et des Produits de Santé

Division
Recherche et Développement

VOTRE LETTRE DU
VOS RÉF.

NOS RÉF. AFMPS/LSA
DATE

ANNEXE(S)

CONTACT : ANNE LENAERS
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Mr Xavier De Cuyper
Administrateur général de l'Agence Fédérale des Médicaments et Produits de Santé
Place Victor Horta 40/bte40
1060 Bruxelles

OBJET : **DOSSIER OGM B/BE/11/BVW1:** A Phase IIb/III randomized, double-blind, placebo-controlled study comparing first-line therapy with or without TG4010 immunotherapy product in patients with stage IV non-small cell lung cancer (NSCLC)

Monsieur l'Administrateur général,

Par la présente, je vous informe 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 est accordée au notifiant Quintiles sur base de l'avis favorable du Conseil de Biosécurité, 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, as described in the dossier. In addition, the technical sheet has to be amended according to the recommendations described under point 4 (The condition of release) and summarized below:
  - the wearing of goggles, mask and gloves is mandatory when preparing and administering the product;
  - in case of skin contamination, an absorbent tissue should be placed on the affected area in order to absorb all viral vectors. The disinfectant should then directly be applied to the tissue. After removing this tissue, the skin should be washed thoroughly;
  - in case of eye contamination wash the eyes over a closed basin where the wash water can be decontaminated with active chlorine bleach before being released into the sewer system;
  - The instructions for preparation of the syringe should stipulate that the needle has to be removed in a hands free operation into a closed container.

- As already agreed by the notifier in his answer of 15 September, the technical sheet as to be amended regarding the presence of a biohazard sign during transport of the product and the need to mark the injection sites subject to swabbing with an indelible felt-tipped pen.

- 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 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 Contained use of genetically modified micro-organisms.

- 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 *Vaccinia* virus.

Je vous prie d'agréer, Monsieur l'Administrateur général, l'expression de mes salutations distinguées.

Laurette Onkelinx

Vice-Première Ministre et Ministre des Affaires Sociales,
de la Santé Publique et de l'Intégration Sociale

Cellule stratégique
de Laurette ONKELINX,
Ministre des Affaires sociales
et de la Santé publique

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Mr Xavier De Cuyper
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Place Victor Horta 40/bte40
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votre lettre du
vos références

nos références
date

annexe(s)

Objet **DOSSIER OGM B/BE/11/BVW1:** A Phase IIb/III randomized, double-blind, placebo-controlled study comparing first-line therapy with or without TG4010 immunotherapy product in patients with stage IV non-small cell lung cancer (NSCLC)

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Paul Magnette

Ministre du Climat et de l'Energie