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

Onderwerp
Titre de l'objet
Subject

Goedkeuring van een klinische proef op 28/11/2018
Approbation d'un essai clinique le 28/11/2018
Authorisation of a clinical trial dated 28/11/2018

A first-time-in human (FTIH), Phase I, randomized, multi-centric, singleblind, controlled dose-escalation study to evaluate the reactogenicity, safety immunogenicity and efficacy of GSK Biologicals' HBV viral vector vaccines given in a prime-boost schedule with sequential or coadministration of adjuvanted proteins therapeutic vaccine (GSK3528869A) in chronic Hepatitis B patients (18-65 years old) well controlled under nucleo(s)tides analogues (NA) therapy.

EudraCT: 2017-001452-55

Chère Madame,

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,

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

Following the provisions laid down in article 22 of the Law of 7 May 2004, a clinical trial cannot start if the conditions defined are not met. For this clinical trial, the conditions is:
All subjects are to be followed up till day 841. Therefore follow-up will be approximately 2 to 2.3 years from the date of ChAd155-hli-HBV vaccine administration. Additional samples in case of immune response against hli may be needed, according to the protocol. GSK will consider additional follow-up should a positive immune response to CD74 be detected.
This is considered acceptable, on the condition that the additional follow-up after the end of the study is warranted and specifically included in the protocol.

Additionally, the sponsor is recommended to take into consideration the following recommendations during further development of the product. They may be readdressed at the time of assessment of future applications related to this investigational medicinal product.

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 should fully comply with the Q&A during the IB updates that follow this publication. Especially, a section Reference safety information should be added in the investigator's brochure. In this section, it should be stated that no SARs are considered expected by the sponsor for the purpose of expedited reporting and identification of SUSARs in the DSUR for the IMP

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

Dossier: B/BE/18/BVW4 (2017-001452-55): A first-time-in human (FTIH), Phase I, randomized, multi-centric, single-blind, controlled dose-escalation study to evaluate the reactogenicity, safety immunogenicity and efficacy of GSK Biologicals' HBV viral vector vaccines given in a prime-boost schedule with sequential or co-administration of adjuvanted proteins therapeutic vaccine (GSK3528869A) in chronic Hepatitis B patients (18-65 years old) well controlled under nucleo(s)tides analogues (NA) therapy

Chère Madame Dewitte,

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 1 octobre 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. The notifier is recommended to further improve the description of procedures for study staff in regards the management of accidental spills or breakage of a vial containing the GMO by means of the 'Biosafety instructions for site staff".

- *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, ChAd155-hIi-HBV and MVA-HBV."*

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