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Votre lettre du	Vos références	Nos références	Annexe(s)	Date
		AFMPS/DGPRE/R&D/BEN 1141605		

Dossier OGM : B/BE/18/BVW9 (2018-000431-27): A Phase 1/2, randomized, observer-blind, controlled, multi-center study to evaluate safety, reactogenicity and immunogenicity of GSK Biologicals' respiratory syncytial virus (RSV) investigational vaccine based on the RSV viral proteins F, N and M2-1 encoded by chimpanzee-derived adenovector (ChAd155-RSV) (GSK3389245A), when administered intramuscularly as a single dose or as two doses according to a 0, 1-month schedule to infants aged 6 and 7 months.

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 22/01/2019, 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.

- *Any protocol amendment has to be previously approved by the Competent Authority.*
- *'Biosafety Instructions for site staff' should be more explitely described and updated as mentioned under section 4 above.*
- *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 ChAd155-RSV."*

Salutations sincères,

Maggie De Block
Ministre des Affaires Sociales, de la Santé publique, de l' Asile et de la Migration

Marie Christine Marghem
Ministre de l'Energie, de l'Environnement et du Développement durable