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Votre lettre du	Vos références	Nos références	Annexe(s)	Date
		AFMPS/DGPRE/R&D[redacted]		13/02/2023

Dossier OGM : B/BE/22/BVW4 (2021-002823-40): A Phase I/II, Multicenter, Open-Label Study of Nous-209 Genetic Vaccine for the Treatment of Microsatellite Unstable Solid Tumors

Chère[redacted],

Par la présente, nous vous informons que votre demande d'autorisation a été approuvée.

L'autorisation est conforme à l'arrêté royal du 21 février 2005 réglementant la dissémination volontaire dans l'environnement ainsi que la mise sur le marché d'organismes génétiquement modifiés ou de produits en contenant.
(http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=fr&la=F&cn=2005022131&table_name=loi)

Votre autorisation est accordée sur base de l'avis favorable du Conseil de Biosécurité daté du 19 janvier 2023, aux conditions reprises dans la conclusion de cet avis, à savoir:

"Based on the scientific assessment of the notification made by the Belgian experts, the Biosafety Advisory Council concludes that it is unlikely that Nous-209 developed as an anti-tumor therapy, will have any adverse effects on human health or on the environment in the context of the intended clinical trial, provided that all the foreseen safety measures are followed.

Therefore, the Biosafety Advisory Council issues a ***positive advice with the following conditions****:*

– The notifier and the investigators must strictly apply the clinical trial protocol and the safety instructions as described in the following documents:
- *o EU_Pharmacy manual v3.1_BEL_22Dec2022*
- *o Common application form for GAd20-209-FSP and MVA-209-FSP v2.0 27sep2022*
- *o Summary Notification Information Format Gad-209-FSP and MVA-209-FSP BEL_SNIF_v3.1_22Dec22*
- *o IB, v4.1, dated 4 Nov 2021*
- *o BEL_Technical sheet_v2.1_22Dec22*
- *o BEL_Patient Instructions_v1_03Jan2023*

– Any protocol amendment has to be previously approved by the Competent Authority.

– The notifier is responsible to verify that the 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 the contained use of genetically modified micro-organisms.

– The BAC 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 the competent authority for the attention of the BAC a report with details concerning the biosafety aspects of the project. This report shall contain at least:

- *o The total number of patients included in the trial and the number of patients included in Belgium;*
- *o A summary of all adverse events marked by the investigators as probably or definitely related to the study medication;*
- *o A report on the accidental releases, if any, of Nous-209."*

Sincères salutations,

Frank Vandenbroucke
Vice-Premier Ministre et
Ministre de la Santé publique et
des Affaires sociales

Zakia Khattabi
Ministre du Climat, de
l'Environnement, du
Développement durable et du
Green Deal