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Votre lettre du	Vos références	Nos références	Annexe(s)	Date
		AFMPS/DGPRE/R&D/ [redacted]		03.09.2025

Dossier OGM : B/BE/25/BVW4 (2025-520665-47-00): An Open-Label Dose-Escalation Study to Assess the Safety and Tolerability of a Single Intravitreal Injection of SPVN20 Gene Therapy in Subjects with No Light Perception Due to End-Stage Rod-Cone Dystrophy, and Who Retain Dormant Foveal Cone Photoreceptors

[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 29 juillet 2025, aux conditions reprises dans la conclusion de cet avis, à savoir:

"Based on the scientific assessment of the notification made by the Belgian expert, the Biosafety Advisory Council concludes that it is unlikely that SPVN20 developed to treat patients with no light perception due to end-stage rod-cone dystrophy, and who retain dormant foveal cone photoreceptors, by means of endogenous production of GIRK1(F137S) variant protein 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 all the safety instructions as described in the following documents :
- *o Latest version of the ICF*
- *o Latest version of the Protocol_NYRVANA*
- *o NYRVANA-SPVN20_SNIF_17APR25*
- *o SPVN20-CLIN-01_AAV_CAF_17APR25_Non Confidential updated with the request to also use goggles in addition to the standard hospital personal protective equipment during preparation and administration of the IMP*
- *o SPVN20-CLIN-01_AAV_CAF_24JUN25_Confidential*
- *o SPVN20-CLIN-01_Patient Precaution Information_v2.0*

- 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 Advisory Council a report with details concerning the biosafety aspects of the project. This report will at least contain:

- *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 SPVN20."*

Sincères salutations,

Frank Vandenbroucke
Vice-premier ministre et
ministre des Affaires sociales et
de la Santé publique, chargé de
la Lutte contre la pauvreté

Jean-Luc Crucke
Ministre de la Mobilité, du
Climat et de la Transition
environnementale