Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten
Galileelaan 5/03
1210 BRUSSEL

www.fagg.be

DG PRE vergunning/afdeling Onderzoek en Ontwikkeling

[redacted]

AstriVax NV
[redacted]
Ambachtenlaan 1
3001 Heverlee
België

uw bericht van	uw kenmerk	ons kenmerk	bijlagen	datum
		FAGG/DGPRE/R&D/[redacted]		22.04.2024

Dossier GMO: B/BE/23/BVW3 (2024-511194-29-00): A Phase I, randomized, double-blind, multi-centre, placebo-controlled, dose-escalation study to evaluate the safety, reactogenicity and immunogenicity of AstriVax' investigational vaccine for the prevention of yellow fever (AVX70120), and of AstriVax' investigational vaccine for the prevention of rabies (AVX70481), in healthy adults aged 18 to 40 years

Geachte [redacted]

Wij informeren u dat uw vergunningsaanvraag werd goedgekeurd.

De vergunning is conform het koninklijk besluit van 21 februari 2005 tot reglementering van de doelbewuste introductie in het leefmilieu evenals van het in de handel brengen van genetisch gemodificeerde organismen of van producten die er bevatten.
(http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=nl&la=N&cn=2005022131&table_name=wet)

Uw vergunning wordt verleend op basis van het gunstig advies van de Adviesraad voor Bioveiligheid van 28 maart 2024, onder de voorwaarden die in de conclusie van bovengenoemd advies zijn vermeld, namelijk:

"*Based on the scientific assessment of the notification made by the Belgian experts, the Biosafety Advisory Council concludes that it is unlikely that PLLAV-YF17D/RabG developed as vaccine against rabies, will have any adverse effects on human health 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 AVX1248-101_Model ICF_ENG_v0.3_clean*
  - *o AVX1248-101_Protocol_v1.0*
  - *o AVX1248-101_Instruction sheet for study personnel_final (adapted as requested below)*
  - *o LAV-YF17D_RabG_CAF_Public_Version 2.0_clean*
  - *o LAV-YF17D_RabG_CAF_Confidential_Version 2.0_clean*
  - *o LAV-YF17D_RabG _SNIF*

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

- *As committed by the notifier, if new information from the current GLP non-clinial study evaluating the shedding of the PLLAV-YF17D/RabG-derived LAVs in hamsters that may impact the risks related to the deliberate release of LAV-YF17D/RabG comes to light, the notifier will inform the competent authority, for the attention of the BAC, and will take the necessary measures to protect health and the environment.*

- *As committed by the notifier, if new information from the current GLP repeated dose toxicity study with PLLAV-YF17D and PLLAV-YF17D/RabG that may impact the risks related to the deliberate release of LAV-YF17D/RabG comes to light, the notifier will inform the competent authority, for the attention of the BAC, and will take the necessary measures to protect health and the environment.*

- *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:*

    - *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 PLLAV-YF17D/RabG."*

Hoogachtend,

Frank Vandenbroucke
Vice-eersteminister en
minister van Volksgezondheid
en Sociale Zaken

Zakia Khattabi
Minister van Klimaat,
Leefmilieu, Duurzame
Ontwikkeling en Green Deal