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

www.fagg.be

DG PRE vergunning/afdeling Onderzoek en Ontwikkeling

[redacted]

PERSEUS BV
[redacted]

uw bericht van	uw kenmerk	ons kenmerk	bijlagen	datum
		FAGG/DGPRE/R&D/[redacted]		09.01.2026

Dossier GMO: B/BE/25/BVW6: A phase 1, placebo-controlled, randomised, participant- and assessor-blind, single-centre study to assess the safety and immunogenicity of 2 dosages of Nipah measles vector vaccine (MV-NiV) administered subcutaneously either a single dose or as 2 consecutive doses at 4 week interval, in healthy non-exposed volunteers, aged 18-40 years

[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 4 december 2025, 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 MV-NiV developed as vaccine against Nipah virus 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*
- *o SNIF*
- *o CAF Amend 251120*

- As commited by the applicant, some documents still need to be updated as follows in the next amendment opportunity:
- *o On top of the good hygiene recommendations described in Appendix A to the ICF, the appendix will be completed with a reminder to participants to closely follow applicable instructions related to contact with vulnerable populations, use of contraception, and tissue/organ/fluid donations, with cross-references to the relevant sections of the ICF.*

o The last sentence of Section 2.3.1.4 of the protocol will be amended as follows: "Nonclinical data for MV-NiV did not provide any evidence for excretion of vaccine virus, although potential shedding cannot be completely excluded at this stage of development".
o The protocol (and other impacted documents) will be updated by adding an additional sampling timepoint on day 28 following each vaccine administration (i.e. D28 and D56 of the study), where participants will be sampled for blood to assess viraemia and nasopharyngeal swab to assess shedding.
o Figure 12 of the IB will be amended to display vaccinated hamsters as "zero" (below the LOD of the NiV-M RT-qPCR assay).

- 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 MV-NiV."

Hoogachtend,

Frank Vandenbroucke
Vice-eersteminister en
minister van Sociale Zaken en
Volksgezondheid, belast met
Armoedebestrijding

Jean-Luc Crucke
Minister van Mobiliteit,
Klimaat en Ecologische
Transitie