Agence fédérale des médicaments et des produits de santé
Avenue Galilée 5/03
1210 BRUXELLES

www.afmps.be

DG PRE autorisation/division Recherche et Développement

[redacted]

AbbVie
[redacted]

Votre lettre du	Vos références	Nos références	Annexe(s)	Date
		[redacted]		22/01/2026

Dossier OGM : B/BE/25/BVW7 (2024-512298-28-00): M24-528: A Randomized, Controlled, Partially Masked, Phase 3b Study to Assess the Injection Burden, Efficacy, Safety, and Long-Term Preservation of Visual Acuity of Surabgene Lomparvovec (ABBV-RGX-314) in a Real-World Context in Subjects with Neovascular Age-Related Macular Degeneration (nAMD)

[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 9 janvier 2026, 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 ABBV-RGX-314 developed to treat patients with Neovascular Age-Related Macular Degeneration (nAMD), by means of endogenous production of anti-VEGF antigen binding fragment (Fab) 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*
- *o SNIF v2.1*
- *o CAF_v1.2_non confidential*
- *o CAF_confidential*
- *o M24-528 – Investigative Site Pharmacy Manual_v3.0*

- As commited by the applicant, some documents still need to be updated as follows in the next amendment opportunity:
- *o IB (Investigator Brochure) section 11.3 : since shedding has only been assessed in a very limited number of bodily fluids (serum and urine), the statement "short-term shedding is not likely to have clinical relevance" is incorrect and should be updated to clearly state that this is true only for the tested samples.*

o IB page 71 : as the term "infect" refers to viruses, it is not appropriate to use it when describing the activity of viral vectors. The term "transduce" should be used instead. Therefore, the following sentence should be corrected accordingly : "release of vectors that did not infect the target cells".
o ICF for Belgium will be implemented with details about care instructions related to preventing dissemination of study product as mentioned in the Agency response to second and third RFI from Belgium (28 november 2025 and 30 december 2025). Furthermore, to limit potential environmental spread, patients should be advised to dispose of waste material arising from dressings, tears and nasal secretions in sealed bags prior to disposal. Disposal will be performed in accordance with site-specific instructions. These handling precautions should be followed for 14 days following ABBV-RGX-314 administration.
o Protocol and ICF will be updated by clarifying that 'The long-term safety of recombinant AAV gene therapies including Sura-Vec remains uncertain. Therefore, a lifelong restriction on donating blood, organs, or cells for transplantation is recommended'

- 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 ABBV-RGX-314."

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