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uw bericht van	uw kenmerk	ons kenmerk	bijlagen	datum
		FAGG/DGPRE/R&D/[redacted]		10.07.2023

Dossier GMO: B/BE/23/BVW2 (2022-500746-16-00): A Phase 2b, Randomized, Double-masked, Multicenter, Dose-ranging, Sham-controlled Clinical Trial to Evaluate Intravitreal JNJ-81201887 (AAVCAGsCD59) Compared to Sham Procedure for the Treatment of Geographic Atrophy (GA) Secondary to Age-related Macular Degeneration (AMD)

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 15 juni 2023, 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 AAVCAGsCD59, which is developed as an ocular gene therapy approach for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration, will have 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 as described in the following updated documents (and for some still to be adapted in accordance with the conditions stipulated below):

- *SNIF v6.0*
- *EU_CAF v2.0 (to be adapted in accordance with condition 4 stipulated below)*
- *EU_CAF confidential v2.0*
- *Safety statement AAV v2.0*
- *Take Home summary_v2.0*
- *Protocol version_Amendment 3*

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

"1. The notifier and the investigators must strictly apply the clinical trial protocol and the safety instructions as described in the dossier and the updated documents listed here above.

2. The notifier makes sure patients are well informed about the precautionary measures to be applied for preventing contamination via tears, saliva, sputum, or cough for 14 days post-injection. Patients should be informed before the start of the treatment and these measures must be recalled during the first visit after the treatment.

3. The notifier takes due account of its commitment to reinforce if necessary the precautionary measures according to the shedding results obtained from this study and the study 81201887MDG2001.

4. In the CAF document page 18/21, prohibition to donate blood, organs, tissues and cells for 12 weeks after intravitreal injection should be reported.

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

6. 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 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.

7. The BAC should be informed within two weeks when the first patient starts the treatment and the last patient receives the last treatment.

8. 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:

a. The total number of patients included in the trial and the number of patients included in Belgium;

b. A summary of all adverse events marked by the investigators as probably or definitely related to the study medication;

c. A report on the accidental releases, if any, of AAVCAGsCD59."

Hoogachtend,

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

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