

DG PRE/Division R&D/CTR



Votre lettre du	Vos références	Nos références	Annexe(s)	Date
				30/05/2026

Dossier OGM B/BE/25/BVW8 (2025-522949-22-00): A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Investigate the Efficacy of a Single Intravenous Dose of SGT-003 in Ambulant Males With Duchenne Muscular Dystrophy



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_lq.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 12 mai 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 SGT-003 developed to treat patients with Duchenne muscular dystrophy (DMD), by means of endogenous production of a human 5-repeat microdystrophin (h- μ D5), 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 BE v3
 - o Public CAF_BE v3
 - o CAF_BE v3
 - o SGT-003-301 Handling Procedures for Medical Personnel Instruction Sheet v2.0
 - o SGT-003-301 BEL_Hygiene and Precautions guidance v2
 - o SGT-003-301 Handling Procedures_v3.0 adapted as requested here below
- Any protocol amendment has to be previously approved by the Competent Authority.
- The Handling procedure document should be updated as follows and provided as soon as possible:
 - o Page 2 : Procedures to be applied in case of accidental exposure e.g., needlestick injury, skin, eye exposure or blood, urine, vomit or other bodily fluids from patients in the initial period after

administration of the IMP are currently unclear and inconsistently presented. Guidance for each type of exposure should be clearly defined and addressed separately.

o Alcohol is still recommended as disinfectant several times in the document : "Disinfect exposed skin with alcohol gel" ; "Apply disinfectant (0.5% [5000 ppm] sodium hypochlorite, or hydrogen peroxide/alcohol based disinfectant), followed by alcohol wipes". However as demonstrated by Korten et al. (2021)³, alcohol-based disinfectants are not suitable for eliminating AVV in cases of laboratory surface disinfection, needle stick injury or contamination of intact skin. Alcohol-based treatments (e.g. alcohol gel and alcohol wipes) must be removed and other alternative disinfection treatments for cases of laboratory surface disinfection after accidental spills and for needle sticks or contamination of intact skin must be reported.

- 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 after the first patient starts the treatment and the last patient receives the last treatment.

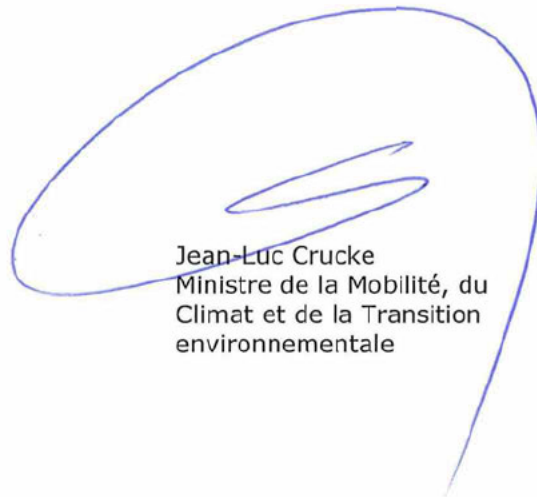
- At the latest six months after the last visit of the last patient included in the trial, the notifier must send to the competent authority at the attention of the Biosafety Advisory Council a report with details concerning the biosafety aspects of the project. This report will contain as a minimum:

- o The total number of patients enrolled in the trial and the number of patients from Belgium;
- o A summary of all adverse events documented by the investigators as likely or definitely related to the study medication;
- o A report on accidental releases, if any, of SGT-003.

Veillez agréer mes salutations distinguées,



Frank Vandembroucke
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