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Votre lettre du	Vos références	Nos références	Annexe(s)	Date
		AFMPS/DGPRE/R&D/VDC		

Dossier OGM: B/BE/20/BVW3 (2020-000505-80): A phase I/IIa study of intra-tumoral BT-001 (TG6030) administered alone and in combination with pembrolizumab in patients with cutaneous or, subcutaneous lesions or easily injectable lymph nodes of metastatic/advanced solid tumors

Cher Monsieur [redacted],

Par la présente, nous vous informons que l'autorisation imposée en vertu de l'arrêté royal du 21 février 2005 règlementant la dissémination volontaire dans l'environnement ainsi que la mise sur le marché d'organismes génétiquement modifiés ou de produits en contenant vous est accordée sur base de l'avis favorable du Conseil de Biosécurité daté du 20 octobre 2020, et ce, aux conditions reprises dans la conclusion de l'avis précité, c'est-à-dire:

"- *The notifier and the investigators must strictly apply the clinical trial protocol, and all the safety instructions as described in the revised documents implementing the remarks addressed by the Biosafety Advisory Council.*

- *The notifier takes due account of the possibility to collect shedding data in forthcoming clinical trials using the recombinant Vaccinia virus vector.*

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

- *The notifier is responsible to verify that each study center 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 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 BT-001."

Sincères salutations,

Frank Vandenbroucke
Vice-Premier Ministre et
Ministre de la Santé publique
et des Affaires sociales

Zakia Khattabi
Ministre du Climat, de
l'Environnement, du
Développement durable et du
Green Deal