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

Dossier OGM: B/BE/20/BVW5 (2019-004759-35): An Open-Label, Multicenter, Non-Randomized, Dose-Confirmation and Cohort-Expansion Phase 1b Study to Evaluate the Safety, Tolerability, and Anti-Tumor Activity of Nous-PEV, with Pembrolizumab, in Patients with Unresectable Stage III / IV Cutaneous Melanoma and with Stage IV NSCLC (PDL1≥ 50%)

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 11 février 2021, 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 the safety instructions as described in the amended documents*
o Pharmacy manual v3.0 dated 18 January 2021 - the notifier may consider to adapt the instructions so as to avoid recapping of needle of the syringes that are prepared in the pharmacy prior administration of Nous-PEV
o Common application form for GAd-PEV and MVA-PEV
o Summary Notification Information Format (SNIF) Gad-PEV and MVA-PEV
o IB, version3.0, dated 21 Jan 2021
o Proposal for public information dd18 Jan 2021

– 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 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.

– The BAC 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 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:
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;

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