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

Dossier OGM: B/BE/20/BVW4 (2019-002921-31): A PHASE 3, MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY TO EVALUATE THE SAFETY AND EFFICACY OF PF-06939926 FOR THE TREATMENT OF DUCHENNE MUSCULAR DYSTROPHY

Chère [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 5 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 dossier and the updated and new documents listed here above.*

– *The notifier takes due account of its commitment to report shedding data obtained from the planned clinical trials in view of any further step in the clinical development of PF-06939926.*

– *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;

o A report on the accidental releases, if any, of PF-06939926.

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