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Research and Development/Unmet Medical Need

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Your letter from	Your reference	Our reference	Annex	Date
		FAGG/R&D/UMN	1	

Onderwerp Goedkeuring van een programma voor gebruik in schrijnende gevallen op 20/04/2020

Titre de l'objet Approbation d'un programme d'usage compassionnel le 20/04/2020

Subject Authorisation of a compassionate use program dated 20/04/2020

Medicinal product : Xospata (gilteritinib)® (40 mg, Tablets)
Indication : adult patients with FMS-like Tyrosine Kinase 3 (FLT3) Mutated Relapsed or Refractory Acute Myeloid Leukemia (AML) or with FLT3-Mutated AML in Complete Remission (CR) with Minimal Residual Disease (MRD)
Modification: Updated IB (Summary of Data and Guidance for the Investigator and Update RSI) and IMPD leading to update of protocol and ICF
Ethics Committee designated: UCL St. Luc
Reference: CUP-201801a2

Pharmacovigilance report cut-off date: 20/10/2020
Pharmacovigilance report deadline submission: 20/11/2020

Chère Madame, Cher Monsieur,

Conformément à l'article 6quater de la loi du 25 mars 1964, relative aux médicaments, j'ai décidé d'autoriser le programme ci-dessus mentionné selon les conditions précisées dans l'annexe I.

Salutations sincères,

Pour la Ministre des Affaires sociales et de la Santé publique

Geachte Mevrouw, Geachte Heer,

In overeenstemming met artikel 6quater van de wet van 25 maart 1964 inzake geneesmiddelen, heb ik besloten het hierboven vermelde programma goed te keuren onder de voorwaarden zoals gepreciseerd in de bijlage I.

Met de meeste hoogachting,

Voor de Minister van Sociale Zaken en Volksgezondheid

Dr. Greet Musch
Unofficial translation

In accordance with article 6quater of the Law of 25 March 1964 concerning medicinal products, I have decided to authorise the above mentioned compassionate use program following the conditions stated in annex I.