Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten
Agence fédérale des médicaments et des produits de santé
Galileelaan - Avenue Galilée 5/03
1210 BRUSSEL – BRUXELLES

Research and Development/Unmet Medical Need

DG PRE/R&D/UMN

Tel. : +32 (0)2 528 40 00
Fax : +32 (0)2 524 80 01
e-mail : umn@fagg-afmps.be

Janssen-Cilag NV
Antwerpseweg 15-17
2340 Beerse

Your letter from	Your reference	Our reference	Annex	Date
		FAGG/R&D/UMN	1	Cfr. digital signature

Onderwerp Goedkeuring van een programma voor gebruik in schrijnende gevallen op 12/08/2022

Titre de l'objet Approbation d'un programme d'usage compassionnel le 12/08/2022

Subject Authorisation of a compassionate use program dated 12/08/2022

Medicinal product : teclistamab (10 and 90 mg/ml, solution for injection)
Indication : monotherapy, for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least three prior lines of therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody and who have exhausted all commercially approved and clinically appropriate treatment options, are ineligible for a clinical trial and have evidence of disease progression after the last therapy
Ethics Committee designated: Universitaire Ziekenhuizen K.U.L.
Reference: CUP-202214

Pharmacovigilance report cut-off date: 12/08/2023
Pharmacovigilance report deadline submission: 12/09/2023

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,

Hugues Malonne
Directeur général – DG PRE Autorisation
Délégué du Ministre 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,

Hugues Malonne
Directeur-generaal – DG PRE Vergunning
Afgevaardigde van de Minister van Volksgezondheid

afmps fagg

Digitally signed by: Hugues Malonne (Signature)
DN: CN = Hugues Malonne (Signature) C = BE
Date: 2022.08.31 09:06:53 +02'00'

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.