

Research and Development/Unmet Medical Need

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Your letter from	Your reference	Our reference FAGG/R&D/UMN	Annex 1	Date Cfr. digital signature
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Onderwerp Goedkeuring van een programma voor gebruik in schrijnende gevallen op 5/10/2023

Titre de l'objet Approbation d'un programme d'usage compassionnel le 5/10/2023
Subject Authorisation of a compassionate use program dated 5/10/2023

Medicinal product : Talquetamab (3 mg (2 mg/ml) and 40 mg (40 mg/ml), solution for injection)

Indication : As monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least 3 prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy

Ethics Committee designated: Universitaire Ziekenhuizen K.U.L.

Reference: CUP-202308

Pharmacovigilance report cut-off date: 5/10/2024

Pharmacovigilance report deadline submission: 5/11/2024

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
Administrateur général
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
Administrateur-generaal
Afgvaardigde van de Minister van
Volksgezondheid

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.