

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

*Clinigen Healthcare Limited, on behalf of Incyte
Biosciences International Sarl
Idis House, Churchfield Road
KT13 8DB
Weybridge UK*

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

Onderwerp
Titre de l'objet
Subject

Opzetten van een medisch noodprogramma op 23/07/2025
Mise sur pied d'un programme médical d'urgence le 23/07/2025
Set up of a medical need program dated 23/07/2025

Medicinal product : Zynyz(retifanlimab) (25mg/ml, concentrate for solution for infusion)
Indication : in combination with carboplatin and paclitaxel for the first-line treatment of adult patients with metastatic or with inoperable locally recurrent Squamous Carcinoma of the Anal Canal (SCAC)
Ethics Committee designated: Universitair Ziekenhuis Gent
Reference: MNP-202510

Pharmacovigilance report cut-off date: 23/01/2026
Pharmacovigilance report deadline submission: 23/02/2026

Chère Madame, Cher Monsieur,

Conformément à l'article 6quater de la loi du 25 mars 1964, relative aux médicaments, j'ai décidé de mettre sur pied 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 op te zetten onder de voorwaarden zoals gepreciseerd in de bijlage I.

Met de meeste hoogachting,

Hugues Malonne
Administrateur-generaal
Afgevaardigde 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 set up the above mentioned medical need program following the conditions stated in annex I.

Company registration number: BE 0884 579 424

1 | 1