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Your letter from	Your reference	Annex	Date
		1	Cfr. digital signature

Onderwerp Goedkeuring van een programma voor gebruik in schrijnende gevallen op 19/06/2026

Titre de l'objet Approbation d'un programme d'usage compassionnel le 19/06/2026

Subject Authorisation of a compassionate use program dated 19/06/2026

Medicinal product : Zepzelca(lurbinectedin) (3.2 mg/m2 body surface area, administered as an intravenous infusion over 1 hour, Powder for concentrate for solution for infusion)
Indication : Zepzelca® (lurbinectedin) in combination with atezolizumab (Tecentriq®) for the maintenance treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC) whose disease has not progressed following first-line induction therapy with atezolizumab, carboplatin, and etoposide.
Ethics Committee designated: Universitaire Ziekenhuizen K.U.L.
Reference: CUP-202607

Pharmacovigilance report cut-off date: 19/06/207
Pharmacovigilance report deadline submission: 19/07/2027

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,

Jamila Hamdani
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,

Jamila Hamdani
Directeur-generaal DG PRE Vergunning
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 authorise the above mentioned compassionate use program following the conditions stated in annex I.