Voydeya

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification[1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
PSUSA/11056 /202407	Periodic Safety Update EU Single assessment - danicopan	13/02/2025	n/a		PRAC Recommendation - maintenance
II/0004/G	This was an application for a group of variations. A grouped application comprised of two Type II	23/01/2025		SmPC and PL	SmPC new text Section 4.8: • ADR Frequency changes: pyrexia 28.10%, from

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

	variations, as follows: C.I.4: Update of sections 4.8 and 5.1 of the SmPC in order to update the list of adverse drug reactions and update clinical efficacy and safety information, based on final results from study ALXN2040-PNH-301; this is a Phase 3 Study of Danicopan (ALXN2040) as Add-on Therapy to a C5 Inhibitor (Eculizumab or Ravulizumab) in patients with Paroxysmal Nocturnal Hemoglobinuria who have clinically evident Extravascular Hemolysis (EVH). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet to bring it in line with the latest QRD template version. C.I.13: Submission of the final report from study ACH471-101; this is a multicenter, open-label, multiple dose Phase 2 study to assess efficacy, safety, and tolerability of add-on danicopan to background eculizumab therapy in adult participants with PNH. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority				25,0%; headache to 25.0% from 19.8%; "Pain in extremity", from very common to common in Table 1. Section 5.1, • An update is provided for efficacy results up to 72 weeks with 80 patients entering LTE including 38 patients receiving danicopan (previously 16) and a mean change of Hgb from baseline to week 72 equal to 2.81 g/dL (previously 2.99 g/dL). Efficacy results up to Week 72 remain consistent with those at Week 12 and Week 24 For more information, please refer to the Summary of Product Characteristics.
IB/0002	B.I.b.z - Change in control of the AS - Other variation	03/12/2024	n/a		

IAIN/0001	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	20/09/2024	n/a		