BESPONSA

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
II/0026	Update of sections 4.2, 4.6, 4.8, 5.1 and 5.2 of the SmPC in order to update paediatric information based on final results from studies ITCC-059 (WI203581) and INO-Ped-ALL-1 (WI235086). Study WI203581 is a Phase 1/2, multicenter, European, multi-cohort, open-label study in pediatric patients (≥1 and <18 years of age) with R/R CD22-positive Acute Lymphoblastic Leukemia (ALL); and study	14/12/2023		SmPC and PL	Please refer to Scientific Discussion Besponsa EMEA/H/C/004119/II/0026 and Besponsa EMEA/H/C/004119/P46/004.

[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).

	WI235086 is an open-label, multi-center Phase 1 study to assess safety and tolerability of InO in Japanese pediatric patients with R/R CD22-positive ALL. The Package Leaflet is updated accordingly. The MAH took also the opportunity to update the ATC code in section 5.1 and to implement some editorial changes in the PI. The RMP version 2.2 has also been submitted. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
PSUSA/10659 /202212	Periodic Safety Update EU Single assessment - inotuzumab ozogamicin	06/07/2023	n/a		PRAC Recommendation - maintenance
PSUSA/10659 /202112	Periodic Safety Update EU Single assessment - inotuzumab ozogamicin	07/07/2022	n/a		PRAC Recommendation - maintenance
R/0023	Renewal of the marketing authorisation.	16/12/2021	16/02/2022	SmPC, Annex II, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of BESPONSA in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
PSUSA/10659 /202012	Periodic Safety Update EU Single assessment - inotuzumab ozogamicin	08/07/2021	n/a		PRAC Recommendation - maintenance
IAIN/0022	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	31/05/2021	03/11/2021	Annex II and PL	

II/0020/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test method or a method using a biological reagent for a biological AS	06/05/2021	n/a		
IB/0019/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.I.a.1.k - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - New storage site of MCB and/or WCB C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	16/10/2020	03/11/2021	SmPC, Annex II, Labelling and PL	
PSUSA/10659 /201912	Periodic Safety Update EU Single assessment - inotuzumab ozogamicin	09/07/2020	n/a		PRAC Recommendation - maintenance
IB/0018	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	23/04/2020	n/a		
PSUSA/10659	Periodic Safety Update EU Single assessment -	16/01/2020	n/a		PRAC Recommendation - maintenance

/201906	inotuzumab ozogamicin				
IAIN/0016	B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	11/12/2019	23/07/2020	Annex II and PL	
IB/0014	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	26/11/2019	n/a		
IB/0013	B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits	20/11/2019	n/a		
N/0015	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	13/11/2019	23/07/2020	PL	
IB/0011	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	21/08/2019	23/07/2020	SmPC and PL	
PSUSA/10659 /201812	Periodic Safety Update EU Single assessment - inotuzumab ozogamicin	11/07/2019	n/a		PRAC Recommendation - maintenance
PSUSA/10659 /201806	Periodic Safety Update EU Single assessment - inotuzumab ozogamicin	17/01/2019	n/a		PRAC Recommendation - maintenance

IB/0008/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	05/10/2018	19/07/2019	SmPC, Annex II and PL	
T/0007	Transfer of Marketing Authorisation	11/07/2018	26/07/2018	SmPC, Labelling and PL	

II/0006	Update of sections 4.8, 5.1 and 5.2 of the SmPC based on the supplemental Clinical Study Report for the pivotal phase 3 Study B1931022 (Study 1022) that was prepared following last patient last visit. The Package Leaflet is updated accordingly. The MAH took the opportunity to make minor editorial changes for added clarity in sections 4.2, 4.4, 4.8, 5.1, 5.3 and 6.6 of the SmPC and Package Leaflet. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	26/07/2018	19/07/2019	SmPC and PL	The variation introduced minor amendments in both efficacy and safety results from the pivotal trial without impact on the recommendations for the use of the medicinal product. For more information please refer to the Summary of Product Characteristics.
PSUSA/10659 /201712	Periodic Safety Update EU Single assessment - inotuzumab ozogamicin	12/07/2018	n/a		PRAC Recommendation - maintenance
IB/0004	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	08/01/2018	n/a		
IB/0003	B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method	08/01/2018	n/a		
N/0002	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	05/12/2017	26/07/2018	PL	
IA/0001/G	This was an application for a group of variations.	30/10/2017	26/07/2018	Annex II	

	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)				