Bimzelx

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
IB/0022	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	09/11/2023		SmPC and PL	
PSUSA/10953 /202302	Periodic Safety Update EU Single assessment - bimekizumab	28/09/2023	n/a		PRAC Recommendation - maintenance

[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).

IB/0019	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	26/06/2023	n/a		
II/0011	Extension of indication to include treatment of active psoriatic arthritis in adults patients who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs (DMARDs) for Bimzelx, based on results of a Phase III study in biological DMARD naïve study participants (PA0010; BE OPTIMAL) and a Phase III study in study participants who are inadequate responders (inadequate response or intolerant) to ≤2 prior TNF inhibitors (PA0011; BE COMPLETE). Both Phase III studies are interventional studies aimed to evaluate the efficacy and safety of bimekizumab. For PA0010, the Initial Treatment Period was placebo- and no inferential active reference (adalimumab)-controlled, while PA0011 was placebo-controlled. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 to the SmPC have been updated. The Package leaflet is updated in accordance. The RMP version 1.7 is acceptable. Furthermore, the PI is brought in line with the latest QRD template version 10.2 rev.1. The variation leads to amendments to the Summary of Product Characteristics and Package Leaflet and to the Risk Management Plan (RMP). C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or	26/04/2023	05/06/2023	SmPC and PL	Please refer to Scientific Discussion 'Bimzelx-H-C-005316-II-Var.0011'.

	modification of an approved one				
II/0010	Extension of indication to include treatment of adults with active axial spondyloarthritis (axSpA), including non-radiographic axial spondyloarthritis (nr-axSpA) and ankylosing spondylitis (AS, radiographic axial spondyloarthritis), based on results from two interventional and controlled phase III clinical studies: AS0010 (BE MOBILE 1) and AS0011 (BE MOBILE 2), which provide evidence of the efficacy and safety of bimekizumab in axSpA (nr-axSpA and AS), both compared to placebo treatment. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package leaflet is updated in accordance. The RMP version 1.8 is acceptable. Furthermore, the PI is brought in line with the latest QRD template version 10.2 rev.1. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	26/04/2023	05/06/2023	SmPC and PL	Please refer to Scientific Discussion 'Bimzelx-H-C-005316-II-Var.0010'.
IA/0017/G	This was an application for a group of variations. B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	26/04/2023	n/a		

PSUSA/10953 /202208	Periodic Safety Update EU Single assessment - bimekizumab	16/03/2023	n/a		PRAC Recommendation - maintenance
IB/0016	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	15/03/2023	n/a		
IB/0015	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	09/01/2023	n/a		
IB/0013	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	05/12/2022	31/05/2023	SmPC and PL	
IB/0012	B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation	21/10/2022	n/a		
PSUSA/10953 /202202	Periodic Safety Update EU Single assessment - bimekizumab	29/09/2022	n/a		PRAC Recommendation - maintenance
IB/0009	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	25/08/2022	n/a		
IB/0006	B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	19/08/2022	n/a		
IB/0008/G	This was an application for a group of variations. B.I.a.1.f - Change in the manufacturer of AS or of a	29/07/2022	n/a		

	starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place				
IB/0007	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	27/06/2022	n/a		
II/0003/G	This was an application for a group of variations. B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.I.b.2.e - Change in test procedure for AS or	19/05/2022	31/05/2023	Annex II and Labelling	

	starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate B.I.c.1.b - Change in immediate packaging of the AS - Qualitative and/or quantitative composition for sterile and non-frozen biological/immunological ASs				
II/0002	Update of section 5.1 of the SmPC in order to update efficacy information based on interim results from study PS0015; this is a multicenter, randomized, double-blind, active comparator controlled, parallel group study to evaluate the efficacy and safety of bimekizumab compared with secukinumab in adult study participants with moderate to severe plaque psoriasis. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.2. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	24/03/2022	31/05/2023	SmPC, Annex II and PL	The efficacy and safety of bimekizumab was evaluated in a double-blind study compared with secukinumab, an IL-17A inhibitor. Bimekizumab-treated patients achieved significantly higher response rates compared to secukinumab. The results are consistent with the previous pivotal study results previously assessed and reported in the SmPC. For more information, please refer to the Summary of Product Characteristics.
II/0004	B.II.g.2 - Introduction of a post approval change management protocol related to the finished product	10/03/2022	n/a		

IB/0001	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	11/10/2021	n/a		