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
IA/0032	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	19/12/2024	n/a		
II/0028	Update of section 5.1 of the SmPC in order to update efficacy information based on the final results from	12/12/2024		SmPC and PL	At week 48, patients were allowed to enter a 96-week open label extension period (OLE) and started or continued with

[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).

	study PS0015 listed as a category 3 study in the RMP; this is a multicenter, randomised, double-blind, secukinumab-controlled, parallel-group study to evaluate the efficacy and safety of bimekizumab in adult subjects with moderate to severe chronic plaque psoriasis. In addition, the MAH has taken the opportunity to update the list of local representatives in the Package leaflet and align the PI with the latest QRD template version 10.4 as well as to update wording on polysorbates in the SmPC and the Package leaflet to align with the annex of the guideline related to excipients. The RMP version 3 is acceptable. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				bimekizumab 320 mg Q4W or 320 mg Q8W depending on their PASI 90 responder status at week 48. Study participants who initially received bimekizumab 320 mg Q4W during the OLE were switched to bimekizumab 320 mg Q8W at week 72 or later. Among the patients remaining in the study, improvements achieved with bimekizumab or secukinumab for the efficacy endpoints PASI 100, PASI 90, PASI 75 and PASI ≤2 responder at week 48 were maintained on treatment with bimekizumab 320 mg Q8W through an additional 96 weeks of open label treatment. The safety profile of bimekizumab up to week 144 was consistent with the safety profile observed up to 48 weeks. For more information, please refer to the Summary of Product Characteristics.
II/0029	Submission of the final report from study PS0014 (BE BRIGHT) listed as a category 3 study in the RMP. This is a multicenter, open-label extension (OLE) study to assess the long-term safety, tolerability, and efficacy of bimekizumab in adult study participants with moderate to severe plaque PSO who completed 1 of the 3 completed feeder studies. The RMP version 2.3 is considered acceptable. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	31/10/2024	n/a		

PSUSA/10953 /202402	Periodic Safety Update EU Single assessment - bimekizumab	03/10/2024	n/a		PRAC Recommendation - maintenance
IB/0030	B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	01/10/2024	n/a		
X/0021	Annex I_2.(c) Change or addition of a new strength/potency	30/05/2024	01/08/2024	SmPC, Labelling and PL	
IB/0027	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	17/05/2024	n/a		
II/0025	Update of section 5.1 of the SmPC in order to add long-term efficacy data based on the interim results (week 144 data) from study PS0014 listed as a category 3 study in the RMP; this is an ongoing, multicenter, open-label extension (OLE) study to assess the long-term safety, tolerability, and efficacy of bimekizumab in adult study participants with moderate to severe plaque PSO who completed 1 of the 3 completed feeder studies (PS0008, PS0009, and PS0013). C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	16/05/2024	01/08/2024	SmPC	Patients who completed one of the pivotal phase 3 studies ('feeder studies') could enter a 144-week open-label extension study (PS0014) to assess the long-term safety and efficacy of bimekizumab. 344 patients who were treated with bimekizumab 320 mg every 8 weeks (BKZ 320 mg Q8W) or every 4 weeks (BKZ 320 mg Q4W) during the feeder study, and who achieved PASI 90 at the end of the feeder study, received bimekizumab 320 mg Q8W throughout PS0014. Of these, 293 (85.2%) patients completed 144 weeks of treatment with bimekizumab 320 mg Q8W. 48 patients (14.0%) discontinued the study during the treatment period, of which 21 (6.1%) discontinued due to an adverse event and 4 (1.2%) discontinued due to lack of efficacy. Among the patients remaining in the study, improvements achieved with bimekizumab for the efficacy endpoints PASI 90 and IGA 0/1 in the feeder studies were maintained through an additional 144 weeks of open-label treatment.

					For more information, please refer to the Summary of Product Characteristics.
II/0020	Extension of indication to include treatment of moderate to severe hidradenitis suppurativa (HS) in adults, based on final results from study HS0003 (BE HEARD I) and study HS0004 (BE HEARD II). These are phase 3, randomised, double blind, placebo controlled, multicenter, pivotal studies evaluating the efficacy and safety of bimekizumab in study participants with moderate to severe HS. Further supportive data are based on the results of phase 2 study HS0001 and phase 3 currently ongoing open-label extension study HS0005. As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package leaflet is updated in accordance. RMP version 1.12 is acceptable. Furthermore, the PI is brought in line with the latest QRD template version 10.3. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	21/03/2024	19/04/2024	SmPC and PL	Please refer to Scientific Discussion 'Bimzelx-H-C-005316-II-Var.0020'.
PSUSA/10953 /202308	Periodic Safety Update EU Single assessment - bimekizumab	07/03/2024	n/a		PRAC Recommendation - maintenance
II/0023/G	This was an application for a group of variations. B.I.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch	14/12/2023	n/a		

	control/testing takes place and any of the test method at the site is a biol/immunol method B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method				
IB/0022	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	09/11/2023	19/04/2024	SmPC and PL	
PSUSA/10953 /202302	Periodic Safety Update EU Single assessment - bimekizumab	28/09/2023	n/a		PRAC Recommendation - maintenance
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-	26/04/2023	05/06/2023	SmPC and PL	Please refer to Scientific Discussion 'Bimzelx-H-C-005316-II-Var.0011'.

	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 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.	26/04/2023	05/06/2023	SmPC and PL	Please refer to Scientific Discussion 'Bimzelx-H-C-005316-II-Var.0010'.

	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
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 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	29/07/2022	n/a		
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	19/05/2022	31/05/2023	Annex II and Labelling	

	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 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	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

	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				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		