Ilumetri

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/0058	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	08/07/2024	n/a		
II/0055	B.IV.1.c - Change of a measuring or administration device - Addition or replacement of a device which is an integrated part of the primary packaging	13/06/2024		SmPC, Labelling and PL	The SmPC sections 1, 2, 4.2, 6.4, 6.5, 6.6 and 8 have been updated to include the new presentation Ilumetri 200 mg solution for injection in pre-filled pen (EU/1/18/1323/005). The Labelling and PL have been updated accordingly.

[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).

II/0054	Update of sections 4.8 and 5.1 of the SmPC in order to update the clinical and safety information based on long-term results from the extension periods of the pivotal clinical studies MK-3222-010 (A 64-Week, Phase 3, Randomized, Placebo-Controlled, Parallel Design Study to Evaluate the Efficacy and Safety/Tolerability of Subcutaneous Tildrakizumab (SCH 900222/MK-3222), followed by an Optional Long-Term Safety Extension Study, in Subjects with Moderate-to-Severe Chronic Plaque Psoriasis (Protocol No. MK-3222-010)) and MK-3222-011 (A 52-Week, Phase 3, Randomized, Active Comparator and Placebo-Controlled, Parallel Design Study to Evaluate the Efficacy and Safety/Tolerability of Subcutaneous Tildrakizumab (SCH 900222 / MK-3222), followed by an Optional Long-Term Safety Extension Study, in Subjects With Moderate-to-Severe Chronic Plaque Psoriasis). The Product information is also updated in accordance with the Annex of the excipients guideline. The RMP version 1.4 has also been submitted. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	16/05/2024		SmPC, Annex II, Labelling and PL	Eligible patients who completed the double-blind periods of reSURFACE 1(Study MK 3222-P010) and reSURFACE 2 (Study MK-3222-P011) with ≥ 50% improvement in PASI from baseline could participate in open-label extension phases of these studies in order to evaluate the long-term safety and maintenance of efficacy of continuous tildrakizumab treatment. Up to 6 years of follow-up data are available. Of the patients who completed the double-blind period, 506 (79%) in reSURFACE 1 and 730 (97%) in reSURFACE 2 entered the extension period. Across studies, at least 76% of patients who had a PASI 90 response at the end of double-blind period, maintained a PASI 90 response during the extension period, when tildrakizumab 100 mg or 200 mg treatment was continued during a period of 192 weeks. The development of neutralizing antibodies to tildrakizumab was associated with lower serum tildrakizumab concentrations. The safety profile of tildrakizumab observed during the long-term extensions periods of reSURFACE 1 and reSURFACE 2 was consistent with that of the double-blind periods. For more information, please refer to the Summary of Product Characteristics.
II/0052	B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	29/02/2024	n/a		
IAIN/0056	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging	27/02/2024	n/a		

	site				
IAIN/0053	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	09/11/2023	n/a		
PSUSA/10720 /202303	Periodic Safety Update EU Single assessment - tildrakizumab	26/10/2023	n/a		PRAC Recommendation - maintenance
IB/0049	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	29/08/2023	n/a		
IB/0051	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	24/08/2023	n/a		
IA/0050	A.7 - Administrative change - Deletion of manufacturing sites	09/08/2023		Annex II	
R/0042	Renewal of the marketing authorisation.	25/05/2023	24/07/2023	SmPC and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Ilumetri in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IA/0047/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites	10/05/2023	n/a		

	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)				
IB/0046/G	This was an application for a group of variations. B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation	21/04/2023	n/a		
PSUSA/10720 /202209	Periodic Safety Update EU Single assessment - tildrakizumab	14/04/2023	n/a		PRAC Recommendation - maintenance
IAIN/0045	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	06/03/2023	n/a		
IA/0044	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	13/02/2023	n/a		
IB/0043	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	31/01/2023	n/a		
II/0036	B.IV.1.c - Change of a measuring or administration device - Addition or replacement of a device which is an integrated part of the primary packaging	26/01/2023	24/07/2023	SmPC, Labelling and PL	The SmPC sections 1, 2, 4.2, 6.4, 6.5, 8, and Annex II has been updated as follows: inclusion of prefilled pen (EU/1/18/1323/004).

					The Labelling and PL have been updated accordingly.
IB/0040	B.II.z - Quality change - Finished product - Other variation	08/12/2022	n/a		
IB/0039	B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation	28/10/2022	n/a		
PSUSA/10720 /202203	Periodic Safety Update EU Single assessment - tildrakizumab	27/10/2022	n/a		PRAC Recommendation - maintenance
IAIN/0038	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	13/10/2022	n/a		
N/0037	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	12/10/2022	24/07/2023	PL	
IA/0035	A.7 - Administrative change - Deletion of manufacturing sites	03/08/2022	n/a		
IB/0033	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	06/07/2022	n/a		
IB/0034	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	04/07/2022	n/a		
PSUSA/10720 /202109	Periodic Safety Update EU Single assessment - tildrakizumab	22/04/2022	20/06/2022		Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10720/202109.

IAIN/0031/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 B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	24/05/2022	n/a		
II/0029/G	This was an application for a group of variations. 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 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 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 control/testing takes place and any of the test method at the site is a biol/immunol method	19/05/2022	n/a		

X/0023	Extension application to introduce a new strength (200 mg solution for injection). Annex I_2.(c) Change or addition of a new strength/potency	24/02/2022	25/04/2022	SmPC, Labelling and PL	
IB/0030	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	19/04/2022	n/a		
IA/0026	B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation	19/11/2021	n/a		
IA/0025	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	02/11/2021	n/a		
PSUSA/10720 /202103	Periodic Safety Update EU Single assessment - tildrakizumab	28/10/2021	n/a		PRAC Recommendation - maintenance
IAIN/0024	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	02/07/2021	n/a		
IB/0019	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	02/06/2021	n/a		

IB/0021	B.I.z - Quality change - Active substance - Other variation	28/05/2021	n/a		
IAIN/0020	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	28/04/2021	05/07/2021	Annex II, Labelling and PL	
PSUSA/10720 /202009	Periodic Safety Update EU Single assessment - tildrakizumab	09/04/2021	n/a		PRAC Recommendation - maintenance
N/0018	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	08/02/2021	05/07/2021	PL	
IA/0016	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	06/11/2020	n/a		
IB/0015/G	This was an application for a group of variations. B.I.z - Quality change - Active substance - Other variation 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	03/11/2020	n/a		

PSUSA/10720 /202003	Periodic Safety Update EU Single assessment - tildrakizumab	01/10/2020	n/a		PRAC Recommendation - maintenance
II/0012/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 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.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.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method 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 control/testing takes place and any of the test method at the site is a biol/immunol method B.I.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS -	23/07/2020	05/07/2021	Annex II	

	Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method 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 control/testing takes place and any of the test method at the site is a biol/immunol method 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 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 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.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.3.z - Change in the manufacturing process of				

	the finished or intermediate product - Other variation 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/0014/G	This was an application for a group of variations. B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place	22/07/2020	n/a		
PSUSA/10720 /201909	Periodic Safety Update EU Single assessment - tildrakizumab	17/04/2020	n/a		PRAC Recommendation - maintenance
II/0010/G	This was an application for a group of variations. B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial change to or replacement of a	20/02/2020	n/a		

	biological/immunological/immunochemical test method or a method using a biological reagent for a biological AS				
PSUSA/10720 /201903	Periodic Safety Update EU Single assessment - tildrakizumab	03/10/2019	n/a		PRAC Recommendation - maintenance
IB/0009/G	This was an application for a group of variations. B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place	06/09/2019	n/a		
II/0005/G	This was an application for a group of variations. B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes	27/06/2019	n/a		

	B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes 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 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 B.II.d.2.c - Change in test procedure for the finished product - Substantial change to or replacement of a biol/immunol/immunochemical test method or a method using a biol. reagent or replacement of a biol. reference preparation not covered by an approved protocol B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)				
IA/0008/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name	25/06/2019	n/a		

	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)				
IAIN/0006	B.II.e.6.a - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that affects the product information	31/05/2019	04/05/2020	SmPC, Labelling and PL	
PSUSA/10720 /201809	Periodic Safety Update EU Single assessment - tildrakizumab	11/04/2019	n/a		PRAC Recommendation - maintenance
N/0004	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	21/03/2019	04/05/2020	PL	
IAIN/0002	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	23/11/2018	n/a		
IB/0001/G	This was an application for a group of variations. B.I.z - Quality change - Active substance - Other variation B.II.z - Quality change - Finished product - Other variation	23/11/2018	n/a		