Cinqaero

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
N/0040	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	08/10/2021		PL	
PSUSA/10523 /202102	Periodic Safety Update EU Single assessment - reslizumab	30/09/2021	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).

R/0038	Renewal of the marketing authorisation.	25/03/2021	01/06/2021	SmPC and PL	
II/0037/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.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	19/11/2020	n/a		
PSUSA/10523 /202002	Periodic Safety Update EU Single assessment - reslizumab	01/10/2020	n/a		PRAC Recommendation - maintenance
IB/0036	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	17/09/2020	n/a		
IB/0035	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	01/09/2020	n/a		
IB/0034	B.III.2.a.2 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/AS starting material	21/07/2020	n/a		
IB/0033	B.I.a.2.a - Changes in the manufacturing process of	13/07/2020	n/a		

	the AS - Minor change in the manufacturing process of the AS				
IA/0032	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	25/05/2020	n/a		
IB/0030/G	This was an application for a group of variations. B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of	21/04/2020	n/a		

	specification limits B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits				
IA/0029	B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits	26/03/2020	n/a		
IB/0028/G	This was an application for a group of variations. 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.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	11/03/2020	n/a		
IA/0027	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	22/11/2019	05/11/2020	SmPC, Annex II and PL	
PSUSA/10523 /201902	Periodic Safety Update EU Single assessment - reslizumab	05/09/2019	n/a		PRAC Recommendation - maintenance
IB/0025	B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement	16/04/2019	n/a		

	or addition) for the AS or a starting material/intermediate				
IA/0024	B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits	29/03/2019	n/a		
PSUSA/10523 /201808	Periodic Safety Update EU Single assessment - reslizumab	14/03/2019	n/a		PRAC Recommendation - maintenance
IAIN/0023	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	10/01/2019	10/12/2019	Annex II and PL	
IB/0022/G	This was an application for a group of variations. B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits	09/01/2019	n/a		
N/0021	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	15/11/2018	10/12/2019	PL	
IAIN/0019/G	This was an application for a group of variations.	19/10/2018	n/a		

	A.7 - Administrative change - Deletion of manufacturing sites B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site 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				
T/0018	Transfer of Marketing Authorisation	30/08/2018	20/09/2018	SmPC, Labelling and PL	
IB/0017	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	20/09/2018	n/a		
PSUSA/10523 /201802	Periodic Safety Update EU Single assessment - reslizumab	06/09/2018	n/a		PRAC Recommendation - maintenance
PSUSA/10523 /201708	Periodic Safety Update EU Single assessment - reslizumab	08/03/2018	n/a		PRAC Recommendation - maintenance
IB/0015/G	This was an application for a group of variations. B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished	14/12/2017	20/09/2018	SmPC, Labelling and PL	

	product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes				
IB/0014	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	05/12/2017	n/a		
IB/0012	B.I.b.z - Change in control of the AS - Other variation	04/10/2017	n/a		
PSUSA/10523 /201702	Periodic Safety Update EU Single assessment - reslizumab	28/09/2017	n/a		PRAC Recommendation - maintenance
II/0005/G	This was an application for a group of variations. Update of section 4.2 of the SmPC in order to include a revised dosing regimen as a result of the new 25mg vial presentation in section 2. Consequential B.II.e.5c variation to change the pack size of the finished product and update sections 6.5 and 6.6 of the SmPC. The Annex II, Package Leaflet, Labelling and Risk Management Plan v. 2.3 are updated accordingly. B.II.e.5.c - Change in pack size of the finished product - Change in the fill weight/fill volume of sterile multidose (or single-dose, partial use) parenteral medicinal products, including biological/immunological medicinal products	23/03/2017	28/04/2017	SmPC, Annex II, Labelling and PL	The Marketing Authorisation Holder has introduced a 25 mg presentation (2.5 ml fill/10 mg/mL). This presentation of reslizumab supports a vial based dosing regimen. CINQAERO is given as intravenous infusion once every four weeks. The recommended dose is based on patient body weight and should only be adjusted for significant changes in body weight.For patients below 35 kg or above 199 kg: the recommended dose is 3 mg/kg body weight. The volume (in mL) required from the vial(s) should be calculated as follows: 0.3 x patient body weight (in kg). For patients between 35 kg and 199 kg: the recommended dose is achieved using the vial based dosing scheme (please refer to Table 1 in section 4.2 of the SmPC.

	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
IB/0009/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.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition of a new in-process test and limits B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation	11/04/2017	n/a		
IAIN/0010	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	07/04/2017	n/a		
IB/0008	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	07/03/2017	n/a		
IB/0007	B.II.b.4.z - Change in the batch size (including batch size ranges) of the finished product - Other variation	01/02/2017	n/a		
IB/0004	B.II.d.2.d - Change in test procedure for the finished	05/12/2016	n/a		

	product - Other changes to a test procedure (including replacement or addition)				
IB/0006/G	This was an application for a group of variations. B.I.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition of a new in-process test and limits B.I.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition of a new in-process test and limits	30/11/2016	n/a		
IA/0003	A.7 - Administrative change - Deletion of manufacturing sites	27/10/2016	n/a		
IAIN/0001/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites 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.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	20/09/2016	n/a		