EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ELZONRIS

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/0022	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	10/03/2023		PL	
PSUSA/10896 /202207	Periodic Safety Update EU Single assessment - tagraxofusp	09/02/2023	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).

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

IB/0019/G	This was an application for a group of variations. 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.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - 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.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation	19/01/2023	n/a		
IB/0018	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	24/11/2022	n/a		
IA/0017	A.7 - Administrative change - Deletion of manufacturing sites	22/09/2022		Annex II and PL	
PSUSA/10896 /202201	Periodic Safety Update EU Single assessment - tagraxofusp	01/09/2022	n/a		PRAC Recommendation - maintenance
IAIN/0015	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	13/07/2022	14/10/2022	Annex II and PL	

II/0009	Update of section 4.4 and 5.3 of the SmPC to reflect safety information from the final report from study 20255431 (CRL-263114) 'Characterization of fixed choroid plexus samples from primate study MPI-2231-007 by Immunohistochemistry with DT, CD123, IL-3 and IgG' (MEA002) listed as a category 3 study in the RMP. This is a non-interventional, post-authorisation study on blood brain barrier (BBB) models in order to determine a potential toxicity biomarker to further investigate the risk of choroid plexus lesions. The updated RMP version 2.2 has also been submitted. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	23/06/2022	14/10/2022	SmPC	SmPC new text: Choroid plexitis was identified during non-clinical studies (see section 5.3). While not observed in clinical studies, if clinical symptoms or signs suggestive of central nervous system (CNS) damage occur, full clinical and neuro-imaging examination, including fundoscopy and brain magnetic resonance imaging, is recommended. For more information, please refer to the Summary of Product Characteristics.
S/0012	1st annual re-assessment	22/04/2022	n/a		The CHMP, having reviewed the evidence of compliance with the specific obligations and the impact of the data submitted by the MAH on the benefit/risk profile of the medicinal product, concluded that marketing authorisation of ELZONRIS should be maintained.
IA/0014/G	This was an application for a group of variations. B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation	08/04/2022	n/a		

	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure				
PSUSA/10896 /202107	Periodic Safety Update EU Single assessment - tagraxofusp	10/02/2022	n/a		PRAC Recommendation - maintenance
IB/0011	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	04/01/2022	14/10/2022	SmPC	
IAIN/0010	A.1 - Administrative change - Change in the name and/or address of the MAH	17/12/2021	14/10/2022	SmPC, Labelling and PL	
IB/0005	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	29/10/2021	n/a		
IB/0007/G	This was an application for a group of variations. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	15/10/2021	14/10/2022	SmPC	
IB/0004/G	This was an application for a group of variations. B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation B.II.d.2.z - Change in test procedure for the finished product - Other variation	01/10/2021	n/a		

IB/0002	B.II.d.2.z - Change in test procedure for the finished product - Other variation	17/09/2021	n/a		
IB/0006	B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation	07/09/2021	n/a		
IA/0003	B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	16/07/2021	n/a		
IA/0001/G	This was an application for a group of variations. B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure 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.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	02/06/2021	n/a		

	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure 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.c.2.a - Change in test procedure for an excipient - 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 B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure A.7 - Administrative change - Deletion of manufacturing sites				