EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Zalmoxis

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/0011	B.II.d.2.z - Change in test procedure for the finished product - Other variation	03/08/2018	n/a		
II/0009/G	This was an application for a group of variations. B.II.b.1.d - Replacement or addition of a manufacturing site for the FP - Site which requires an initial or product specific inspection B.II.b.2.c.3 - Change to importer, batch release	26/07/2018		Annex II and PL	

[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).

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	arrangements and quality control testing of the FP - Including batch control/testing for a biol/immunol product and any of the test methods is a biol/immunol/immunochemical method				
IB/0012	B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation	30/05/2018	n/a		
PSUSA/10530 /201708	Periodic Safety Update EU Single assessment - allogeneic T cells genetically modified with a retroviral vector encoding for a truncated form of the human low affinity nerve growth factor receptor (ΔLNGFR) and the herpes simplex I virus thymidine kinase (HSV-TK Mut2)	08/03/2018	n/a		PRAC Recommendation - maintenance
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	01/03/2018	n/a		
II/0005/G	This was an application for a group of variations. B.II.b.3.c - Change in the manufacturing process of the finished or intermediate product - The product is a biological/immunological medicinal product and the change requires an assessment of comparability 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	25/01/2018	n/a		

	procedure				
PSUSA/10530 /201702	Periodic Safety Update EU Single assessment - allogeneic T cells genetically modified with a retroviral vector encoding for a truncated form of the human low affinity nerve growth factor receptor (ΔLNGFR) and the herpes simplex I virus thymidine kinase (HSV-TK Mut2)	28/09/2017	n/a		PRAC Recommendation - maintenance
R/0003	Renewal of the marketing authorisation.	18/05/2017	13/07/2017		The CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the positive benefit-risk balance, is of the opinion that the quality, safety and efficacy of this medicinal product continue to be adequately and sufficiently demonstrated and therefore recommends the renewal of the conditional MA for Zalmoxis, subject to the Specific Obligations and Conditions as laid down in Annex II to the Opinion.
IB/0002	B.II.d.2.z - Change in test procedure for the finished product - Other variation	08/02/2017	n/a		
IB/0001	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	08/02/2017	n/a		