Tibsovo

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
II/0012	Submission of an updated RMP version 3.0 for TIBSOVO and a replacement study protocol for study S095031-218. This is a phase 1, multicenter, open-label, safety and pharmacokinetic study of orally administered ivosidenib in participants with IDH1-mutated malignancies and hepatic or renal	13/03/2025	n/a		The Risk Management Plan version 3.0 for TIBSOVO was updated to replace the previously planned organ impairment substudy (OI-SS) of Study AG120-C-001 with a new category 3 study S095031-218, to further characterise the use of ivosidenib in patients with moderate and severe hepatic impairment. This is a phase 1, multicenter, open-

[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).

	impairment. Study milestones in RMP were updated accordingly. C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required				label, safety and pharmacokinetic study of orally administered ivosidenib in participants with IDH1-mutated malignancies and hepatic or renal impairment. Study milestones in RMP were updated accordingly
PSUSA/11048 /202405	Periodic Safety Update EU Single assessment - ivosidenib	28/11/2024	n/a		PRAC Recommendation - maintenance
IB/0010	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	12/08/2024	n/a		
N/0009	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	02/08/2024	12/12/2024	PL	
IA/0008	B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	24/06/2024	n/a		
PSUSA/11048 /202311	Periodic Safety Update EU Single assessment - ivosidenib	13/06/2024	n/a		PRAC Recommendation - maintenance
IA/0006/G	This was an application for a group of variations. B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size	19/01/2024	n/a		

	B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits				
IB/0004	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)	22/12/2023	12/12/2024	SmPC	
IB/0003/G	This was an application for a group of variations. B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products 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.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size	16/11/2023	n/a		
IB/0002/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	27/10/2023	n/a		

	B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation				
IA/0001	B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size	14/07/2023	n/a		