Lytgobi

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
R/0008	Renewal of the marketing authorisation.	27/03/2025	02/06/2025		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

[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).

					renewal of the conditional MA for Lytgobi, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion.
PSUSA/68/202409	Periodic Safety Update EU Single assessment - futibatinib	08/05/2025	n/a		PRAC Recommendation - maintenance
PSUSA/68/202403	Periodic Safety Update EU Single assessment - futibatinib	31/10/2024	n/a		PRAC Recommendation - maintenance
IB/0006/G	This was an application for a group of variations. B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)	13/08/2024	n/a		
IB/0005	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	26/07/2024	n/a		

R/0003	Renewal of the marketing authorisation.	21/03/2024	22/05/2024		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 Lytgobi, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion.
PSUSA/68/202309	Periodic Safety Update EU Single assessment - futibatinib	16/05/2024	n/a		PRAC Recommendation - maintenance
IB/0001	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	10/10/2023	22/05/2024	SmPC and PL	