

Portrazza

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
PSUSA/10471 /201605	Periodic Safety Update EU Single assessment - NECITUMUMAB	01/12/2016	n/a		PRAC Recommendation - maintenance
II/0002	Submission of study I4X-MC-JFCL, investigating necitumumab in combination with paclitaxel and carboplatin chemotherapy versus paclitaxel and carboplatin chemotherapy alone as the first line therapy in patients with Stage IV metastatic squamous non-small cell lung cancer (NSCLC). This variation leads to amendments of the	10/11/2016		SmPC, Labelling and PL	Assessment of the data provided in the context of this variation led to amendments of the SmPC to reflect the findings. The following text was added to sections 4.4 and 5.1. Section 4.4: Infections

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).



IB/0006	Product Information: sections 4.4 and 5.1 of the SmPC were updated to reflect the findings of the study submitted. The update is being reflected in the PL. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority B.I.a.2.a - Changes in the manufacturing	25/10/2016	n/a	ider and	In a phase 2 clinical trial investigating necitumumab in combination with paclitaxel and carboplatin versus paclitaxel and carboplatin alone as the first¬ line therapy in patients with stage IV metastatic squamous NSCLC, an increased rate of infections was observed early after start of treatment, which led to subsequent infectious complications such as pneumonia and/or sepsis. A similar observation was made in a clinical trial investigating necitumumab in combination with pemetrexed and cisplatin versus pemetrexed and cisplatin alone as the first line therapy in patients with advanced non squamous NSCLC. Special attention should be given to patients with clinical evidence of concomitant infectious conditions including early signs of active infections. Treatment of any infection should be initiated according to local standards. Section 5.1: In a phase 2 clinical trial investigating necitumumab in combination with paclitaxel and carboplatin versus paclitaxel and carboplatin alone (106 versus 55 patients, 2:1 randomisation) as the first line therapy in patients with Stage IV metastatic squamous NSCLC, a higher rate of death, including death due to infection, was observed for the necitumumab plus paclitaxel/carboplatin arm during the first 4 months (see also section 4.4), with a later trend towards improved survival after 4 months. The overall survival hazard ratio [HR] was 0.83 [0.55, 1.52]. The PL was amended accordingly.
,	process of the AS - Minor change in the manufacturing process of the AS		,		

IB/0004/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.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	18/07/2016	n/a		inoiised
IB/0003/G	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.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.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	16/06/2016	n/a	ider an	
IAIN/0001	A.1 - Administrative change - Change in the name and/or address of the MAH	22/03/2016		SmPC, Labelling and PL	