Tabrecta

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/0016	Update of sections 4.8 and 5.1 of the SmPC in order to update information on based on the results of the clinical study CINC280A2201 'GEOMETRY mono-1' and add 'body temperature increased' to the list of adverse drug reactions (ADRs) with frequency 'very common'. CINC280A2201 is a global, multi-cohort,	13/03/2025		SmPC and PL	SmPC new text Sections 4.8 and 5.1 of the SmPC have been updated to reflect final efficacy and safety data from a global, multi-cohort, non-randomized, open-label Phase II study designed to evaluate the efficacy and safety of single-agent capmatinib in adult patients with a MET exon 14 (METex14)

[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).

	non-randomized, open-label Phase II study designed to evaluate the efficacy and safety of single-agent capmatinib in adult patients with a MET exon 14 (METex14) skipping mutation, advanced non-small cell lung cancer (NSCLC). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce editorial changes to the PI. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				skipping mutation, advanced non-small cell lung cancer (NSCLC). The results are in line with the existing data. In section 4.8, in addition to the frequencies of adverse reactions being slightly adjusted, the frequency of the adverse reaction "rash" was changed from "common" to "very common". Also, the preferred term "body temperature increased" has been included in the grouped term of "pyrexia". In section 5.1 , the upper limit of the 95% CI of median DOR was changed from "not estimable" to 27.6 months. For more information, please refer to the Summary of Product Characteristics.
IB/0017/G	This was an application for a group of variations. B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.a.3.a.1 - Changes in the composition (excipients) of the finished product - Changes in components of the flavouring or colouring system - Addition , deletion or replacement B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change	07/02/2025		SmPC	

	in the manufacturing process B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.4.b - Change in the batch size (including batch size ranges) of the finished product - Downscaling down to 10-fold 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 B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation B.II.e.1.a.1 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Solid pharmaceutical forms B.II.e.2.b - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Addition of a new specification parameter to the specification with its corresponding test method 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 A.7 - Administrative change - Deletion of manufacturing sites				
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	04/12/2024		Annex II and PL	
PSUSA/11022 /202405	Periodic Safety Update EU Single assessment - capmatinib	28/11/2024	n/a		PRAC Recommendation - maintenance
IB/0014/G	This was an application for a group of variations. B.I.b.z - Change in control of the AS - Other variation B.I.b.z - Change in control of the AS - Other variation	05/11/2024	n/a		
IA/0013/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place	28/08/2024	n/a		

IAIN/0011/G	This was an application for a group of variations. B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	24/07/2024	n/a		
II/0007/G	This was an application for a group of variations. B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation 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.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	18/07/2024	n/a		

	or addition) for the AS or a starting material/intermediate B.I.b.1.f - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Change outside the approved specifications limits range for the AS				
PSUSA/11022 /202311	Periodic Safety Update EU Single assessment - capmatinib	13/06/2024	n/a		PRAC Recommendation - maintenance
IAIN/0010	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	08/03/2024	n/a		
IAIN/0008/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites 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.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	14/12/2023	n/a		
PSUSA/11022 /202305	Periodic Safety Update EU Single assessment - capmatinib	30/11/2023	n/a		PRAC Recommendation - maintenance
IA/0006	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or	12/09/2023	n/a		

	intermediate used in the manufacture of the AS or manufacturer of a novel excipient				
PSUSA/11022 /202211	Periodic Safety Update EU Single assessment - capmatinib	08/06/2023	n/a		PRAC Recommendation - maintenance
II/0003/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.3.b - Change in batch size (including batch size ranges) of AS or intermediate - Downscaling down to 10-fold B.I.b.2.b - Change in test procedure for AS or starting material/reagent/intermediate - Deletion of a test procedure for the AS or a starting	02/02/2023	n/a		

	material/reagent/intermediate, if an alternative test procedure is already authorised B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.b.2.c - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure for a reagent, which does not have a significant effect on the overall quality of the AS B.I.a.3.b - Change in batch size (including batch size ranges) of AS or intermediate - Downscaling down to 10-fold B.I.a.3.b - Change in batch size (including batch size ranges) of AS or intermediate - Downscaling down to 10-fold B.I.a.3.b - Change in batch size (including batch size ranges) of AS or intermediate - Downscaling down to 10-fold B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.4.d - Change to in-process tests or limits applied during the manufacture of the AS - Widening of the approved in-process test limits, which may have a significant effect on the overall quality of the				

	AS B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.I.a.3.b - Change in batch size (including batch size ranges) of AS or intermediate - Downscaling down to 10-fold B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS 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.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.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS 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.I.a.2.a - Changes in the manufacturing process of				

	the AS - Minor change in the manufacturing process of the AS				
II/0002	Update of section 4.8 of the SmPC in order to add hypersensitivity to the list of adverse drug reactions (ADRs) with frequency uncommon, based on cumulative assessment of hypersensitivity cases in studies CINC280A2201, CINC280X1101, CINC280X2102, CINC280A2108, CINC280A2103 (post-DDI phase only), and CINC280A2105 (post-DDI phase only) and MAH global safety database. The Package Leaflet is updated accordingly C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	01/12/2022	29/11/2023	SmPC and PL	Not applicable For more information, please refer to the Summary of Product Characteristics.
IAIN/0001	B.II.g.5.a - Implementation of changes foreseen in an approved change management protocol - Requires no further supporting data	24/08/2022	n/a		