Tenkasi

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
IA/0046	A.7 - Administrative change - Deletion of manufacturing sites	19/11/2024		Annex II and PL	
PSUSA/10368 /202403	Periodic Safety Update EU Single assessment - oritavancin	03/10/2024	n/a		PRAC Recommendation - maintenance

[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).

IA/0045	B.I.c.z - Container closure system of the AS - Other variation	05/08/2024	n/a		
IAIN/0044/G	This was an application for a group of variations. 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 B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	10/06/2024		Annex II and PL	
IA/0042	A.7 - Administrative change - Deletion of manufacturing sites	09/11/2023	n/a		
PSUSA/10368 /202303	Periodic Safety Update EU Single assessment - oritavancin	26/10/2023	n/a		PRAC Recommendation - maintenance
IA/0041	B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier	17/10/2023	n/a		
X/0036	Annex I_2.(c) Change or addition of a new strength/potency	22/06/2023	15/09/2023	SmPC, Labelling and PL	
IB/0040	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	25/08/2023	n/a		

II/0037	Extension of indication to include treatment of paediatric population, aged between 3 months and less than 18 years for Tenkasi (oritavancin) 400 mg based on interim results from study TMC-ORI-11-01. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 and 6.6 of the SmPC were updated. The Package Leaflet is updated in accordance. In addition, the MAH has taken the opportunity to make minor editorial amendments and QRD updates (v10.2) to the SmPC/PL.. Furthermore, the PI is brought in line with the latest QRD template version 10.2 rev 1. Version 5.1 of the RMP has also been approved. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	30/03/2023	15/05/2023	SmPC and PL	Please refer to Scientific Discussion 'Tenkasi-H-C-003785-II-0037'.
IB/0038/G	This was an application for a group of variations. B.I.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change to an approved stability protocol	25/11/2022	n/a		
IA/0035/G	This was an application for a group of variations. B.II.c.1.c - Change in the specification parameters and/or limits of an excipient - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.c.1.c - Change in the specification parameters and/or limits of an excipient - Deletion of a non-	09/02/2022	n/a		

	significant specification parameter (e.g. deletion of an obsolete parameter)				
IAIN/0034	A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs	09/08/2021	15/03/2023	SmPC, Labelling and PL	
IA/0033/G	This was an application for a group of variations. 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 procedure	26/05/2021	n/a		
PSUSA/10368 /202003	Periodic Safety Update EU Single assessment - oritavancin	15/10/2020	09/12/2020	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10368/202003.
IB/0032	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	08/12/2020	n/a		
II/0030	Submission of the final report from 14-TMC-01, a Surveillance study investigation, listed as a category 3 study in the RMP, part of the global SENTRY Antimicrobial Surveillance Program platform to monitor the activity of oritavancin against Gram-positive clinical isolates collected from Europe and the US. This application addresses PAM MEA 003.4,	26/11/2020	n/a		

	presenting the cumulative surveillance data from 2010 to 2019 (including the first 5-year post-approval period). The RMP version 3.1 is approved with this variation. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority				
IA/0029	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)	06/04/2020	n/a		
IB/0028	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)	30/03/2020	09/12/2020	SmPC	
R/0027	Renewal of the marketing authorisation.	14/11/2019	13/01/2020	SmPC, Annex II, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Orbactiv in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
PSUSA/10368 /201903	Periodic Safety Update EU Single assessment - oritavancin	17/10/2019	18/12/2019	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10368/201903.
IAIN/0026/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites	14/06/2019	18/12/2019	Annex II and PL	

	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site 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				
PSUSA/10368 /201809	Periodic Safety Update EU Single assessment - oritavancin	11/04/2019	n/a		PRAC Recommendation - maintenance
IA/0024/G	This was an application for a group of variations. 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 procedure	17/03/2019	n/a		
N/0023	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	22/02/2019	18/12/2019	Labelling	
T/0022	Transfer of Marketing Authorisation	06/12/2018	11/01/2019	SmPC, Labelling and PL	
PSUSA/10368 /201803	Periodic Safety Update EU Single assessment - oritavancin	04/10/2018	n/a		PRAC Recommendation - maintenance
T/0020	Transfer of Marketing Authorisation	12/07/2018	13/08/2018	SmPC,	

				Labelling and PL	
PSUSA/10368 /201709	Periodic Safety Update EU Single assessment - oritavancin	26/04/2018	25/06/2018	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10368/201709.
IAIN/0018	C.I.11.a - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of wording agreed by the competent authority	11/04/2018	n/a		
PSUSA/10368 /201703	Periodic Safety Update EU Single assessment - oritavancin	28/09/2017	n/a		PRAC Recommendation - maintenance
PSUSA/10368 /201609	Periodic Safety Update EU Single assessment - oritavancin	06/04/2017	n/a		PRAC Recommendation - maintenance
IA/0014	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	12/12/2016	n/a		
PSUSA/10368 /201603	Periodic Safety Update EU Single assessment - oritavancin	29/09/2016	n/a		PRAC Recommendation - maintenance
II/0012/G	This was an application for a group of variations. Group of variations consisting of: 1. Update of sections 4.4 and 4.5 of the SmPC in order to delete the warning related to the interaction with warfarin and include the results of the	15/09/2016	12/12/2016	SmPC and PL	Update of sections 4.4 and 4.5 of the SmPC in order to delete the warning related to the interaction with warfarin and include the results of the new interaction study (MDCO-ORI-14-02). This study was to assess the drug-drug interaction effect of a single 1200mg dose of oritavancin on the pharmacokinetics of S-warfarin

	interaction study (MDCO-ORI-14-02) , respectively. The Package Leaflet and RMP (version 2.2) are updated in accordance. 2. Update of the RMP (version 2.2) to delete the category 3 study MDCO-ORI-14-03 C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data 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				following a single dose was conducted in 36 healthy subjects. S-warfarin pharmacokinetics were evaluated following a single dose of warfarin 25mg given alone, or administered at the start, 24, or 72 hours after a single 1200mg dose of oritavancin. The results showed no effect of oritavancin on S-warfarin exposure (AUC) and maximum concentration (Cmax).
PSUSA/10368 /201509	Periodic Safety Update EU Single assessment - oritavancin	14/04/2016	n/a		PRAC Recommendation - maintenance
IB/0010	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	30/03/2016	n/a		
II/0008	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	17/03/2016	n/a		
IB/0009	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	05/02/2016	n/a		

IB/0007	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	22/12/2015	n/a		
II/0003	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	17/12/2015	12/12/2016	SmPC and PL	
IB/0005/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.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 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	30/10/2015	n/a		
IA/0004/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	14/10/2015	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				
II/0002	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	17/09/2015	n/a		
IB/0001	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	22/05/2015	n/a		