Xydalba

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/0050	Extension of indication to include the treatment of acute bacterial skin and skin structure infections (ABSSSI) in paediatric patients from birth for Xydalba, based on final results from study DUR001-306, together with data from three Phase 1 PK studies (A8841004, DUR001-106, and DUR001-107	27/03/2025	02/05/2025	SmPC, Labelling and PL	Please refer to Scientific Discussion 'Xydalba-EMEA/H/C/002840/II/0050

[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).

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	(DAL-PK-02); DUR001-306 was a Phase 3, multicenter, open-label, randomised, comparator controlled trial evaluating the safety and efficacy of a single dose of IV dalbavancin and a 2-dose regimen of once weekly IV dalbavancin (for a total of 14 days of coverage) for the treatment of ABSSSI known or suspected to be due to susceptible Gram-positive organisms in children. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 8.1 of the RMP is approved with this variation. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI, update the list of local representatives in the Package Leaflet in line with the latest QRD template version 10.4, and replace the MIC breakpoints table in section 5.1 of the SmPC with the agreed reference to the EMA website, in line with EMA's Guideline on the evaluation of medicinal products indicated for treatment of bacterial infections. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
IB/0052	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	19/12/2024	n/a		
IAIN/0051	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer	20/09/2024	02/05/2025	Annex II and	

	responsible for batch release			PL	
PSUSA/10350 /202311	Periodic Safety Update EU Single assessment - dalbavancin	11/07/2024	n/a		PRAC Recommendation - maintenance
N/0049	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	05/04/2024	02/05/2025	PL	
IA/0048	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	06/03/2024	n/a		
II/0043	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	13/10/2022	09/12/2022	SmPC and PL	Please refer to the Scientific Discussion 'Xydalba-H-C-002840-II-0043'
IA/0046	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	24/06/2022	n/a		
T/0045	Transfer of Marketing Authorisation	29/04/2022	13/06/2022	SmPC, Labelling and PL	
IA/0044/G	This was an application for a group of variations. B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process A.4 - Administrative change - Change in the name	04/02/2022	n/a		

	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				
N/0042	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	11/10/2021	13/06/2022	PL	
PSUSA/10350 /202011	Periodic Safety Update EU Single assessment - dalbavancin	10/06/2021	n/a		PRAC Recommendation - maintenance
IA/0041	A.7 - Administrative change - Deletion of manufacturing sites	03/03/2021	n/a		
IAIN/0039/G	This was an application for a group of variations. 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	25/01/2021	19/10/2021	Annex II and PL	
II/0037	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	14/01/2021	n/a		
IB/0038	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	26/10/2020	19/10/2021	SmPC and PL	

IB/0035/G	This was an application for a group of variations. B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	23/10/2020	n/a		
IA/0036/G	This was an application for a group of variations. B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.III.2.a.2 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/AS starting material	02/10/2020	n/a		
PSUSA/10350 /201911	Periodic Safety Update EU Single assessment - dalbavancin	11/06/2020	n/a		PRAC Recommendation - maintenance
IA/0034	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	20/05/2020	n/a		
IA/0033	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	20/05/2020	n/a		

N/0030	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	18/02/2020	19/10/2021	PL	
IB/0031	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	17/02/2020	n/a		
R/0028	Renewal of the marketing authorisation.	19/09/2019	05/12/2019	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 Xydalba in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IA/0029	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	13/11/2019	n/a		
PSUSA/10350 /201811	Periodic Safety Update EU Single assessment - dalbavancin	14/06/2019	n/a		PRAC Recommendation - maintenance
IAIN/0027/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site 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.c.2 - Change to importer, batch release arrangements and quality control testing of the FP -	12/03/2019	31/07/2019	Annex II and PL	

	Including batch control/testing				
IB/0025	B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	17/12/2018	n/a		
IB/0024	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	14/12/2018	31/07/2019	SmPC and PL	
IAIN/0023/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of the MAH 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	01/08/2018	31/07/2019	SmPC, Annex II, Labelling and PL	
PSUSA/10350 /201711	Periodic Safety Update EU Single assessment - dalbavancin	14/06/2018	n/a		PRAC Recommendation - maintenance
IA/0020	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	18/01/2018	n/a		
PSUSA/10350 /201705	Periodic Safety Update EU Single assessment - dalbavancin	30/11/2017	n/a		PRAC Recommendation - maintenance
IB/0018/G	This was an application for a group of variations. B.I.a.1.f - Change in the manufacturer of AS or of a	08/11/2017	n/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.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation 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.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				
IA/0019	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	27/09/2017	n/a		
PSUSA/10350 /201611	Periodic Safety Update EU Single assessment - dalbavancin	09/06/2017	n/a		PRAC Recommendation - maintenance
N/0016	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/03/2017	31/07/2019	PL	
T/0014	Transfer of Marketing Authorisation	16/12/2016	27/01/2017	SmPC, Labelling and PL	

IB/0013	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)	01/12/2016	27/01/2017	SmPC	
PSUSA/10350 /201605	Periodic Safety Update EU Single assessment - dalbavancin	01/12/2016	n/a		PRAC Recommendation - maintenance
IB/0011	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	31/08/2016	n/a		
IA/0010	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	11/07/2016	n/a		
N/0009	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	22/06/2016	27/01/2017	PL	
PSUSA/10350 /201511	Periodic Safety Update EU Single assessment - dalbavancin	09/06/2016	n/a		PRAC Recommendation - maintenance
IA/0007/G	This was an application for a group of variations. B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits	25/04/2016	n/a		

N/0008	Update of the package leaflet with revised contact details of the local representatives for Hungary and Slovenia. The MAH also took the opportunity to make corrections to some of the local representatives contact details in the Spanish, Greek, Croatian, Hungarian, Icelandic, Lithuanian, Slovakian and Slovenian package leaflets in line with the English texts. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	22/04/2016	27/01/2017	PL	
II/0004	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	28/01/2016	02/03/2016	SmPC and PL	
PSUSA/10350 /201505	Periodic Safety Update EU Single assessment - dalbavancin	03/12/2015	n/a		PRAC Recommendation - maintenance
II/0003	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	24/09/2015	n/a		
IAIN/0001	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the PSMF location	28/04/2015	n/a		
N/0002	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/04/2015	02/03/2016	PL	