Beyfortus

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
T/0017	Transfer of Marketing Authorisation	06/11/2023	01/12/2023	SmPC, Labelling and PL	
PSUSA/11026 /202304	Periodic Safety Update EU Single assessment - nirsevimab	30/11/2023	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).

IB/0015/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.1.z - Replacement or addition of a manufacturing site for the FP - Other variation	14/11/2023	n/a		
IB/0013	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	14/09/2023	n/a		
IB/0012	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	13/09/2023	n/a		
IB/0009	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	26/07/2023	n/a		
IB/0007	B.I.e.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	24/07/2023	n/a		
IB/0008	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	23/06/2023	01/12/2023	SmPC	

IB/0006/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 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	20/06/2023	n/a		
IB/0004/G	This was an application for a group of variations. B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol B.II.f.1.e - Stability of FP - Change to an approved stability protocol	27/04/2023	01/12/2023	SmPC	
IB/0003	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	04/04/2023	n/a		
II/0001	Update of sections 4.8, 5.1 and 5.2 of the SmPC in order to update efficacy information based on additional results from study D5290C00004 (MELODY); this is a Phase III Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety and Efficacy of MEDI8897, for the Prevention of Medically Attended Lower Respiratory Tract Infection Due to Respiratory Syncytial Virus in	23/02/2023	01/12/2023	SmPC	At the time of the original MA, data were available from 1490 subjects in MELODY (Primary Cohort); this was approximately half of the planned total study population due to an enrolment pause in response to the COVID-19 pandemic. Data are now available for an additional 1522 subjects (MELODY [Safety Cohort]) enrolled after recommencement of MELODY following relaxation of COVID-19 restrictions, making a total of 3012 term and

	Healthy Late Preterm and Term Infants. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				late preterm infants in MELODY (All Subjects). The purpose of this submission was to present efficacy and safety results for MELODY (All Subjects) and rationale to support updating efficacy results for severe RSV disease in the SmPC. Please refer to Scientific Discussion 'Beyfortus-H-C-005304-II-001' For more information, please refer to the Summary of Product Characteristics.
IB/0002	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	11/01/2023	n/a		