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
II/0026/G	This was an application for a group of variations. B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol	03/10/2024	n/a		

[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).

	product and any of the test methods at the site is a biol/immunol method B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes				
II/0024	Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to add warning on excipient with known effect and hypersensitivity including anaphylaxis, and to add 'hypersensitivity' to the list of adverse drug reactions (ADRs) with frequency not known. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the Product Information. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	05/09/2024		SmPC, Annex II, Labelling and PL	Further to a safety review including all known hypersensitivity reactions (both serious and non-serious) reported following the administration of Beyfortus, the MAH found potential cases of hypersensitivity and/or anaphylaxis related to Beyfortus and hence proposed changes to the product information. As a result of their assessment, inclusion of serious hypersensitivity reactions following Beyfortus administration was proposed, with frequency "not known". As regards to anaphylaxis reactions, no causality could be found between Beyfortus and anaphylaxis. Considering the above, the sections 4.4 and 4.8 of the SmPC were updated accordingly. These changes were considered acceptable to the CHMP based on the information provided by the MAH. The CHMP also noted that amendments were made in the section 2 of the SmPC to bring it in line with the current Excipients guideline with respect to Polysorbates; this is endorsed by the Committee. For more information, please refer to the Summary of Product Characteristics.
II/0005	Extension of indication to include treatment of	27/06/2024	01/08/2024	SmPC and PL	Please refer to Scientific Discussion 'Product Name-H-C-

	children up to 24 months of age who remain vulnerable to severe Respiratory Syncytial Virus (RSV) disease through their second RSV season for BEYFORTUS, based on interim results from studies D5290C00005 and D5290C00008. Study D5290C00005 (MEDLEY) is a Phase II/III, randomized, double-blind, placebo-controlled study to evaluate the safety of Beyfortus in high-risk children. Study D5290C00008 (MUSIC) is a Phase II, open-label, uncontrolled, single-dose study to evaluate the safety and tolerability, pharmacokinetics, and occurrence of antidrug antibody for Beyfortus in immunocompromised children ≤ 24 Months of Age. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 of the SmPC are updated, together with sections 6.6 (instructions for administration) and 7 (change of MAH). The Package Leaflet is updated accordingly. Also, Annex II and IIIA (labelling) are amended (administrative change). Version 2.3 of the RMP has been agreed. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				Product Number-II-Var II-005’
II/0022/G	This was an application for a group of variations. B.II.b.1.c - Replacement or addition of a	25/07/2024	n/a		

	manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method B.II.b.4.c - Change in the batch size (including batch size ranges) of the finished product - The change requires assessment of the comparability of a biological/immunological medicinal product or a new bioequivalence study B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier				

IB/0023	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	15/07/2024		SmPC	
PSUSA/11026 /202310	Periodic Safety Update EU Single assessment - nirsevimab	16/05/2024	n/a		PRAC Recommendation - maintenance
IB/0021	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	25/04/2024	n/a		
II/0018/G	This was an application for a group of variations. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	25/04/2024	01/08/2024	SmPC	
IB/0020	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	01/03/2024	n/a		
IB/0016/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	05/01/2024	n/a		

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
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	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

	(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 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				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 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		