# Casgevy

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 |
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| N/0011 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 02/12/2024 | | Labelling and PL | |
| PSUSA/244/202405 | Periodic Safety Update EU Single assessment - exagamglogene autotemcel | 28/11/2024 | 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).

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| IB/0010/G | This was an application for a group of variations.<br><br>B.II.c.2.d - Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition)<br>B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS<br>B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS<br>B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS | 12/11/2024 | n/a | | |
| II/0003/G | This was an application for a group of variations.<br><br>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<br>B.II.b.2.c.3 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing for a biol/immunol product and any of the test methods is a biol/immunol/immunochemical method<br>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 | 19/09/2024 | | Annex II and PL | Annex II has been updated as follows:<br>Addition of Lonza Netherlands B.V., Urmonderbaan 20 B, 6167 RD Geleen, Netherlands as manufacturer of the biological active substance and manufacturer responsible for batch release.<br>Annex IIIb has been updated as follows:<br>Addition of Lonza Netherlands B.V., Urmonderbaan 20 B, 6167 RD Geleen, Netherlands as manufacturer.<br>Various editorial updates have been implemented in Annex I and Annex IIIb. |

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| | 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<br>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site<br>B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure<br>B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure<br>B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product | | | | |
| IB/0005 | B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits | 10/09/2024 | n/a | | |
| IA/0004 | B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process | 28/05/2024 | n/a | | |
| IB/0001 | B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation | 18/04/2024 | n/a | | |

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| IAIN/0002/G | This was an application for a group of variations.<br><br>A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release<br>A.1 - Administrative change - Change in the name and/or address of the MAH | 21/03/2024 | | SmPC, Annex II, Labelling and PL | |