



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Sunlenca

Procedural steps taken and scientific information after the authorisation

| Application number | Scope                                                                                                                                                                                                                                                                                              | Opinion/ Notification <sup>1</sup> issued on | Commission Decision Issued <sup>2</sup> / amended on | Product Information affected <sup>3</sup> | Summary                                                                                                                                                                                                                                                                                                                         |
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| II/0022/G          | <p>This was an application for a group of variations.</p> <p>Grouping of two type II variations:</p> <ul style="list-style-type: none"><li>- Update of section 5.1 of the SmPC to include efficacy and resistance data based on Week 156 interim data from Study GS-US-200-4625; a phase</li></ul> | 08/05/2025                                   |                                                      | SmPC and PL                               | <p>New SmPC text</p> <p>Section 4.4 of the SmPC was updated to include a warning about the potential for slow or non-resolving injection site nodules and indurations. Section 4.8 was also updated to include information related to injection site nodules and induration that were non-resolved at the end of follow-up.</p> |

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).



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|  | <p>2/3 study to evaluate the safety and efficacy of long-acting capsid inhibitor GS-6207 in combination with an optimized background regimen in heavily treatment experienced people living with HIV-1 infection with multidrug resistance (category 3 study in the RMP). Additionally, upon request by the CHMP following the assessment of II/0013, the MAH proposes to update section 4.8 of the SmPC to include information related to injection site nodules and induration that were non-resolved at the end of follow-up. Section 4.4 of the SmPC and the patient information leaflet were also updated to include a warning about the potential for slow or non-resolving injection site nodules and indurations.</p> <p>- Provision of the final study report of Study GS-US-200-4334: a phase 2 randomized, open label, active controlled study evaluating the safety and efficacy of long-acting capsid inhibitor GS-6207 in combination with other antiretroviral agents in people living with HIV (category 3 study in the RMP). The MAH submitted an updated RMP (version 2.2) which included removal of two Category 3 studies (GS-US-200-4625 and GS-US-200-4334) from the Pharmacovigilance Plan and removal of "Long-term safety information" as a safety concern (missing information).</p> <p>C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority</p> <p>C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance</p> |  |  |  | <p>Section 5.1 was updated to include long-term efficacy (Week 156) and resistance data</p> <p>For more information, please refer to the Summary of Product Characteristics.</p> |
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|                    | data                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |            |     |                        |                                   |
| PSUSA/11012/202408 | Periodic Safety Update EU Single assessment - lenacapavir                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 13/03/2025 | n/a |                        | PRAC Recommendation - maintenance |
| II/0025            | <p>Update of sections 4.2 and 4.4 of the SmPC in order to reinforce the importance of injecting Sunlenca subcutaneously and not intradermally, and to add a new warning on 'Injection Site Reactions with Improper Administration' to describe that intradermal administration has been associated with serious injection site reactions including necrosis and ulcer, based on a cumulative safety review. Moreover, section 4.8 was updated to include necrosis as an example of an injection site reaction. The Package Leaflet is updated accordingly. The Instructions for Use (IFU) of Sunlenca solution for injection have also been updated to improve readability for healthcare professionals. In addition, the MAH took the opportunity to introduce editorial and formatting changes to the PI.</p> <p>C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data</p> | 30/01/2025 |     | SmPC, Labelling and PL |                                   |
| IB/0024/G          | <p>This was an application for a group of variations.</p> <p>B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation</p> <p>B.I.a.1.z - Change in the manufacturer of AS or of a</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 26/11/2024 | n/a |                        |                                   |

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|           | <p>starting material/reagent/intermediate for AS - Other variation</p> <p>B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation</p> <p>B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation</p> <p>B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer</p> <p>B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer</p> <p>B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer</p> |            |     |  |  |
| IB/0021/G | <p>This was an application for a group of variations.</p> <p>B.II.b.4.z - Change in the batch size (including batch size ranges) of the finished product - Other variation</p> <p>B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation</p> <p>B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 31/10/2024 | n/a |  |  |

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|           | <p>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site</p> <p>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</p> <p>B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the FP - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/immunological medicinal products</p> |            |     |  |  |
| IB/0020/G | <p>This was an application for a group of variations.</p> <p>B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)</p> <p>B.II.d.z - Change in control of the Finished Product - Other variation</p> <p>B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)</p> <p>B.II.d.z - Change in control of the Finished Product - Other variation</p> <p>B.I.b.z - Change in control of the AS - Other variation</p> <p>B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other</p> | 08/10/2024 | n/a |  |  |

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|                    | changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate                                                                                                                                                                                                                                                                                                                                                                                     |            |     |      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| PSUSA/11012/202402 | Periodic Safety Update EU Single assessment - lenacapavir                                                                                                                                                                                                                                                                                                                                                                                                                                          | 03/10/2024 | n/a |      | PRAC Recommendation - maintenance                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| II/0019            | <p>Update of section 4.5 of the SmPC in order to include information on co-administration of lenacapavir with systemic dexamethasone based on post-marketing data and literature. In addition, the MAH took the opportunity to implement editorial changes to the SmPC.</p> <p>C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data</p>                                                                                               | 05/09/2024 |     | SmPC | <p>4.5 is updated to include the dexamethasone drug drug interaction (DDI) with Lenacapavir. Plasma concentrations of lenacapavir may decrease when co-administered with systemic dexamethasone. Caution is advised if Sunlenca is coadministered with a sensitive CYP3A and/or P gp substrate with a narrow therapeutic index.</p> <p>For more information, please refer to the Summary of Product Characteristics.</p>                                                              |
| II/0013            | <p>Update of section 5.3 of the SmPC in order to include non-clinical information based on final results from study TX-200-2046 entitled, "104 Week Subcutaneous Injection Carcinogenicity and Toxicokinetic Study of GS-6207 Administered Every 13 Weeks in Wistar-Han Rats". In addition, the MAH took the opportunity introduce minor editorial changes to the PI.</p> <p>C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data</p> | 25/07/2024 |     | SmPC | <p>SmPC new text</p> <p>In this variation, 5.3 of the SmPC is updated to include the results of the life-time (2-year) rat carcinogenicity study where they were exposed to SC-injected lenacapavir every 13 weeks. Moreover, MAH committed to include more injection-site nodule information into SmPC 4.8 within the expected submission of the study GS-US-200-4625 by 30 September 2024.</p> <p>For more information, please refer to the Summary of Product Characteristics.</p> |

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| IB/0015            | C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation                                                                                                                                                                 | 22/04/2024 | n/a |  |                                   |
| IA/0017/G          | This was an application for a group of variations.<br><br>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - 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 | 04/04/2024 | n/a |  |                                   |
| IA/0016            | B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure                                                                                                                                                                           | 20/03/2024 | n/a |  |                                   |
| PSUSA/11012/202308 | Periodic Safety Update EU Single assessment - lenacapavir                                                                                                                                                                                                                                                     | 07/03/2024 | 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                                                                  | 08/12/2023 | n/a |  |                                   |
| IA/0011            | 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                                                                                                                                    | 31/10/2023 | n/a |  |                                   |

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| IB/0010/G           | <p>This was an application for a group of variations.</p> <p>B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation</p> <p>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</p> | 26/10/2023 | n/a        |             |                                   |
| IA/0009             | B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process                                                                                                                                                                                                                                                                                                    | 04/10/2023 | n/a        |             |                                   |
| PSUSA/11012 /202302 | Periodic Safety Update EU Single assessment - lenacapavir                                                                                                                                                                                                                                                                                                                                                                               | 28/09/2023 | n/a        |             | PRAC Recommendation - maintenance |
| IB/0008/G           | <p>This was an application for a group of variations.</p> <p>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)</p> <p>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)</p>                                                                             | 23/06/2023 | 06/06/2024 | SmPC and PL |                                   |
| IA/0007             | B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure                                                                                                                                                                                                                                                                                                     | 12/06/2023 | n/a        |             |                                   |

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| IB/0006     | C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 09/06/2023 | n/a |  |  |
| IAIN/0004/G | <p>This was an application for a group of variations.</p> <p>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</p> <p>B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer</p> <p>B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer</p> | 23/02/2023 | n/a |  |  |
| IA/0003     | 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 21/11/2022 | n/a |  |  |
| IA/0002     | B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 19/09/2022 | n/a |  |  |
| IA/0001/G   | This was an application for a group of variations.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 19/09/2022 | n/a |  |  |

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|  | <p>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</p> <p>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</p> <p>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</p> |  |  |  |  |
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