



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## SIILTIBCY

### Procedural steps taken and scientific information after the authorisation\*

\*Due to the Agency's update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

| Application number  | Scope                                         | Opinion/<br>Notification<br><sup>1</sup> issued on | Commission<br>Decision<br>Issued <sup>2</sup> /<br>amended on | Product<br>Information<br>affected <sup>3</sup> | Summary                                          |
|---------------------|-----------------------------------------------|----------------------------------------------------|---------------------------------------------------------------|-------------------------------------------------|--------------------------------------------------|
| Variation type IB / | B.II.f.1.b Extension of the shelf life of the | 24/10/2025                                         |                                                               | SmPC, Annex                                     | To extend the shelf-life of the finished product |

<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).



|                                             |                                                                                                                                                                                                                                                                |            |  |                                  |                                                                                                                                                                  |
|---------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|--|----------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| EMA/VR/0000294621                           | finished product - B.II.f.1.b.5 Extension of the shelf-life of a biological/ immunological medicinal product in accordance with an approved stability protocol - Accepted                                                                                      |            |  | II and PL                        | SIILTIBCY (0.5 microgram + 0.5 microgram)/mL solution for injection, in accordance with the approved stability protocol, from 2 to 3 years when stored at 2-8°C. |
| Variation type IA_IN /<br>EMA/VR/0000259160 | A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.a The activities for which the manufacturer/importer is responsible include batch release - Accepted | 24/03/2025 |  | SmPC, Annex II, Labelling and PL |                                                                                                                                                                  |