17 October 2024
EMA/CHMP/265104/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Siiltibcy

Mycobacterium tuberculosis derived antigens (rdESAT-6 / rCFP-10)

On 17 October 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Siiltibcy, intended for the diagnosis of *Mycobacterium tuberculosis* infection.

The applicant for this medicinal product is Serum Life Science Europe GmbH.

Siiltibcy will be available as a solution for injection containing 0.5 µg/ml rdESAT-6 and 0.5 µg/ml rCFP-10. The active substances of Siiltibcy are *Mycobacterium tuberculosis* derived antigens (rdESAT-6 and rCFP-10). The intradermal presentation of the antigens to the immune system induces a delayed-type hypersensitivity reaction in people carrying the bacteria, seen as an induration at the site of injection.

The diagnostic performance of Siiltibcy (sensitivity and specificity) was compared to two products intended for the diagnosis of *Mycobacterium tuberculosis*: Quantiferon TB Gold In-Tube test (QFT, an in vitro test) and Tuberculin purified derivative (PPD RT23, a test used intradermally like Siiltibcy). In comparison to QFT, Siiltibcy is easier to use. When compared to PPD RT23, Siiltibcy has a slightly lower sensitivity but the advantage of a higher specificity in Bacillus Calmette-Guérin-vaccinated people and gives fewer false positives as it better excludes people infected by mycobacteria other than *Mycobacterium tuberculosis*. The most common side effects with Siiltibcy are pruritus, pain and hematoma at the site of injection.

The full indication is:

> SIILTIBCY is indicated as a diagnostic aid for detection of *Mycobacterium tuberculosis* infection, including disease, in adults and children aged 28 days or older.
>
> This medicinal product is for diagnostic use only.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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