Unit: Technical Assessment Unit

Public assessment report for biological products

Jemperli

Administrative information:

Trade name of the medicinal product:	Jemperli
INN (or common name) of the active substance(s):	Dostarlimab 500 mg/10ml
Manufacturer of the finished product	Glaxo operations (UK) ltd (trading as Glaxo wellcome operations),Harmire road, Barnard Castle, County Durham, DL12 8DT - UNITED KINGDOM
Marketing Authorization holder	GlaxoSmithkline (Ireland) Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24 - IRELAND
Applied Indication(s):	JEMPERLI is indicated in combination with carboplatin and paclitaxel for the first-line treatment of adult patients with primary advanced or recurrent endometrial cancer (EC) and who are candidates for systemic therapy. JEMPERLI is indicated as monotherapy for the treatment of adult patients with mismatch repair deficient (dMMR)/ microsatellite instability-high (MSI-H) recurrent or advanced EC that has progressed on or following prior treatment with a platinum-containing regimen
Pharmaceutical form(s) and strength(s):	IV INFUSION 500 mg/10ml
Route of administration	IV
Approved pack	Each carton contains one borosilicate clear (glass type I) vial of 10 mL with a grey chlorobutyl elastomer laminated with

	fluoropolymer stopper, sealed with an aluminum flip-off cap, with an innerleaflet.
Registration track	Reliance level 1
Type of registration (EMA/FDA – Local)	EMA approved

List of abbreviations

DP	Drug Product
DS	Drug substance
dMMR	DNA mismatch repair
MSI-H	microsatellite instability-high
IV	intravenus
CHO	Chinese hamster ovary
PD-1	anti-programmed cell death protein 1
IgG4	immunoglobulin G4
EC	endometrial cancer

Table of contents

Dossier initial submission and evaluation process:

- The product was submitted for registration via reliance level I.
- The dossier evaluation by the registration administration units was started on 6.3.2025 after providing all the required documents (**Complete CTD file. -EMA list of questions for Day 90 and Day 180. - EMA List of variations**)

1. **General introduction about the product including brief description of the AI, its mode of action and indications**

- Dostarlimab is an anti-programmed cell death protein 1 (PD-1) immunoglobulin G4 (IgG4) humanized monoclonal antibody produced by recombinant DNA technology in a mammalian expression system using a stable Chinese hamster ovary (CHO) cell line. Prior to approval of the drug substance INN name dostarlimab, the molecule/product name was referred to as TSR-042, the name given and used by TESARO during development. While the drug substance (DS) and drug product (DP) was developed by TESARO Inc., TESARO was acquired by GSK, and GSK is the applicant for the MAA.
- Dostarlimab is indicated in combination with carboplatin and paclitaxel for the first-line treatment of adult patients with primary advanced or recurrent endometrial cancer (EC) and who are candidates for systemic therapy. And also, indicated as monotherapy for the treatment of adult patients with mismatch repair deficient (dMMR)/ microsatellite instability-high (MSI-H) recurrent or advanced EC that has progressed on or following prior treatment with a platinum-containing regimen.

2. **Quality aspects:**

- **Manufacturer**
- **Drug Substance**

Manufacture of drug substance in WuXi Biologics Co., Ltd., 108 Meiliang Road, Mashan, Binhu District, Wuxi, Jiangsu 214092, China

- **Drug Product:**

Manufacturer of the Drug Product and Batch releaser site:

Glaxo operations (UK) ltd (trading as Glaxo wellcome operations),Harmire road, Barnard Castle, County Durham, DL12 8DT - UNITED KINGDOM

- **Stability**

Drug substance :

➢ **Approved shelf life:**60 months

➢ **Approved Storage Conditions:** ≤ -35ºC

Drug Product:

➢ **Approved shelf life (unopened vial):** 36 months

➢ **Approved Storage Conditions: Drug product:**

•Store in a refrigerator (2- 8 °C).
•Don't freeze
•Store in the original carton in order to protect from light**.**

➢ **After Dilution:**

If not used immediately, chemical and physical in-use stability has been demonstrated for 24 hours at (2- 8 °C) and 6 hours at room temperature (up to 25°C) from the time of preparation/ dilution until the end of administration.

•Do not shake the final infusion bag.

3.Non –Clinical aspect & Clinical aspect:

- Overall, - Treatment with dostarlimab in combination with carboplatin-paclitaxel in participants with dMMR/MSI-H primary advanced or recurrent endometrial cancer prolonged PFS versus placebo in combination with carboplatin-paclitaxel in all participants with primary advanced or recurrent endometrial cancer (PFS appeared to be independent of AUC and Cmin, participants with dMMR/MSI-H having longer PFS compared to MMRp/MSS-EC (consistent with the favorable HRs found in the subgroup analysis of PFS by investigator assessment in the dMMR/MSI-H population compared with the MSS/MMRp population).

- Dostarlimab monotherapy provides a clinically meaningful benefit in patients with recurrent or advanced dMMR/MSI-H EC that has progressed on or following prior treatment with a platinumcontaining regimen. Overall, dostarlimab demonstrated an acceptable safety profile with manageable toxicity, with a risk profile that is consistent with that of other agents of its class. Therefore, dostarlimab has a favourable benefit-risk profile that makes it a valuable treatment option for patients with recurrent or advanced dMMR/MSI-H EC.

-In conclusion the overall benefit/risk of JEMPERLI is favorable in the following indications: - JEMPERLI is indicated as monotherapy for the treatment of adult patients with mismatch repair deficient (dMMR)/ microsatellite instability-high (MSI-H) recurrent or advanced endometrial cancer (EC) that has progressed on or following prior treatment with a platinum-containing regimen.
- JEMPERLI is indicated in combination with carboplatin and paclitaxel for the first-line treatment of adult patients with primary advanced or recurrent endometrial cancer (EC) and who are candidates for systemic therapy.

4.General Conclusion and Recommendations if any:

Based on the review of CTD modules and other supplementary documents, the product is approved.

For more information, please visit EMA published assessment report link:

https://www.ema.europa.eu/en/documents/product-information/jemperli-epar-product-information_en.pdf