



27 June 2019
EMA/366637/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Tecentriq atezolizumab

On 27 June 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending changes to the terms of the marketing authorisation for the medicinal product Tecentriq. The marketing authorisation holder for this medicinal product is Roche Registration GmbH.

The CHMP recommended the approval of a new indication and a new strength, Tecentriq 840 mg concentrate for solution for infusion, to be used in the following indications:

“Tecentriq as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma (UC):

- after prior platinum containing chemotherapy, or
- who are considered cisplatin ineligible, and whose tumours have a PD-L1 expression $\geq 5\%$.

Tecentriq as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic NSCLC after prior chemotherapy. Patients with EGFR mutant or ALK positive NSCLC should also have received targeted therapies before receiving Tecentriq.

Tecentriq in combination with nab-paclitaxel is indicated for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumours have PD-L1 expression $\geq 1\%$ and who have not received prior chemotherapy for metastatic disease.²”

For information, the indications for the other strength, Tecentriq 1,200 mg concentrate for solution for infusion, remain as follows:

“Tecentriq as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma (UC):

- after prior platinum containing chemotherapy, or
- who are considered cisplatin ineligible, and whose tumours have a PD-L1 expression $\geq 5\%$.

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

² New indication added, which is not present in the existing Tecentriq strength.



Tecentriq, in combination with bevacizumab, paclitaxel and carboplatin, is indicated for the first-line treatment of adult patients with metastatic non-squamous non-small cell lung cancer (NSCLC). In patients with EGFR mutant or ALK-positive NSCLC, Tecentriq, in combination with bevacizumab, paclitaxel and carboplatin, is indicated only after failure of appropriate targeted therapies.

Tecentriq as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic NSCLC after prior chemotherapy. Patients with EGFR mutant or ALK positive NSCLC should also have received targeted therapies before receiving Tecentriq.”

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.