



20 July 2017  
EMA/CHMP/372183/2017  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (initial authorisation)

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### Tecentriq atezolizumab

On 20 July 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Tecentriq, intended for the treatment of locally advanced or metastatic urothelial carcinoma (UC) and locally advanced or metastatic non-small cell lung cancer (NSCLC). The applicant for this medicinal product is Roche Registration Limited.

Tecentriq will be available as a 1200 mg concentrate for solution for infusion. The active substance of Tecentriq is atezolizumab, an antineoplastic monoclonal antibody that potentiates T-cell response, including anti-tumour response, through blockade of PD-L1 binding to PD-1 ligand.

The benefit of Tecentriq is its ability to show durable responses in first-line cisplatin-ineligible and second-line urothelial carcinoma. In the NSCLC indication, the benefit of Tecentriq is its ability to improve survival compared with docetaxel in patients previously treated with chemotherapy.

The most common side effects are fatigue, decreased appetite, nausea, dyspnoea, diarrhoea, rash, pyrexia, vomiting, arthralgia, asthenia and pruritus. Tecentriq is also associated with immune-related adverse reactions including pneumonitis, hepatitis, colitis, hypothyroidism or hyperthyroidism, adrenal insufficiency, hypophysitis, type 1 diabetes mellitus, Guillain-Barré syndrome, meningoencephalitis and pancreatitis.

The full indication is:

"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 (see section 5.1).

Tecentriq as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) after prior chemotherapy. Patients with EGFR activating mutations or ALK-positive tumour mutations should also have received targeted therapy before receiving Tecentriq (see section 5.1)."

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion



It is proposed that Tecentriq be prescribed by physicians experienced in the treatment of cancer.

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 granted by the European Commission.