31 January 2019
EMA/CHMP/904817/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Tecentriq

atezolizumab

On 31 January 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change 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 adopted an extension to one of the existing indications as follows[2]:

> "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 ≥ 5% (see section 5.1).
>
> **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 (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~~**mutant** or ALK-positive ~~tumour mutations~~**NSCLC** should also have received targeted therap~~y~~**ies** before receiving Tecentriq (see section 5.1)."

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.

[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 text in bold, removed text as strikethrough

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact