27 February 2020
EMA/CHMP/99918/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Alunbrig

brigatinib

On 27 February 2020, 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 Alunbrig. The marketing authorisation holder for this medicinal product is Takeda Pharma A/S.

The CHMP adopted a new indication as follows:

> "Alunbrig is indicated as monotherapy for the treatment of adult patients with anaplastic lymphoma kinase (ALK) positive advanced non small cell lung cancer (NSCLC) previously not treated with an ALK inhibitor."

For information, the full indications for Alunbrig will be as follows[2]:

> "**Alunbrig is indicated as monotherapy for the treatment of adult patients with anaplastic lymphoma kinase (ALK) positive advanced non small cell lung cancer (NSCLC) previously not treated with an ALK inhibitor.**
>
> Alunbrig is indicated as monotherapy for the treatment of adult patients with ~~anaplastic lymphoma kinase (~~ALK~~)~~ positive advanced ~~non-small cell lung cancer (~~NSCLC~~)~~ previously treated with crizotinib."

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

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