22 June 2017
EMA/CHMP/333095/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Fotivda

tivozanib hydrochloride monohydrate

On 22 June 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 Fotivda, intended for the treatment of advanced renal cell carcinoma. The applicant for this medicinal product is EUSA Pharma.

Fotivda will be available as 890 µg and 1340 µg hard capsules. The active substance of Fotivda is tivozanib hydrochloride monohydrate, a protein kinase inhibitor (ATC code: L01XE34) which, by blocking vascular endothelial growth factor receptors (VEGFR), inhibits angiogenesis leading to inhibition of tumour growth.

The benefits with Fotivda are its ability to improve progression-free survival in patients with advanced disease. The most common side effects are hypertension, dysphonia, fatigue and diarrhoea.

The full indication is: "first line treatment of adult patients with advanced renal cell carcinoma (RCC) and for adult patients who are VEGFR and mTOR pathway inhibitor-naïve following disease progression after one prior treatment with cytokine therapy for advanced RCC."

It is proposed that Fotivda 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.

[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

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