EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 September 2013
EMA/CHMP/543900/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Votubia

everolimus

On 19 September 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product Votubia. The marketing authorisation holder for this medicinal product is Novartis Europharm Ltd. They may request a re-examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a change to the indication for subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC), extending the use to younger children. The change adopted is as follows:

Subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC)

Votubia is indicated for the treatment of patients ~~aged 3 years and older~~ with subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC) who require therapeutic intervention but are not amenable to surgery.

The evidence is based on analysis of change in SEGA volume. Further clinical benefit, such as improvement in disease-related symptoms, has not been demonstrated."

Detailed conditions 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 the variation to the marketing authorisation has been granted by the European Commission.

For information, the full indications for Votubia will be as follows:

Renal angiomyolipoma associated with tuberous sclerosis complex (TSC)

Votubia is indicated for the treatment of adult patients with renal angiomyolipoma associated with tuberous sclerosis complex (TSC) who are at risk of complications (based on factors such as tumour

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.

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size or presence of aneurysm, or presence of multiple or bilateral tumours) but who do not require immediate surgery.

The evidence is based on analysis of change in sum of angiomyolipoma volume.

Subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC)

Votubia is indicated for the treatment of patients with subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC) who require therapeutic intervention but are not amenable to surgery.

The evidence is based on analysis of change in SEGA volume. Further clinical benefit, such as improvement in disease-related symptoms, has not been demonstrated.