EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 April 2014
EMA/CHMP/236261/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Nexavar

sorafenib

On 25 April 2014, 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 Nexavar. The marketing authorisation holder for this medicinal product is Bayer Pharma AG.

Nexavar is currently indicated for the treatment of patients with hepatocellular carcinoma and for the treatment of patients with advanced renal cell carcinoma who have failed prior interferon-alpha or interleukin-2 based therapy or are considered unsuitable for such therapy. The CHMP has now recommended an extension to the indication to include the treatment of patients with progressive, locally advanced or metastatic, differentiated thyroid carcinoma, refractory to radioactive iodine.

The full indication for Nexavar will be as follows[2]:

"Hepatocellular carcinoma

Nexavar is indicated for the treatment of hepatocellular carcinoma (see section 5.1).

Renal cell carcinoma

Nexavar is indicated for the treatment of patients with advanced renal cell carcinoma who have failed prior interferon-alpha or interleukin-2 based therapy or are considered unsuitable for such therapy.

Differentiated thyroid carcinoma

Nexavar is indicated for the treatment of patients with progressive, locally advanced or metastatic, differentiated (papillary / follicular / Hürthle cell) thyroid carcinoma, refractory to radioactive iodine."

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.

[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.
[2] The text in bold represents the new or the amended indication.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7<sector fax>
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union