25 April 2014
EMA/242564/2014
Press Office

**Press release**

# EMA recommends extending use of Nexavar to include treatment of differentiated thyroid cancer

## New option for patients who no longer respond to standard treatment

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended extending the use of the cancer medicine Nexavar (sorafenib) to the treatment of progressive, locally advanced or metastatic, differentiated thyroid cancer.

Thyroid cancer is a rare disease which affects the thyroid, a small gland at the base of the neck that produces thyroid hormones. In the European Union (EU), close to 37,000 new cases of thyroid cancer were reported in 2012 and over 3,600 deaths. Differentiated thyroid cancer is the most common type of thyroid cancer. It originates from the follicular cells of the thyroid gland, the cells which produce hormones that help regulate growth and metabolism (the process of breaking down substances in the body).

Current treatment options for thyroid cancer include radioactive iodine and surgery as well as therapy to suppress thyroid-stimulating hormone (TSH). The CHMP has recommended the approval of Nexavar for use in patients who no longer respond to treatment with radioactive iodine. Although chemotherapy with doxorubicin is authorised in some EU Member States for treatment of these patients, there is currently no generally recommended treatment option for this group, who therefore represent an unmet medical need.

In a study in patients with differentiated thyroid cancer that had spread elsewhere in the body and no longer responded to radioactive iodine, Nexavar was of benefit in slowing the growth of the cancer compared with placebo (a dummy treatment). Adverse reactions, including 'hand-foot syndrome' (a skin reaction with rash and pain on the hands and feet), rash, diarrhoea and weight loss, were commonly observed in patients treated with Nexavar. However, the CHMP considered these risks could be mitigated with appropriate evaluation and monitoring of the patient's symptoms by the physician. Suspected adverse reactions may require temporary interruption of treatment or dose reduction.

The active substance in Nexavar, sorafenib, is a protein-kinase inhibitor. This means that it blocks some enzymes known as protein kinases. These enzymes can be found in some receptors on the surface of cancer cells, where they are involved in the growth and spread of cancer cells, and in the blood vessels that supply the tumours, where they are involved in the development of new blood

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
**Telephone** +44 (0)20 7418 8427 **Facsimile** +44 (0)20 7418 8409
**E-mail** press@ema.europa.eu **Website** www.ema.europa.eu

vessels. By blocking these enzymes, Nexavar can reduce the growth of cancer cells and the blood supply that keeps cancer cells growing.

Nexavar was first authorised in the EU in July 2006. It is currently approved to treat patients who have hepatocellular carcinoma (a type of liver cancer), or advanced renal-cell carcinoma (a type of kidney cancer). These are both rare diseases for which Nexavar was designated as an orphan medicine.

The marketing-authorisation holder for Nexavar is Bayer Pharma AG.

The CHMP opinion on the new indication for Nexavar will now be sent to the European Commission for adoption of a decision on a variation to the terms of the marketing authorisation.

## Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. More information on Nexavar can be found here: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000690/human_med_000929.jsp&mid=WC0b01ac058001d124
3. Country-specific and EU data on thyroid cancer, made available by EUCAN on the basis of data collected by the existing cancer registries and from the WHO mortality database, can be found here: http://eco.iarc.fr/EUCAN/Cancer.aspx?Cancer=35#block-table-a
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

## Contact our press officer

Monika Benstetter

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu