



Bayer HealthCare  
Bayer Schering Pharma



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## Company Statement

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**Newbury, 19 November 2009: Bayer Healthcare** today confirmed that it is to appeal the decision by NICE to deny NHS funding for Nexavar® (sorafenib), a treatment for a type of primary liver cancer known as advanced hepatocellular carcinoma (HCC). NICE's Final Appraisal Determination (FAD) will be available on the NICE website on 19 November 2009.

Whilst NICE acknowledged that Nexavar is the only systemic treatment which could prolong the survival of eligible patients and meets their end of life criteria, it was rejected on the grounds that it was not a cost effective use of NHS resources, even in light of Bayer's UK patient access scheme. NICE does not appear to have acted in accordance with its own processes.

Nicole Farmer Business Unit Head of Bayer Schering Pharma Oncology in the UK commented: "While we recognise that NICE has difficult decisions to make, we are without doubt that today's guidance goes completely against UK HCC treatment guidelines, NICE's own 'end of life' criteria and the current government strategy to bring cancer outcomes in line with Europe. Bayer has proposed an excellent patient access scheme for Nexavar®, unique to the UK, to enable patients in this country to benefit from this life-extending medicine. We believed we had satisfied NICE's criteria for how Nexavar® would be assessed - however, the 'goal posts' appeared to have moved.

We shall appeal against the decision and if we are successful, this will enable the NHS to offer a similar level of access to Nexavar® as other EU countries such as France, Germany, Spain, Italy and Romania where it has already been granted funding," Nicole Farmer concluded.

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**Note to Editors:****Glossary:**

Primary liver cancer: Primary liver cancer is where the cancer originates in the liver.

Systemic therapy: Treatment using substances which travel through the bloodstream, reaching and affecting cells all over the body.

**NICE HCC Decision:**

NICE have today issued FAD for Nexavar in advanced hepatocellular carcinoma. The FAD and evaluation report will be posted on the Institute's website on 19 November 2009.

**About sorafenib for liver cancer:**

Sorafenib was licensed in the UK by the EMEA in October 2007 for the treatment of patients with hepatocellular carcinoma (HCC). Nexavar® is the first systemic drug for advanced HCC to show a significant survival benefit after 30 years of randomised, comparative trials and has demonstrated a 44% increase in survival for advanced HCC patients, compared to best supportive care alone<sup>1</sup>. Cases of liver cancer have almost tripled over the last three decades according to figures recently published by Cancer Research UK<sup>2</sup>. In 1975 there were 865 cases of primary liver cancer and in 2006 that had risen to around 3,200 new cases in the UK<sup>2</sup>. HCC accounts for 80-90% of these primary liver cancers<sup>3</sup>.

**Sorafenib's differentiated mechanism**

Sorafenib targets both the tumour cell and tumour vasculature. In preclinical studies, sorafenib has been shown to target kinases known to be involved in both cell proliferation (growth) and angiogenesis (blood supply) – two important processes that enable cancer growth. These kinases included Raf kinase, VEGFR-2, VEGFR-3, PDGFR-B, c-KIT, FLT-3 and RET<sup>4</sup>. Preclinical models have also demonstrated that the Raf/MEK/ERK pathway has a role in HCC<sup>5</sup>.

**About Bayer Schering Pharma**

Bayer Schering Pharma is a worldwide leading specialty pharmaceutical company. Its research and business activities are focused on the following areas: Diagnostic Imaging, General Medicine, Oncology, Specialty Medicine and Women's Healthcare. With innovative products, Bayer Schering Pharma aims for leading positions in specialised markets worldwide. Using new ideas, Bayer Schering Pharma aims to make a contribution to medical progress and strives to improve the quality of patients' lives.

Further information can be found at [www.bayerscheringpharma.co.uk](http://www.bayerscheringpharma.co.uk)

**Forward-Looking Statements**

This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer Group or subgroup management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at [www.bayer.com](http://www.bayer.com). The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

## References

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