


News Release

**NICE to meet again to discuss Final Appraisal Determination of  Nexavar[®]
(sorafenib) for patients with hepatocellular carcinoma (HCC) – the most common
primary liver cancer in the UK**

HCC patients not yet able to access treatment proven to extend overall survival

Newbury, Berkshire, 21 July 2009: The anticipated National Institute for Health and Clinical Excellence (NICE) decision on the Final Appraisal Determination (FAD) for Nexavar[®] (sorafenib) for the treatment of advanced hepatocellular carcinoma (HCC) has been delayed, to allow consideration of the patient access scheme, Bayer Schering Pharma has agreed with the Department of Health

In response to this delay, Bayer Schering Pharma, manufacturer of Nexavar[®] makes this statement:

"Bayer Schering Pharma is encouraged that NICE has delayed its decision to issue final guidance for Nexavar[®] in HCC. We hope that NICE takes this opportunity to evaluate and fully understand the benefit of our proposed patient access scheme and to listen to leading healthcare professionals in the field who were unanimous in their condemnation of the initial negative proposal.

However, continued lack of funding for Nexavar[®] in the UK for the (approximately) 600 patients for whom it would be appropriate, is frustrating and distressing for both patients and their families who would like to spend vital extra time together.

The incidence of liver cancer is increasing in the UK, with over 3,100 new cases diagnosed in 2005.¹ Liver cancer causes more than 3,000 deaths every year in the UK.² HCC accounts for 80-90 percent of all primary liver tumours.³ Nexavar (sorafenib) is the first systemic therapy to show a survival advantage for patients with HCC in over 30 years of randomised controlled trials. It is proven to extend overall survival by 44 percent compared to best supportive care alone⁴.

NICE has already taken 18 months to review Nexavar for the treatment of advanced HCC, a treatment which is readily available to patients in other European countries and in other parts of the world.

There is wide UK specialist support for Nexavar's role in the treatment of advanced liver cancer. The Hepatobiliary UK Group (HUG) of doctors who specialise in treatment of HCC recently launched guidelines which clearly state that sorafenib is the standard of care for patients with advanced HCC for whom no potential curative option is available⁵.

Bayer Schering Pharma will continue to work with the NICE and the Department of Health through this delay, to secure access to Nexavar for NHS patients with advanced hepatocellular cancer. We hope a favourable decision for patients waiting for access to this treatment is reached. "

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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.

HCC: HCC is the most common form of liver cancer accounting for 80-90 percent of all primary liver tumours.¹

About sorafenib for liver cancer:

Sorafenib was licensed by the EMEA in October 2007. Sorafenib is licensed in the UK for the treatment of patients with hepatocellular carcinoma (HCC) the most common form of primary liver cancer who are unsuitable for loco-regional therapies.

Sorafenib is the only licensed systemic therapy in the UK proven to significantly prolong survival for patients with advanced HCC versus best supportive care alone.

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 RET³. Preclinical models have also demonstrated that the Raf/MEK/ERK pathway has a role in HCC⁴.

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

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