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**NICE Appraisal Consultation Document does not recommend funding Nexavar®[▼]
(sorafenib) for advanced liver cancer patients**

Patients denied chance for extra time with family and loved ones after initial refusal to fund first systemic therapy proven to extend overall survival

Newbury, 6th May 2009: The National Institute for Health and Clinical Excellence (NICE) has issued its Appraisal Consultation Document (ACD) for Nexavar® (sorafenib) for the treatment of advanced liver cancer. The NICE appraisal consultation document does not recommend the use of sorafenib for the treatment of hepatocellular carcinoma (HCC – a type of liver cancer). The recommendations are preliminary and open for consultation. This decision directly conflicts with current UK and Global guidelines for recommended treatment of HCC.

HCC is the most common form of liver cancer accounting for 80-90 percent of all primary liver tumours.¹ The incidence of liver cancer is increasing in the UK, with over 3,100 new cases diagnosed in 2005.² Liver cancer causes more than 3,000 deaths every year in the UK.³

"Recently the Hepatocellular UK Group (HUG) - doctors who specialise in treatment of HCC - launched guidelines for the management of suspected HCC in adults. These guidelines clearly state that sorafenib is the standard of care for patients with advanced HCC for whom no potential curative option is available. Patients with advanced HCC should be able to access the latest specialised medicines via the NHS. This enables physicians to provide the best possible care for patients and allow as good a quality of life as possible at such an important time." said Dr. Graeme Poston, on behalf of the Hepatocellular UK Group (HUG), President-Elect of the Association of Upper Gastrointestinal Surgeons (AUGIS) and former President of the British Association of Surgical Oncologists (BASO).

Nicole Farmer, Business Unit Head of Bayer Schering Pharma Oncology in the UK said "Bayer Schering Pharma is gravely disheartened by this latest NICE announcement. Nexavar is the first systemic therapy to show a survival advantage for patients with advanced HCC, the most common form of primary liver cancer¹. Nexavar is proven to extend overall survival by 44 percent compared to best supportive care alone⁴, as well as maintain quality of life."

"It has taken NICE 18 months to review Nexavar for the treatment of advanced liver cancer. In that time, many patients have been fighting for access to Nexavar with the hope NICE would fund the only systemic therapy proven to extend overall survival. The time it has taken to review Nexavar in advanced liver cancer, and the decision to not recommend it, clearly undermine the government's own cancer strategy particularly for a disease for which the mortality is increasing. This is a major blow for UK HCC patients who will be denied access to the only effective systemic treatment available for their condition, a treatment that is readily available to patients in other European countries."

The consultation period for this ACD closes on 29th May 2009 with a second appraisal committee meeting scheduled for 11th June 2009.

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Notes for 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 RET⁵. Preclinical models have also demonstrated that the Raf/MEK/ERK pathway has a role in HCC⁶.

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.

Bayer Schering Pharma's portfolio of oncological products includes treatments for both solid and haematological malignancies. Intensive research is ongoing as Bayer Schering Pharma strives to discover and advance therapeutic solutions for the benefit of all cancer patients.

For more information, please visit www.bayerscheringpharma.co.uk

Nexavar® (sorafenib) tablets is a registered trademark of Bayer Pharmaceuticals Corporation.

Forward-Looking Statements

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References:

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