

News release for consumer media

Nexavar[®] ▼ (sorafenib): New hope and new treatment for hepatocellular carcinoma, the most common primary liver cancer in the UK

Sorafenib is the first systemic therapy for patients, with hepatocellular carcinoma (HCC) the most common form of primary liver cancer, proven to extend survival compared to best supportive care alone

Newbury, Berkshire – 2 November, 2007 – From today, doctors in the UK are able to prescribe a new treatment option for patients with hepatocellular carcinoma (HCC), the most common form of primary liver cancer. Sorafenib, an oral treatment, is now approved for treating patients with HCC.¹ This type of cancer accounts for 80-90 percent of all primary liver tumours.²

“Before the availability of sorafenib there were no licensed systemic therapies in the UK proven to significantly prolong survival for patients with advanced HCC versus best supportive care alone,” said Philip Johnson, Professor of Oncology at the University of Birmingham. “The availability of sorafenib is an important milestone in the treatment of advanced HCC. For three decades clinical trials with different drugs have been undertaken in HCC, yet none has provided robust data to demonstrate prolongation of survival versus best supportive care alone until the sorafenib SHARP Phase III trial results were reported in June this year.”

The licence for sorafenib was based on data from the Phase III **Sorafenib HCC Assessment Randomized Protocol (SHARP)** trial which demonstrated that sorafenib improved overall survival by 44 percent in patients with advanced HCC (HR=0.69; p=0.0006) versus best supportive care alone.³

Sorafenib is a multikinase inhibitor and works against two important factors in cancer growth. It works by slowing down the rate of growth of cancer cells and by cutting off the blood supply that keeps cancer cells growing.⁴

“Great strides have been made in the past 20 years to unravel the basic biological processes that are disturbed by the onset of cancer, and these discoveries have led to an understanding about the processes involved in ‘switching on’ cancer. This has led to the hunt for rationally-designed anticancer drugs, such as sorafenib, that can intervene in or “turn down” these cancer processes,” commented Karol Sikora, Professor of Cancer Medicine, Imperial College School of Medicine, Hammersmith Hospital.

HCC is a type of primary liver cancer. Primary liver cancer is the sixth most common cancer worldwide,⁵ and the third leading cause of cancer-related deaths globally.⁵ Primary liver cancer disproportionately affects men, giving a male: female ratio of around 3:2.⁶

‘Primary’ liver cancer is when the cancer begins in the liver and this type of cancer is relatively rare in the UK. Each year there are around 2,800⁶ new cases of primary liver cancer diagnosed and every year the disease is responsible for causing around 2,800 deaths in the UK.⁷ The

outlook for patients diagnosed with primary liver cancer is often poor as the disease typically does not cause symptoms until the cancer is in its later stages.⁸ Only around 1 in 20 patients are alive 5 years after diagnosis.⁹

“The UK is currently the only developed nation experiencing an increase in liver disease and the number of cases of primary liver cancer in the UK has increased by 44% over the last decade. Current lifestyles clearly show that we are storing up serious liver problems for the future. This will have a knock-on effect and the diagnosis of primary liver cancer is likely to continue to increase,” commented Alison Rogers, Chief Executive of the British Liver Trust.

“Sorafenib represents a breakthrough for advanced HCC patients and the rapid approval of this treatment by the European Authority emphasises the potential of sorafenib to become the standard of care for the treatment of advanced HCC,” commented Philip Ashman, Business Unit Head of Bayer Schering Pharma (BSP) Oncology Division in the UK. He continued: “This is the second licensed indication for sorafenib – which is already approved in advanced renal carcinoma (RCC), the most common form of kidney cancer. In advanced HCC, sorafenib has been shown to improve overall survival – and the translation of science into clinical practice and patient benefit is something to be proud of.”

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NOTE TO EDITORS:

Glossary:

Hepatocellular Carcinoma (HCC)	The most common form of primary liver cancer
Systemic Therapy	A drug which when administered affects the whole body and not just part of it.
Overall Survival (OS)	The time that a patient continues to live after randomisation
Renal Cell Carcinoma (RCC)	The most common type of kidney cancer in adults
EMA	European Medicines Agency. Responsible for the scientific evaluation of applications for European marketing authorisation for medicinal products (centralised procedure)

About Sorafenib:

Primary Liver cancer:

Nexavar[®] (sorafenib) was approved by the EMA in October 2007 and licensed for the treatment of patients with hepatocellular carcinoma (HCC)

The licence for sorafenib was based on data from the Phase III **Sorafenib HCC Assessment Randomized Protocol (SHARP)** trial which demonstrated that sorafenib improved overall survival

by 44 percent in patients with advanced HCC (HR=0.69; p=0.0006) versus placebo.^{1,3} The most commonly observed (occurring in >5% of subjects) adverse reactions (CTC-Grade 3) were diarrhoea and hand-foot skin reaction. The incidence of Grade 4 adverse reactions is less than 1%.¹

Kidney cancer:

Sorafenib was first approved by the EMEA in July 2006. Sorafenib is approved in the UK for the treatment of patients with advanced renal cell carcinoma (the most common form of kidney cancer), who have failed prior interleukin-2 or interferon-alpha based therapy, or are considered unsuitable for such therapy. Prior to EMEA approval of sorafenib, there had not been any new classes of licensed kidney cancer treatment in Europe for over 10 years.

Bayer Schering Pharma:

Bayer Schering Pharma is a leading, worldwide speciality pharmaceutical company. Its research and business activities are focussed on the fields of oncology, haematology & cardiology, diagnostic imaging, primary care, specialised therapeutics and women's healthcare. With innovative products and using new ideas, Bayer Schering Pharma aims to make a contribution to medical progress and strives to improve the quality of life of patients - a factor of particular importance in Oncology.

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.

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