



Press Release

FINAL CHANCE FOR LIVER CANCER PATIENTS

On 26th February 2010

NICE to hear Bayer's appeal on the Institute's decision not to recommend NHS funding for Nexavar® in patients with the most common primary liver cancer

The National Institute for Health and Clinical Excellence (NICE) will convene today to decide the fate of 600 UK patients with advanced hepatocellular carcinoma (HCC). The institute will consider Bayer's appeal (submitted 3rd December 2009) of its draft negative Final Appraisal Determination (FAD) for Nexavar® (sorafenib) in HCC, published on its website on the 19th November 2009, after nearly two years of consultation. Bayer appealed on the grounds that NICE failed to act fairly and in accordance with its own published procedures. Following the outcome of today's hearing, NICE will issue their final ruling in March 2010 (exact date tbc). The consultation process does not allow for further appeals.

Nicole Farmer, Business Unit Head of Bayer Schering Pharma Oncology in the UK, said: "It is so frustrating that for the 600 liver cancer patients who could really benefit from Nexavar, there still remains the chance that they will be denied. We really hope that NICE takes this opportunity to reconsider some of the data and ensures that real innovations in healthcare, like Nexavar, are made available to all who need it, not just those who could afford to pay privately".

Today's appeal is not in isolation. A number of 'unofficial' appeals have revealed a national sense of injustice and sadness throughout the UK since the negative ruling in November. Patients and clinicians publicly expressed their despair through a high profile media appeal, patient groups publically damned the decision in published press statements and a systematic letter writing campaign by oncologists to NICE and the media, revealed the extent of the disappointment and frustration experienced by the UK medical community.

"In rare cancers such as HCC, the statistically proven benefit and quality of life that sorafenib can offer patients is unique. That is why so many members of the oncology community in the UK have

spoken out publically against the decision”, commented Mr Graeme Poston, Director of the Liver Surgery Unit at Aintree University Hospitals NHS Foundation, one of the largest liver cancer surgery centres in Europe.

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 alone¹. Cases of liver cancer have almost tripled over the past three decades according to figures recently published by Cancer Research UK². In 1975 there were 865 cases of primary liver cancer and in 2006 that had risen to around 3,200 new cases in the UK². HCC accounts for 80-90% of these primary liver cancers³.

Professor Karol Sikora, Professor of Cancer Medicine and Medical Director of CancerPartnersUK said: “Since NICE’s decision not to fund the drug in November, many clinicians (a number of whom would have been involved in the UK trials of the drug) have been put in the painful position of having to deny their patients the only survival option for them. As we reach the end of this laborious process, which has left both patients and clinicians in limbo for far too long, we can only hope that NICE will use this final window of time to properly consider the very strong recommendations from UK oncologists, who only want the best for their patients”.

Bayer has appealed the decision on a number of counts, including that:

- The Appraisal Committee has failed to explain why it has changed its conclusions with respect to the modelling of overall survival following Nexavar treatment, in the absence of new data regarding this effect.
- The Institute has acted in a non-transparent and unfair manner by not stating the degree to which they considered evidence received during the appraisal regarding appropriate survival extrapolation methods
Insufficient time was allowed for consideration of the response to consultation by the Appraisal Committee in this case
- In reaching its recommendation, the Institute has failed to place adequate weight on innovation and has therefore acted unfairly and not fulfilled its obligations to the Secretary of State in considering the long term benefits of innovation to the NHS

Ends

Contact(s) for further information:

Janine Hogan

Bayer Schering Pharma

Tel: +44 (0)1635 563 587

Mob: +44 (0) 7990 696 970

Email: janine.hogan@bayerhealthcare.com

Vanessa Leon

Leon PR

Tel: +44 (0) 8202 0182

Mob: +44 (0) 7904 958 323

Email: vanessa.leon@leonpr.com

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.

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 alone¹.

Cases of liver cancer have almost tripled over the last three decades according to figures recently published by Cancer Research UK².

In 1975 there were 865 cases of primary liver cancer and in 2006 that had risen to around 3,200 new cases in the UK². HCC accounts for 80-90% of these primary liver cancers³.

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 RET⁴. Preclinical models have also demonstrated that the Raf/MEK/ERK pathway has a role in HCC⁵.

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

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. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

References

1. Sorafenib in advanced Hepatocellular Carcinoma. J. Llovet, S. Ricci, V. Mazzaferro, P. Hilgard, J. Raoul, S. Zeuzem, M. Poulin-Costello, M. Moscovici, D. Voliotis, J. Bruix, For the SHARP Investigators Study Group. *N Eng J Med* 2008; 359:378-90.
2. Cancer Research UK Liver Cancer (Increasing incidence) website. Accessed 18th February 2010 .<http://info.cancerresearchuk.org/cancerstats/types/liver/incidence>
3. Wilson JF. Liver Cancer on the Rise. *Ann Int Med*, 2005; 142(12):1029-32. Sorafenib in advanced Hepatocellular Carcinoma. J. Llovet, S. Ricci, V. Mazzaferro, P. Hilgard, J. Raoul, S. Zeuzem, M. Poulin-Costello, M. Moscovici, D. Voliotis, J. Bruix, For the SHARP Investigators Study Group. *N Eng J Med* 2008; 359:378-90.
4. Nexavar (sorafenib) Summary of Product Characteristics, Bayer HealthCare AG.
5. Liu, L, Y. Cao, et al. *Cancer Res*, 2006; 66(24):11851-8.