



Company Statement

Newbury 03 December 2009, Bayer Healthcare today submitted its appeal to NICE, contesting the institute's Final Appraisal Determination (FAD) to deny patients with advanced hepatocellular carcinoma (HCC), the commonest form of primary liver cancer, NHS funding for Nexavar® (sorafenib). Bayer appealed on the grounds that NICE's final guidance is 'perverse' in light of the evidence submitted and that it failed to act fairly and in accordance with its own published procedures. NICE's FAD was published on its website on 19th November 2009, following almost two years of consultation.

Nicole Farmer, Business Unit Head of Bayer Schering Pharma Oncology in the UK said: "Bayer has appealed NICE's negative decision because we believe that the Institute has acted outside its own protocol and failed to adequately consider clinical need and innovation in its decision making. Nexavar® is only suitable for a very small number of patients with advanced HCC - about 600 in the UK - who have a very high clinical need. Equally, Nexavar is a truly innovative product - the first systemic therapy to show survival advantage in 30 years and in more than 75 clinical trials."

"As well as not accounting for the Secretary of State's direction, the FAD is also out of line with both the Kennedy report and the Office of Life Sciences (OLS) Blueprint in not making explicit how NICE has assessed the innovative nature of Nexavar. And it also flies in the face of the UK HCC treatment guideline, NICE's own 'end of life' criteria and the Government's strategy to bring cancer outcomes in line with Europe. Bayer will continue to fight to make Nexavar® available to the 600 UK patients who desperately need it", concluded Nicole.

In reaction to Bayer's appeal submission, Andrew Wilson Webb, Chief Executive of the *Rarer Cancer Forum* said: "In rare cancers such as HCC, the survival benefit and quality of life that sorafenib can offer patients is unique and so we stand behind Bayer's appeal to NICE".

He continues: "Sadly, NICE was established to increase innovation and to ensure that effective, innovative drugs are funded by the NHS, but it seems to have instead become a gatekeeper to protect the NHS budget.

One has to question how many lives could have been saved in the two years NICE took to assess the treatment and how much financial waste was incurred during this time, that could have been used to fund patients with sorafenib. The larger question is of course what kind of impact such decisions by NICE will have on the future of medical science in the UK?”.

Alison Rogers, Chief Executive of the British Liver Trust commented: “We understand that NICE exists to run an evidence-based process for decision-making in the NHS about clinical effectiveness and cost. We also understand that every treatment has an opportunity cost for other patients. Nonetheless the decision is a bitter blow for the patients with liver cancer who have no other treatment options and who may often have been stigmatized through the incorrect assumption that most liver disease is alcohol related. A patient with an auto-immune or genetic liver disease who has spent years being asked if they are drinker whilst suffering gradually decreased quality of life and developing cirrhosis and then cancer is very much at the harsh end of this process.”

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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.

Appeal Submission

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

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

In reaching its recommendation, the Institute has failed to take into account the follow up research programme offered by Bayer as part of the Patient Access Scheme (PAS) which would address any residual uncertainty regarding survival, and has therefore acted unfairly.

The Institute has acted unfairly by not accounting for the degree of clinical need of patients under consideration as directed by the Secretary of State.

The Appraisal Committee's approach to the difference between independent and investigator assessments of time to disease progression in the SHARP trial is inappropriate and unfair

The Appraisal Committee has not explained its conclusion that the magnitude of additional weight that would need to be assigned to the original QALY benefits would be too great for the product to be cost-effective.

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

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References

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2. Cancer Research UK Liver Cancer (Increasing incidence) website. Accessed 5th November 2009 .<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.