

## **PRESS RELEASE**

### **Liver cancer drug not recommended for the NHS**

NICE has been unable to recommend sorafenib (Nexavar, Bayer) for treating advanced hepatocellular carcinoma (HCC) because its high cost could not be justified by its marginal benefit.

HCC is a cancer that originates in the liver, not as the result of tumours spreading to the liver from other parts of the body. The only potentially curative treatment for HCC is surgery, but only a small proportion of patients will be eligible for this. Normal life expectancy for these patients is less than 24 months. The trial evidence seen by NICE's independent advisory committee showed that sorafenib increases survival by an average further 2.8 months, but at a cost of £27,000 per patient. Half of the patients who gained some benefit received less than this amount of additional life.

In final guidance published today (26 May, 2010) NICE has not recommended sorafenib for treating advanced HCC in patients for whom surgery or therapies in the region the cancer arose have failed or are not suitable.

**Andrew Dillon, Chief Executive of NICE said:** "We were disappointed not to have been able to recommend the use of sorafenib, but after carefully considering all the evidence, including the proposed 'patient access scheme', in which the manufacturer offered to provide every fourth pack free, sorafenib does not provide enough benefit to patients to justify its high cost.

"We have changed our approach to appraising high cost treatments which can potentially extend life for terminally ill patients. This has meant that more of them are now being recommended. We looked at sorafenib in just the same way but the price is simply too high to justify using NHS money which could be spent on better value, more effective cancer treatments."

The appeal against the Final Appraisal Determination from Bayer was not upheld.

## Ends

## Notes to Editors

### About the guidance

1. The guidance can be found on the NICE website - <http://guidance.nice.org.uk/TA189>
2. Cost-effectiveness is the additional cost of one year of healthy life (expressed as the cost per quality adjusted life year, or QALY, gained). The Committee did not consider that there was a single estimate of the cost-effectiveness of sorafenib; instead there was a range of plausible cost-effectiveness estimates. When the Patient Access Scheme for sorafenib was included, the lowest end of the range was £52,600 per QALY gained and the highest end of the range was substantially greater. NICE typically recommends the NHS to use treatments when they fall within a range from £20-30,000 per QALY. This can be extended to between £40-50,000 per QALY for treatments, used when a patient is close to death and which can extend life for more than 3 months.
3. The Pharmaceutical Price Regulation Scheme 2009 makes provisions for manufacturers and sponsors to submit proposals for patient access schemes to the Department of Health. These schemes involve innovative pricing agreements designed to improve cost effectiveness and facilitate patient access to specific drugs or other technologies.
4. The manufacturer (Bayer) would pay for every fourth pack of sorafenib under the proposed patient access scheme.
5. Bayer submitted an appeal on the final draft guidance which was heard on 26 February, 2010. The appeal was dismissed by the Appeal Panel.

### About NICE

6. The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health.
7. NICE produces guidance in three areas of health:
  - **public health** – guidance on the promotion of good health and the prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector
  - **health technologies** – guidance on the use of new and existing medicines, treatments and procedures within the NHS
  - **clinical practice** – guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS.