

EXTERNAL BRIEFING DOCUMENT FOLLOWING NICE DECISION



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NICE continues to ration access to kidney cancer medicines, preventing doctors from providing the best possible treatment option for each individual patient

Newbury, 28th April, 2009: Today the National Institute for Health and Clinical Excellence (NICE) announced the Final Appraisal Determination (FAD) for Nexavar® (sorafenib), Sutent® (sunitinib), Avastin® (bevacizumab) and Torisel® (temsirolimus) in advanced kidney cancer. NICE has not recommended sorafenib, bevacizumab and temsirolimus as first line treatment option for kidney cancer. Furthermore, it does not recommend sorafenib or sunitinib for second line treatment for renal cell carcinoma (RCC) patients.

More than 7,000 people in the UK are diagnosed with kidney cancer each year, of which 1,700¹ will have the advanced form of the disease.

“By approving only one of the four active drugs for renal cell carcinoma NICE is pursuing a one size fits all policy for this complicated disease. This one dimensional approach will leave some patients without potentially beneficial treatments, indeed some patients will not be eligible for any effective treatments whatsoever.” said Dr. Thomas Powles, Clinical Senior Lecturer, Barts and The London NHS Trust.

Kate Spall, Head of The Pamela Northcott Fund, commented "For those currently living with advanced kidney cancer and fighting for access to treatment options, NICE's final pronouncement will be devastating news. By rejecting these treatments used to prolong the lives of advanced kidney cancer patients, patients and their families will be denied additional time together. Furthermore by limiting the treatment options doctors will be unable to give individual patients their best possible treatment which could mean better quality of life at such an important time."

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Nicole Farmer, Business Unit Head of Bayer Schering Pharma Oncology in the UK said “Bayer Schering Pharma is disappointed with the NICE decision and feels that patients with RCC should have the chance to access life prolonging medication. For those that can benefit from sunitinib, the earlier recommendation was a step forward. Unfortunately, not all RCC patients will be able to benefit from this treatment or be suitable to try it in the first instance.” She added: “NICE have recognised that Nexavar is a clinically effective² life-extending end-of-life treatment³ with robust evidence in its support. It is widely accepted that allowing healthcare professionals greater access to a fuller range of treatment options for RCC patients, will make them better able to tailor treatment decisions to each patient individually. The patient, ultimately, benefits. This decision by NICE reaffirms why the UK currently sits 16 out of 18 EU countries with regard to cancer outcomes.”

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Notes for Editors:

NICE RCC Decision:

NICE have today issued a Final Appraisal Determination (FAD) for the four kidney cancer drugs. NICE has not recommended Nexavar® (sorafenib), Avastin® (bevacizumab) and Torisel® (temsirolimus) as first-line treatment options for people with advanced and/or metastatic RCC. NICE also did not recommend Nexavar® and Sutent® (sunitinib) as second line treatment options for people with advanced and/or metastatic RCC.

About sorafenib for 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

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approval of sorafenib, there had not been any new classes of licensed kidney cancer treatment in Europe for over 10 years.

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 HCC⁵.

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.

References:

1. Kidney cancer drug gets go-ahead; BBC News <http://news.bbc.co.uk/1/hi/health/7867817.stm> Accessed 23 April 2009
2. Appraisal consultation document – Bevacizumab, sorafenib, sunitinib (second line) and temsirolimus for the treatment of advanced and/or metastatic renal cell carcinoma, section 4.3.18.
3. Appraisal consultation document – Bevacizumab, sorafenib, sunitinib (second line) and temsirolimus for the treatment of advanced and/or metastatic renal cell carcinoma, section 4.3.20.
4. Nexavar (sorafenib) Summary of Product Characteristics, Bayer HealthCare AG, 2007.
5. Liu, L, Y. Cao, et al. Cancer Res, 2006; 66(24):11851-8