Bayer

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Nexavar Fact Sheet

Approval and Usage

- Nexavar® (sorafenib) tablets, currently approved in more than 50 countries, were approved by the U.S. Food and Drug Administration (FDA) in December 2005, making it the first FDA-approved treatment for advanced RCC, or kidney cancer, in more than a decade.
- In July 2006, Nexavar was approved by the European Medicines Agency (EMEA) for the treatment of patients with advanced RCC who have failed prior interferon-alpha or interleukin-2 based therapy or are considered unsuitable for such therapy.

Background

- Nexavar was co-developed by Bayer Schering Pharma, AG and Onyx Pharmaceuticals, Inc.
- Nexavar is being evaluated by the companies, international study groups, government agencies or individual investigators as a single agent or combination treatment in a wide range of cancers, including adjuvant RCC, advanced liver cancer (HCC), metastatic melanoma, non-small cell lung cancer (NSCLC) and breast cancer.

Mechanism of Action

Nexavar is an oral multi-kinase inhibitor that targets both the tumor cell and tumor vasculature. In preclinical models, Nexavar targeted members of two classes of kinases that are involved in cell proliferation (growth) and angiogenesis (blood supply) - two important processes that enable cancer growth. These kinases included RAF kinase, VEGFR-1, VEGFR-2, VEGFR-3, PDGFR-β, KIT, FLT-3 and RET.

Important Safety Considerations

Hypertension may occur early in the course of therapy and blood pressure should be monitored weekly during the first six weeks of therapy and treated as needed. Incidence of bleeding regardless of causality was 15% for Nexavar vs. 8% for placebo and the incidence of treatment-emergent cardiac ischemia/infarction was 2.9% for Nexavar vs. 0.4% for placebo. Gastrointestinal perforation was an uncommon event and has been reported in less than 1% of patients taking Nexavar. Most common treatment-emergent adverse events with Nexavar were diarrhea, rash/desquamation, fatigue, hand-foot skin reaction, alopecia, and nausea. Grade 3/4 adverse events were 38% for Nexavar vs. 28% for placebo. Women of child-bearing potential should be advised to avoid becoming pregnant and advised against breast-feeding. In cases of any severe or persistent side effects, temporary treatment interruption, dose modification or permanent discontinuation should be considered.

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Forward Looking Statements
This information contains forward-looking statements based on current assumptions and forecasts made by Bayer Group 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 filed with the Frankfurt Stock Exchange and with the U.S. Securities and Exchange Commission (including its Form 20-F). Bayer assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

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