



Fact Sheet

Bayer Schering Pharma Development Projects

Business Unit: Oncology

Development candidate sorafenib – multi-kinase inhibitor with a dual-action mechanism against cancer

- First agent ever to demonstrate a significant survival benefit in liver cancer (hepatocellular carcinoma, or HCC) patients
- Significantly extends overall survival in liver cancer patients
- Development potential in various cancer indications

Status: June 2007

<p>Project description</p> <p>The small molecule active substance sorafenib is recently being tested in various cancer indications. The cancer medication has been approved for advanced renal cancer.</p> <p>The positive results of a Phase III study (SHARP) in patients with hepatocellular carcinoma were presented at the annual meeting of the American Society of Clinical Oncology (ASCO) in the beginning of June 2007. Sorafenib is the first active substance to significantly prolong the overall survival (by 44 percent) of patients with HCC. Median overall survival was 10.7 months in sorafenib-treated patients compared to 7.9 months in those taking placebo. The trial was halted in February 2007 when an independent data monitoring committee determined in a pre-scheduled analysis that the overall survival endpoint</p>	<p>At a glance</p>
	<p>Name of the active substance</p> <p>Sorafenib</p>
	<p>Type of substance</p> <p>Small molecule</p>
	<p>Administration form</p> <p>Tablets</p>

<p>had been met. All patients taking part in the trial were offered to continue sorafenib treatment. There were no significant differences in serious adverse events between the sorafenib and placebo-treated groups. Based on the strength of the data, Bayer and Onyx are now in the process of preparing applications to the U.S. Food and Drug Administration (FDA) and European health authorities for this new indication for Nexavar in treatment of patients with liver cancer.</p>	<p>Targeted Indication</p> <ul style="list-style-type: none"> ▪ Renal cancer (approved) ▪ Clinical programs are underway in other, various solid tumors (liver cancer, lung cancer, breast cancer, skin cancer)
<p>Hepatocellular carcinoma</p> <p>Hepatocellular carcinoma (HCC) is the most common form of liver cancer and is responsible for about 90 percent of the primary malignant liver tumors in adults. It is the fifth most common cancer in the world and the third leading cause of cancer-related deaths globally. Over 600,000 new cases of HCC are diagnosed globally each year (19,000 in the United States and 32,000 in the European Union), and in 2002 approximately 600,000 people (about 13,000 Americans and 57,000 Europeans) died of HCC. Although overall cancer incidence and mortality are decreasing in the United States, both the incidence and mortality of liver cancer are increasing.</p>	<p>Mode of action</p> <p>Multi-kinase inhibitor with a dual-action mechanism: inhibition of cancer cell proliferation and prevention of angiogenesis</p>
<p>Sorafenib</p> <p>Sorafenib is a multi-kinase inhibitor with a dual-action mechanism against cancer. It targets both the tumor cell and tumor vasculature, which are existential for tumor growth.</p> <p>In preclinical studies, sorafenib has been shown to target members of two classes of 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-1, VEGFR-2, VEGFR-3, PDGFR-B, KIT, FLT-3 and RET. Preclinical models have also demonstrated that the Raf/MEK/ERK-pathway has a role in HCC; therefore</p>	<p>Status</p> <ul style="list-style-type: none"> ▪ Phase III study (SHARP) in liver cancer completed ▪ Registration for approval in the EU submitted ▪ Broad trial program in various oncological indications ▪ Approved for the indication renal cancer

<p>blocking signaling through Raf-1 may offer therapeutic benefits in HCC.</p> <p>Nexavar (sorafenib) is currently approved in more than 50 countries, including the United States and in the European Union, for the treatment of patients with advanced renal cancer: In Europe, sorafenib is approved for the treatment of patients with advanced renal cell carcinoma (RCC) who have failed prior interferon-alpha or interleukin-2 based therapy or are considered unsuitable for such therapy.</p> <p>The SHARP trial in liver cancer</p> <p>The international, Phase III, placebo-controlled Sorafenib HCC Assessment Randomized Protocol (SHARP) trial randomized and evaluated 602 liver cancer patients who had no prior systemic therapy at sites in the Americas, Europe, and Australia/New Zealand. The primary objective of the study was to compare overall survival and the time until disease progression in patients administered sorafenib versus those administered placebo. With regard to severe side effects, no significant differences could be observed. The most frequent adverse events monitored in patients receiving sorafenib were diarrhea and skin irritations on the hands and feet.</p> <p>Clinical trials in other oncological indications</p> <p>Recent data show a broad development potential for sorafenib in the area of oncology. Hence, sorafenib is tested as a mono- and combination therapy in various other cancer indications by Bayer and Onyx, as well as international study groups, public authorities, and individual clinicians. This research includes the possible adjuvant therapy of renal carcinoma, melanoma, breast cancer, and non-small cell lung cancer(NSCLC). Recently, the recruitment of over 900 patients with NSCLC for the Phase III study ESCAPE (Evaluation of sorafenib, carboplatin, and paclitaxel efficacy in NSCLC) was completed.</p>	<p>Collaborating partner Onyx Pharmaceuticals, Inc. Emeryville, CA, USA www.onyx-pharm.com</p>
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Bayer HealthCare

Bayer HealthCare, a subsidiary of Bayer AG, is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. The company combines the global activities of the Animal Health, Consumer Care, Diabetes Care and Pharmaceuticals divisions. The pharmaceuticals business operates under the name Bayer Schering Pharma and as Bayer HealthCare Pharmaceuticals in the US and Canada. Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide.

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, Hematology/Cardiology, Oncology, Primary Care, Specialized Therapeutics and Women's Healthcare. With innovative products, Bayer Schering Pharma aims for leading positions in specialized markets worldwide. Using new ideas, Bayer Schering Pharma aims to make a contribution to medical progress and strives to improve the quality of life.

Research and Development at Bayer Schering Pharma

Bayer Schering Pharma concentrates its R&D activities on innovative treatment approaches for diseases with a high unmet medical need to improve patients' quality of life and prolong lives. In this context, Bayer Schering Pharma focuses on its core competencies and its many years of experience. Thus, Bayer Schering Pharma holds a leading position in many therapeutic fields: for example, in the treatment of hemophilia and multiple sclerosis, in contrast media and oral contraception. We are also striving for a leading position in oncology. With new approaches in cancer therapy, for cardiovascular diseases, gynaecological therapies and in molecular imaging, Bayer Schering Pharma aims to become an innovation leader in these fields. In addition, Bayer Schering Pharma further develops products already on the market in order to improve their application and/or extend their range of indications.

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