



Nexavar[®] (sorafenib) tablets

Nexavar emerged from our collaboration with Bayer focused on identifying and developing inhibitors of inappropriate signaling which causes cancer. Nexavar targets both the tumor cell and the tumor vasculature. In preclinical studies, Nexavar has been shown to inhibit 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- β , KIT, FLT-3, and RET.

Nexavar is approved in more than 60 countries for patients with advanced kidney cancer and in the U.S. and EU for liver cancer.

Onyx and Bayer are conducting a comprehensive development program to realize the full potential of Nexavar as an anticancer agent. Our goal is to leverage Nexavar's tolerability, convenient oral administration, and combinability to address significant unmet needs in the treatment of a broad range of cancers. As part of this program, Nexavar is currently being investigated in several ongoing trials in non-small cell lung cancer, metastatic melanoma, breast cancer and other tumor types.

KIDNEY CANCER

In December 2005, the FDA approved Nexavar[®] (sorafenib) tablets for the treatment of patients with advanced kidney cancer. The companies also announced the initiation of the Resources for Expert Assistance and Care Helpline (REACH[®]), which is available to answer questions about Nexavar treatment, reimbursement, and patient support. For more information, healthcare providers and patients may contact the REACH program at 1.866.NEXAVAR (1.866.639.2827).

Nexavar's approval in the U.S. followed a report at the annual meeting of the American Society of Clinical Oncology (ASCO) in May 2005 that Nexavar was generally well tolerated and significantly delayed disease progression in an ongoing Phase 3 clinical trial in patients with advanced kidney cancer. As assessed by independent radiologic review, progression-free survival (PFS) was doubled to a median value of 24 weeks (167 days) in patients receiving Nexavar, compared to 12 weeks (84 days) for patients receiving placebo.

In July 2006, the European Commission granted marketing authorization to Nexavar for the treatment of patients with advanced renal cell carcinoma who have failed prior interferon-alpha or interleukin-2 based therapy or are considered unsuitable for such therapy.

LIVER CANCER

We were recently granted approval in the U.S. and the EU for Nexavar in a second indication, liver cancer. The approvals were based on positive data from the international, Phase 3, placebo-controlled Sorafenib HCC Assessment Randomized Protocol (SHARP) trial, which demonstrated that Nexavar extended overall survival in patients with hepatocellular cancer (HCC), or primary liver cancer, versus those taking placebo by 44% (HHR=0.69; p=0.0006). Presented at the ASCO annual meeting in June 2007, these data showed that median overall survival for Nexavar-treated patients was 10.7 months compared to 7.9 months in those taking placebo.

Bayer and Onyx halted the SHARP trial in February 2007 when an independent data monitoring committee determined in a pre-scheduled analysis that the overall survival endpoint had been met. There were no significant differences in serious adverse event rates between the Nexavar- and placebo-treated groups, with the most commonly observed serious adverse events in patients receiving Nexavar being diarrhea and hand-foot-skin reaction.

PARTNER STATUS

We and Bayer are developing and marketing Nexavar under our collaboration and co-promotion agreements. We fund 50 percent of the development costs for Nexavar worldwide, except in Japan. With Bayer, we are co-promoting Nexavar in the United States and sharing equally in any profits or losses. Everywhere else in the world, except in Japan, Bayer has exclusive marketing rights and we share profits 50/50. In Japan, Bayer funds all product development, and will receive a royalty. Our agreement with Bayer also provides that we receive creditable milestone-based payments totaling \$40 million, all of which have been received. These payments will be repayable by us to Bayer from a portion of any of our profits and royalties.