



Nexavar[®] (sorafenib) tablets

Nexavar[®] (sorafenib) tablets, is a novel, oral multiple kinase inhibitor that targets proteins involved in both tumor cell proliferation and angiogenesis (the formation of new blood vessels to support cancer cell growth).

Nexavar is approved in more than 90 countries for the treatment of patients with hepatocellular carcinoma (HCC), or liver cancer and in more than 95 countries for the treatment of patients with advanced renal cell carcinoma (RCC), or kidney cancer. Nexavar is the first approved oral targeted therapy for liver cancer and the only one shown to significantly improve overall survival in patients with the disease.

Nexavar emerged from a collaboration with Bayer Healthcare Pharmaceuticals, focused on identifying and developing inhibitors of inappropriate signaling, which causes cancer.

In preclinical studies, Nexavar was shown to inhibit the enzyme RAF kinase, which is a critical component of the RAS pathway - an important cascade of chemical signals that controls cell division. Abnormal activation of the RAS pathway is believed to play an integral role in the genesis of many cancers. Additionally, Nexavar inhibits VEGFR-2 and PDGFR- β , key receptors of vascular endothelial growth factor (VEGF) and platelet-derived growth factor (PDGF), which play important roles in angiogenesis. Nexavar also inhibits other tyrosine kinases such as c-KIT and FLT-3.

Our goal is to leverage Nexavar's tolerability, convenient oral administration, and combinability to address significant unmet needs in the treatment of a variety of cancers. Nexavar is currently being evaluated in randomized Phase 3 trials in non-small cell lung cancer, thyroid cancer, and as an adjuvant treatment for liver and kidney cancer. The agent is also being studied in multiple Phase 2 trials in breast cancer, colorectal cancer and ovarian cancer, as well as in several Phase 1b studies evaluating its use in combination with standard chemotherapies and other anticancer agents.

KIDNEY CANCER

In December 2005, the FDA approved Nexavar for the treatment of patients with advanced kidney cancer.

Nexavar was approved in the U.S. following data presented at the 2005 Annual Meeting of the American Society of Clinical Oncology (ASCO) from an ongoing Phase 3 clinical trial that demonstrated Nexavar was well-tolerated and significantly delayed disease progression in patients with advanced kidney cancer. As assessed by independent radiologic review, progression-free survival (PFS) doubled to a median value of 24 weeks (167 days) in patients

receiving Nexavar, compared to 12 weeks (84 days) for patients receiving placebo. (HR=0.72; p=< 0.000001).

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

LIVER CANCER

In 2007, the FDA approved Nexavar in a second indication, unresectable HCC, or liver cancer, in the U.S. In the EU, Nexavar was approved in HCC. 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 liver cancer versus those taking placebo by 44% (HR=0.69; p=0.0006).

Data presented at the ASCO annual meeting in June 2007 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 (DMC) concluded during a planned interim analysis that the trial met its primary endpoint, resulting in superior overall survival (OS) in those patients receiving Nexavar versus those patients receiving placebo. 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 were diarrhea and hand-foot-skin reaction. As a result of the DMC analysis, the trial was stopped and all patients enrolled in the trial were given access to Nexavar.

PARTNER STATUS

Onyx and Bayer are developing and marketing Nexavar under collaboration and co-promotion agreements. Onyx and Bayer each fund 50 percent of the development costs for Nexavar worldwide, excluding Japan, where Bayer funds all product development. With Bayer, Onyx is co-promoting Nexavar in the U.S. and sharing equally in any profits or losses. Outside of the U.S., Bayer has exclusive marketing rights and Onyx shares profits 50/50, excluding Japan, where Onyx receives a royalty.