Bayer



Investor News

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New Nexavar® Data Presented in Multiple Tumor Types at 44th American Society of Clinical Oncology (ASCO) Annual Meeting

Leverkusen, June 2, 2008 – Bayer HealthCare and Onyx Pharmaceuticals, Inc. today announced the presentation of new clinical data from Phase II trials in the development program for Nexavar® (sorafenib) tablets in multiple tumor types including lung, thyroid, gastric and ovarian cancers. Nexavar is currently approved in more than 40 countries for the treatment of patients with unresectable liver cancer and in more than 70 countries for the treatment of patients with advanced kidney cancer. In Europe, Nexavar is approved for the treatment of hepatocellular carcinoma and 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.

“We continue to be encouraged by Nexavar’s potential activity as a single agent or in combination with other chemotherapeutic agents in these early stage clinical trials in tumor types with high unmet treatment needs,” said Susan Kelley, MD, vice president, Therapeutic Area Oncology, Bayer HealthCare. “The more data we compile from various studies in multiple tumor types, the better informed we are to determine the appropriate direction for further development of Nexavar in additional clinical cancer settings.”

Highlights from Nexavar data presented include:

Lung Cancer

A Randomized, Discontinuation Phase 2 Study of Sorafenib vs. Placebo in Patients with Non-Small Cell Lung Cancer (NSCLC) Who Have Failed at Least Two Prior Chemotherapy Regimens

Preliminary findings from this randomized discontinuation Phase 2 study showed that treatment with Nexavar yielded encouraging results in heavily pre-treated patients with NSCLC. The study data showed that randomized patients who remained on Nexavar treatment experienced a longer period of disease control and disease stabilization than

patients who discontinued Nexavar after the initial run-in phase of treatment. The primary endpoint of the study –difference in percentage of patients without disease progression after 2 months of randomized treatment- was met. In the study, the most common treatment-emergent adverse events included fatigue, hand/foot syndrome and skin rash.

The lead investigator for this study is Joan Schiller, MD, professor and chief of the hematology/oncology division at the University of Texas Southwestern and Andrea L. Simmons distinguished chair in cancer research, Dallas, TX. (abstract #8014).

Thyroid Cancer

A Phase 2 Study of Sorafenib in Metastatic Thyroid Carcinoma

Findings from this single-arm Phase 2 study showed that treatment with Nexavar resulted in meaningful anti-tumor activity in the majority of patients with encouraging overall clinical benefit (both disease stabilization and partial responses) in patients with advanced thyroid cancer. In the study, Nexavar was well-tolerated; the most common treatment-related adverse events included fatigue, rash, diarrhea, palmer-plantar erythema, musculoskeletal pain and weight loss. Patients enrolled in this study had been diagnosed with metastatic, iodine-refractory, unresectable or locally-advanced thyroid cancer.

The lead investigator for this study is Marcia S. Brose, MD, PhD, assistant professor, director of cancer genetics laboratory, University of Pennsylvania Health System, Philadelphia, PA. (abstract #6026).

Gastrointestinal Stromal Tumors

Activity of Sorafenib in Patients with Imatinib and Sunitinib-Resistant Gastrointestinal Stromal Tumors (GIST): A Phase 2 Trial of the University of Chicago Phase 2 Consortium

Findings from this single-arm Phase 2 study suggest that Nexavar is active and well tolerated in patients with Gleevec or Gleevec and Sutent resistant GIST. The most common treatment-emergent adverse events included hand-foot syndrome, hypertension, rash and diarrhea.

The lead investigator for this study is Lauren Wiebe, MD, fellow, University of Chicago, Chicago, IL. (abstract #10502).

Gastric/GEJ Cancer

A Phase 2 Study: Combination of Sorafenib with Docetaxel and Cisplatin in the Treatment of Metastatic or Advanced Unresectable Gastric and Gastroesophageal Junction (GEJ) Adenocarcinoma (ECOG 5203)

Findings from this single-arm Phase 2 study provide encouraging data for the potential use of Nexavar in combination with docetaxel and cisplatin to treat patients with metastatic/advanced gastric/GEJ adenocarcinoma. The most common treatment-emergent adverse events included neutropenia, fatigue, anorexia, hand-foot reaction, nausea, diarrhea and dehydration.

The lead investigator for this study is Weijing Sun, MD, assistant professor of medicine, University of Pennsylvania, director of the Upper GI and Pancreatic-Biliary-Hepatic Cancer Group and the associate director of the GI Cancer Program. (abstract #4535).

Ovarian Cancer

Phase 2 Trial of Sorafenib in Persistent or Recurrent Epithelial Ovarian Cancer or Primary Peritoneal Cancer: A Gynecologic Oncology Group Study

Preliminary findings from this Phase 2 study suggest that Nexavar is active and tolerated in patients with recurrent epithelial ovarian cancer. The most common treatment-emergent adverse events were dermatologic and metabolic.

The lead investigator for this study is Daniela Matei, M.D., Ph.D., assistant professor, department of medicine, Walther Oncology Center, Indiana University, Bloomington, IN. (abstract #5537).

About Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of health care, nutrition and high-tech materials. 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. Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide. Find more information at www.bayerhealthcare.com.

Bayer Schering Pharma is a worldwide leading specialty pharmaceutical company. Its research and business activities are focused on the following areas: Diagnostic Imaging, General Medicine, Specialty Medicine 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. Find more information at www.bayerscheringpharma.de.

Note to editors:
Details on the studies can be found on the ASCO website: http://www.abstract.asco.org/.

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