Bayer

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Investor News

Bayer and Onyx Announce Results of Phase I Studies Evaluating BAY 43-9006 in Combination with Conventional Chemotherapy Drugs

Leverkusen / November 2, 2004 – Bayer Pharmaceuticals Corporation (NYSE: BAY) and Onyx Pharmaceuticals, Inc. (Nasdaq: ONXX) announced results from several Phase I clinical trials of BAY 43-9006 administered in combination with conventional chemotherapy drugs in patients with various tumor types including, hepatic cancer and colorectal cancer. The data were presented at the 29th European Society of Medical Oncology (ESMO) meeting in Vienna, Austria.

Data from these Phase I safety and pharmacokinetic (metabolism) interaction studies showed that BAY 43-9006 could be combined with the other anticancer agents evaluated (doxorubicin, oxaliplatin, fluorouracil and leucovorin). In addition, data show that BAY 43-9006 required no dose adjustment when administered with ketoconazole (CYP3A inhibitor). Safety data generated across all studies showed no unexpected treatment-related adverse events.

BAY 43-9006, a novel RAF kinase and VEGFR inhibitor under investigation for the treatment of different types of cancer, combines two anticancer activities: inhibition of tumor cell proliferation and angiogenesis (the growth of new blood vessels).

BAY 43-9006 ESMO Data

BAY 43-9006 data being presented at this year's ESMO meeting include:

- Results of a Phase I trial of BAY 43-9006 in combination with doxorubicin in patients with primary hepatic cancer. H. Richly, MD.

- Results of a Phase I combination trial of BAY 43-9006 with oxaliplatin in patients with colorectal cancer. P. Kupsch, MD.

- Phase I trial of BAY 43-9006 in combination with 5-fluorouracil (5-FU) and leucovorin (LCV) in patients with advanced refractory solid tumors. A. Figer, MD.

- A randomized Phase I clinical and biologic study of two schedules of the C-RAF kinase inhibitor BAY 43-9006 in patients with Myelodysplastic Syndrome (MDS) or Acute Myeloid Leukemia (AML): A NCI Canada Clinical Trials Group study. M. Crump, MD.

- Lack of effect of ketoconazole, a CYP3A inhibitor, on BAY 43-9006 clinical pharmacokinetics. C.D. Lathia, Ph. D.

About BAY 43-9006

BAY 43-9006, a novel investigational drug candidate, has demonstrated anti-proliferative and anti-angiogenic properties – two important anticancer activities. In preclinical models, BAY 43-9006 inhibited tumor cell proliferation by targeting the RAF/MEK/ERK signaling pathway at the level of RAF kinase. BAY 43-9006 also exerted an antiangiogenic effect by targeting the receptor tyrosine kinases VEGFR-2 and PDGFR and their associated signaling cascades.

BAY 43-9006 is currently undergoing Phase III evaluation for the treatment of advanced kidney cancer and Bayer and Onyx intend to initiate additional Phase II and Phase III trials in other tumor types. For more information on BAY 43-9006 clinical trials, visit www.clinicaltrials.gov.

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The company combines the global activities of the divisions Animal Health, Biological Products, Consumer Care, Diagnostics and Pharmaceuticals. 34,600 people are employed by Bayer HealthCare worldwide.

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