



News Release

45th American Society of Clinical Oncology Annual Meeting (ASCO):

Bayer Schering Pharma Announces New Data on Novel Anti-cancer Compound BAY 73-4506

Abstracts #: 5033 and 3560

Orlando, Florida, USA and Berlin, Germany, May 30, 2009 – Bayer Schering Pharma AG today announced results from Phase I and II trials of BAY 73-4506, a potent oral multi-kinase inhibitor currently being studied in multiple tumor types. These data were presented at the 45th Annual Meeting of the American Society of Clinical Oncology (ASCO).

“Bayer is committed to discovering new cancer-fighting therapies,” said Kemal Malik, MD, member of the Board of Management and Head of Global Development at Bayer Schering Pharma AG. “We are encouraged by these Phase I and II data being presented on BAY 73-4506. These data will help further determine our next steps as we move forward with a comprehensive Phase III clinical development program in various tumor types for this new drug candidate.”

Preliminary data from the Phase II, open-label study in renal cell carcinoma (RCC) demonstrated a 27 percent partial response (PR) rate according to the Response Evaluation Criteria in Solid Tumors (RECIST) and a disease control rate of 79 percent. The most common drug-related adverse events were hand-foot skin reaction, fatigue, hypertension, mucositis, dysphonia, rash, diarrhea, and anorexia. The Phase II study enrolled 49 previously untreated patients with predominantly clear cell RCC. BAY 73-4506 (160 mg) was administered once daily on a three weeks on/one week off schedule. The primary endpoint was to evaluate response rate according to RECIST.

“We are encouraged by these data of BAY 73-4506,” said lead investigator Professor Tim Eisen, F.R.C.P., PhD, of Addenbrooke's Hospital at the University of Cambridge, UK. “These data provide a rationale to move into a Phase III trial in one of the multiple tumor types that may be responsive to BAY 73-4506.”

Additional data presented on BAY 73-4506 include a Phase I study of patients with advanced refractory colorectal carcinoma (CRC). The data were presented by lead investigator Dirk Strumberg, MD, Department of Hematology and Medical Oncology, Marienhospital Herne, University Medical School of Bochum, Germany.

Data from the Phase I dose-finding study in CRC showed BAY 73-4506, dosed at 160 mg daily, using a treatment schedule of 21 days on/7 days off, was feasible in patients with advanced refractory CRC. Disease control rate (PR + SD) was 74 percent in evaluable patients. The most common drug-related adverse events were hand-foot skin reaction, fatigue, hoarseness, mucositis, diarrhea, anorexia and hypertension. Data presented are based on 38 patients with actively progressing CRC enrolled in a Phase I study. Patients were treated with BAY 73-4506 at doses of 60 mg, 120 mg, 160 mg, and 220 mg once daily.

About BAY 73-4506 (DAST-Inhibitor)

BAY 73-4506 is a dual targeted VEGFR2-TIE2 anti-angiogenic oral tyrosine kinase inhibitor (TKI) with a kinase inhibition profile targeting angiogenic, stromal and oncogenic receptor tyrosine kinases (TK). In preclinical studies, BAY 73-4506 has been shown to inhibit tumor growth by hitting targets along a spectrum of angiogenic pathways, including VEGFR and TIE2. BAY 73-4506 has also been shown in preclinical studies to prevent the proliferation of tumor cell lines while promoting apoptosis (cell death) by directly targeting several oncogenic TK receptors. The clinical significance of these studies is not known and warrant further investigation in a broad spectrum of tumors.

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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.

Details on the studies can be found on the ASCO website: **www.abstract.asco.org**.

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