



Investor News

Results of a Phase II study in Renal Cell Carcinoma (RCC):

Bayer's Novel Anti-Cancer Compound Regorafenib (BAY 73-4506) Showed Stabilization or Regression in 81 Percent of Kidney Cancer Patients

- Presentation of complete results at joint 15th ECCO and 34th ESMO Multidisciplinary Congress
 - Confirmation of topline data presented at ASCO 2009
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Leverkusen, September 22, 2009 – Bayer Schering Pharma AG, Germany, today announced results from a Phase II trial of regorafenib (BAY 73-4506), a potent oral multi-kinase inhibitor, which demonstrated that treatment with regorafenib resulted in a 31 percent partial response rate and 50 percent stabilization rate in patients with metastatic renal cell carcinoma (RCC). These data were presented in an oral session at the joint 15th Congress of the European CanCer Organisation and 34th Congress of the European Society for Medical Oncology (ECCO 15 - 34th ESMO). Preliminary results from this study were presented earlier this year at the 45th American Society of Clinical Oncology (ASCO) Annual Congress, May 29 – June 2, 2009, Orlando, Florida.

"Bayer is committed to researching and developing potential anti-cancer agents like regorafenib, which may eventually help physicians and patients manage this devastating disease," said Kemal Malik, MD, Member of the Board of Management of Bayer Schering Pharma AG and Head of Global Development. "We look forward to continuing the comprehensive clinical development program for regorafenib, which we believe could potentially represent a promising new treatment option for various tumor types."

At the time of data analysis, 81 percent of patients (n=48) in the trial experienced disease stabilization or regression. Specifically, 31 percent of patients (n=15) experienced a confirmed partial response (PR), according to the Response Evaluation Criteria in Solid

Tumors (RECIST), and 50 percent of patients (n=24) experienced stable disease (SD). The data also showed an estimated median progression-free survival of 8.3 months at the time of protocol-defined end of study. Importantly, the time of data analyses, which occurred on May 31, 2009, was prospectively defined in the protocol as when the last patient was treated for at least six months. At the time of analysis, 25 patients remained on treatment and 80 percent (12 of 15) of patients who achieved a PR had an ongoing response. Two additional patients who were classified as having SD achieved a confirmed PR past the data analysis date, bringing the total PR to 35 percent (n=17) of patients. Study data continue to be reviewed.

The most common drug-related adverse events (all grades) were hand-foot skin reaction (HFSR), fatigue, hypertension, mucositis, diarrhea, alopecia, rash, voice changes, anorexia, nausea, constipation and vomiting.

“This study suggests encouraging activity of regorafenib as a potential first-line treatment option for patients with advanced RCC. These results, coupled with those from Phase I studies in other tumor types, provide rationale for further testing,” said lead investigator Professor Tim Eisen, F.R.C.P., PhD, of Addenbrooke's Hospital at the University of Cambridge, UK. “I am excited about the potential of this compound becoming a potential treatment option for patients and physicians.”

About the Trial

This Phase II, multicenter, open-label, single-arm study of regorafenib enrolled 49 previously untreated patients with metastatic or unresectable, predominantly clear-cell RCC. Regorafenib (160 mg) was administered once daily on a three weeks on/one week off schedule. The primary end point was to evaluate response rate according to RECIST. The secondary end points included safety, progression-free survival, duration of response, duration of stable disease, pharmacokinetics, and biomarker data.

About Regorafenib (BAY 73-4506)

Regorafenib (BAY 73-4506) is a potent oral multi-kinase inhibitor with a kinase inhibition profile targeting angiogenic, stromal and oncogenic receptor tyrosine kinases (TK). The distinct anti-angiogenic profile includes inhibition of both VEGFR2 and TIE2 TK. Regorafenib 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.

About Bayer Schering Pharma

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, Bayer Schering Pharma, Consumer Care and Medical Care divisions. 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.

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Details on the studies and the abstract #7105 can be found on the ECCO 15 - 34th ESMO website:

<http://www.ecco-org.eu/Conferences-and-Events/ECCO-15/page.aspx/216>

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