Bayer AG
Investor Relations
51368 Leverkusen
Germany
www.investor.bayer.com

Sorafenib Fact Sheet

Mechanism of action

- Sorafenib (formerly BAY 43-9006), a novel investigational drug candidate, is the first oral multi-kinase inhibitor that targets serine/threonine and receptor tyrosine kinases in both the tumor cell and tumor vasculature (arrangement of blood vessels in the tumor).
- In preclinical models, sorafenib targeted members of two classes of kinases known to be involved in both tumor cell proliferation (tumor growth) and tumor angiogenesis (tumor blood supply) - two important cancer growth activities. These kinases included RAF kinase, VEGFR-2, VEGFR-3, PDGFR-β, KIT, FLT-3 and RET.

Clinical development program

- Sorafenib is being co-developed by Bayer Pharmaceuticals Corporation and Onyx Pharmaceuticals, Inc.
- Approximately 2,000 patients have received this oral compound for various tumor types.
- Sorafenib is being evaluated both as a single agent therapy and in combination with other anticancer agents in a number of tumor types, including advanced renal cell carcinoma (RCC), advanced hepatocellular carcinoma (HCC) and metastatic melanoma.

Clinical study results

Advanced RCC, or kidney cancer:

- An independent data monitoring committee (DMC) reviewed the safety and efficacy data from the Phase III trial and concluded that the trial met its surrogate endpoint - resulting in statistically significant longer progression-free survival (PFS) in patients administered sorafenib versus patients administered placebo.
    - Following further review of data from the PFS analysis, as well as additional discussions with the principal investigators, DMC and regulatory authorities, Bayer and Onyx recommended that all patients in the ongoing Phase III trial be offered access to sorafenib.
- As a result of the favorable PFS data, Bayer and Onyx are preparing a New Drug Application (NDA) for possible approval in the United States for advanced RCC.

- The multi-national, placebo-controlled Phase III study recently finished enrolling more than 800 patients; it is the largest trial of its type in this patient population. Endpoints of the study include overall survival, progression-free survival, overall response rate and safety.
- The Phase II RCC trial met its primary endpoint of tumor stabilization, demonstrating that stable disease is a drug effect.
    - There was a statistically significant higher percentage of participants whose disease did not progress in the sorafenib group as compared to patients who received placebo.
    - The most commonly reported drug-related events included mild-to-moderate hand-foot syndrome, rash, diarrhea, and hypertension, which were shown to be manageable and reversible.

Advanced HCC, or liver cancer:

- A randomized, double-blind, placebo-controlled Phase III trial of sorafenib administered as a single agent was initiated in March 2005.
- The Phase III HCC trial is designed to measure differences in overall survival, time to symptom progression and time to tumor progression of sorafenib versus placebo. The trial will also evaluate safety and pharmacokinetics. The trial is expected to enroll more than 500 patients in the Americas, Europe and Australia/New Zealand who have not received prior systemic treatment for advanced HCC.
- In the Phase II HCC trial, 52 percent of patients experienced disease stabilization or tumor shrinkage.
    - Safety data generated showed that sorafenib was well tolerated and side effects were predictable and manageable. The most common grade 3/4 drug-related toxicities were fatigue, diarrhea and hand–foot syndrome.

Metastatic melanoma:

- Phase III trials administering sorafenib with chemotherapy in advanced metastatic melanoma patients will begin in the first half of 2005.
- In the Phase I/II combination trial, interim, investigator-reported results indicated that 83 percent of trial participants treated with the combination of sorafenib plus carboplatin and paclitaxel were observed to have tumor shrinkage (40 percent) or disease stabilization (43 percent) while on trial treatments.
    - The non-hematologic side effects observed with the combination were consistent with those known to occur with each agent delivered alone. The most common side effects included hand-foot syndrome, infection, vomiting and rash. No pharmacokinetic interaction between sorafenib and paclitaxel or carboplatin was reported.

Leverkusen, May 17, 2005

Forward Looking Statements
This news release contains forward-looking statements based on current assumptions and forecasts made by Bayer Group management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports filed with the Frankfurt Stock Exchange and with the U.S. Securities and Exchange Commission (including its Form 20-F). Bayer assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

Bayer Investor Relations contacts:

Dr. Alexander Rosar (+49-214-30-81013)
Dr. Juergen Beunink (+49-214-30-65742)
Peter Dahlhoff (+49-214-30-33022)
Ute Krippendorf (+49-214-30-33021)
Ilia Kürten (+49-214-30-35426)
Judith Nestmann (+49-214-30-66836)