



## **ACT Biotech Files Special Protocol Assessment With FDA for Phase 3 Trial of Telatinib for Front-Line Treatment of Stomach Cancer**

SAN FRANCISCO, CA – February 28, 2011 – ACT Biotech, Inc., a biopharmaceutical company focused on the development of highly targeted, oral therapeutics for the treatment of cancer, announced today that it has filed a Special Protocol Assessment (SPA) with the U.S. Food and Drug Administration (FDA) related to a randomized Phase 3 trial of telatinib in combination with chemotherapy for the first-line treatment of patients with advanced stomach cancer. The FDA's SPA program is in place to allow the FDA to review and comment on clinical trial protocols, the data from which will form the primary basis of an efficacy claim for drug registration.

Telatinib is the most selective and highly potent next generation antiangiogenic drug currently in clinical trials and the only antiangiogenic in development for front-line treatment of stomach cancer in combination with chemotherapy. The telatinib Phase 3 multi-center, double-blind, randomized trial will compare telatinib in combination with a standard regimen of chemotherapy versus chemotherapy alone in advanced stomach cancer patients.

“The patient benefit observed from telatinib treatment in our recently completed Phase 2 trial in the same patient population with the same chemotherapy regimen compelled us to advance rapidly into a registration program,” said Ali Fattaey, Ph.D., chief operating and scientific officer, ACT Biotech. “Rapid objective tumor responses in two thirds of patients, strong evidence of antiangiogenic activity, an increase in survival over historical controls, and excellent safety in combination with chemotherapy all suggest that telatinib could become an important option for patients with this deadly disease.”

If the Phase 3 trial analysis agreed upon in the SPA is positive, the data would then provide the basis for the filing of a U.S. New Drug Application (NDA) for marketing approval of telatinib for the treatment of metastatic stomach cancer. ACT has also received feedback on the Phase 3 trial design from the European Medicines Agency (EMA) and will pursue a global development program.

Previously, a broad Phase 1 program established not only the safety and potent activity of single agent telatinib, but also demonstrated that telatinib can be combined with taxane, platinum, fluoropyrimidine and topoisomerase chemotherapies at full dose, with no required pauses in treatment. To date, 300 patients have been treated with telatinib as monotherapy or in combination with chemotherapy. The ability to combine with chemotherapy at full, uninterrupted dose has been difficult to achieve with first generation molecules, and telatinib may be well positioned for broad applicability in major solid tumor markets.

### **About stomach cancer**

Stomach, or gastric, cancer is responsible for more than 865,000 deaths globally each year, making it the second leading cause of cancer death in the world. According to Globocan, in

the Americas in 2008 there were 89,000 new cases of stomach cancer and 67,000 deaths. In Europe there were 165,000 new cases and 133,000 deaths.

Stomach cancer is a very difficult cancer to treat since most cases are detected late (in the Americas and Europe), and once detected, the cancer has already spread and is usually fatal within a year. Most patients do not respond to standard chemotherapy treatment and 85-90 percent of stomach cancer patients have no targeted therapy options.

**About ACT Biotech, Inc.**

ACT Biotech is a biopharmaceutical company focused on the development and commercialization of highly targeted, oral cancer drugs. ACT's lead product candidate is telatinib, a highly selective, potent, orally available antiangiogenic therapeutic that targets the VEGFR and PDGFR receptor tyrosine kinases to inhibit the blood supply to tumors. Telatinib showed robust antitumor activity with a solid safety profile in a Phase 2 combination chemotherapy clinical trial for front-line treatment of stomach cancer patients. These results have triggered ACT to move telatinib to Phase 3 development. Telatinib has also been studied in other solid tumors including colorectal and kidney cancers. In addition to telatinib, the company's product pipeline includes three other oncology candidates. ACT's pipeline products were originally discovered at Bayer Pharmaceuticals and were licensed by ACT Biotech in 2008 following Bayer's merger with Schering AG. ACT Biotech is headquartered in San Francisco, CA, and backed by NGN Capital. To learn more about ACT Biotech and the company's pipeline of innovative medicines, visit [www.actbiotech.com](http://www.actbiotech.com).

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