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Abstract #4122

Poster Board: #37H

Clinical and pharmacodynamic results of TEL0805 trial: A phase 2 study of telatinib (TEL) in combination with capecitabine (X) and cisplatin (P) as first-line treatment in patients (pts) with advanced gastric or gastro-esophageal junction (GEJ) cancer.



ACT Biotech's Telatinib Demonstrates Significant Progress in Stomach Cancer Treatment; Phase 2 Data To Be Presented at ASCO

FDA Agrees on SPA for Phase 3 Combination Trial in Stomach Cancer

SAN FRANCISCO, CA – June 2, 2011 – ACT Biotech, Inc., a biopharmaceutical company focused on the development of highly targeted, oral therapeutics for the treatment of cancer, announced positive data from the Phase 2 clinical trial evaluating the novel oral antiangiogenic agent telatinib in combination with standard-of-care chemotherapy regimen as first-line treatment for patients with metastatic stomach cancer, the second most deadly tumor type in the world. The trial was conducted in multiple centers in the U.S. and Spain. These data will be presented at the eighth annual American Society of Clinical Oncology annual meeting that will take place June 3-6, 2011, in Chicago, IL.

In the Phase 2 clinical trial, the addition of telatinib to chemotherapy resulted in rapid and sustained tumor regression in two thirds of evaluable patients with inoperable metastatic stomach cancer, regardless of the tumor location or whether it had already spread to the liver. Among 39 evaluable patients treated with telatinib, 25 (64 percent) showed a partial response and one patient had a complete response; an additional 10 patients (26 percent) achieved stable disease, resulting in an overall disease control rate of 92 percent. The median progression free survival was 140 days and the combination of telatinib plus chemotherapy was well tolerated at the full recommended dose of telatinib. The most common telatinib-related side effects, such as hypertension and fatigue, were manageable and reversible. In general, the side effects experienced by the clinical trial patients were consistent with side effects related to chemotherapy.

“Antiangiogenic agents are an important class of drugs for the treatment of gastrointestinal cancers. Telatinib’s high response rate coupled with a lack of overlapping side effects with chemotherapy suggest that telatinib may be an important combination therapy candidate for patients with stomach cancer,” said Jaffer Ajani, M.D., professor of medicine at the University of Texas M.D. Anderson Cancer Center in Houston and one of the leading telatinib investigators in the United States.

ACT also announced that the company reached an agreement with the U.S. Food and Drug Administration on a Special Protocol Assessment (SPA) for a randomized Phase 3 international trial of telatinib in previously untreated metastatic stomach cancer patients. The SPA is a written agreement on the design and planned analysis for this pivotal trial and indicates that the Phase 3 program design adequately addresses objectives in support of a regulatory submission for drug approval. The Phase 3 multicenter, double-blind, randomized trial will compare overall survival among metastatic stomach cancer patients treated with telatinib in combination with cisplatin and capecitabine as compared to chemotherapy alone.

“These Phase 2 data build on our previous telatinib results in gastrointestinal cancers. The promising response rates and exceptional tolerability in combination with chemotherapy in a difficult to treat patient population is beyond what has been seen previously with other oral antiangiogenic agents,” said Lori Kunkel, M.D., chief medical officer, ACT Biotech. “The SPA enables us to initiate the Phase 3 pivotal trial with increased clarity on approval endpoints and brings us closer to providing a safe and effective therapy for patients with stomach cancer.”

“Phase 3 clinical testing of telatinib for front-line treatment of stomach cancer patients will start this year, putting us on a path to file for telatinib approval in 2014,” said Ali Fattaey, Ph.D., president and chief operating officer, ACT Biotech. “With its ability to combine with multiple chemotherapy regimens at full, continuous dosing, telatinib is well-positioned for broad utility as the backbone antiangiogenic agent for a number of solid tumors that are currently treated with chemotherapy, including colorectal, breast, and ovarian cancers.”

About Telatinib

Telatinib, a new chemical entity, is a highly selective and potent, oral antiangiogenic drug. Its unique mechanism of action specifically inhibits cell surface receptors critical for tumor

growth: vascular endothelial growth factor receptor (VEGFR) and platelet derived growth factor receptor (PDGFR), both of which are involved in angiogenesis, the process of new blood vessel formation needed for tumor growth. Telatinib, because of its highly selective nature, only interferes with angiogenesis without disruption of off-target pathway, thereby distinguishing it from other oral antiangiogenic tyrosine kinase inhibitors. The selectivity and safety profile likely account for cancer patients' ability to tolerate treatment with telatinib in combination with chemotherapy for long periods of time without increasing toxicity of the chemotherapy. Telatinib was granted orphan drug status for stomach cancer in 2010.

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 the NCI, in the U.S. alone, more than 21,000 people were diagnosed with stomach cancer and more than 10,500 died from the disease in 2010. Currently, more than 64,000 Americans are living with stomach cancer and studies have shown that the incidence of stomach cancer in younger patients is on the rise.

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. Telatinib showed robust antitumor activity with a solid safety profile in a Phase 2 clinical trial in stomach cancer. These results have triggered ACT to move telatinib to Phase 3 development. Telatinib has shown encouraging antitumor activity in a broad clinical trial program as a single agent in colorectal, kidney, stomach and liver cancers. Based on the encouraging efficacy and safety profile to date in a Phase 2 chemotherapy combination trial, ACT is advancing telatinib for untreated stomach cancer patients in a Phase 3 study, expected to be initiated this year. In addition to telatinib, the company's product pipeline includes three other oncology candidates. 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.

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