QualityStocks News - Genta Initiates Phase 2b Trial for Tesetaxel as Initial Therapy for Women with Recurrent Breast Cancer

Randomized trial will compare two chemotherapy agents; follows two preliminary studies that hint toward favorability

Scottsdale, Arizona (PRWEB) June 01, 2012 -- QualityStocks would like to highlight Genta, Inc., a publicly traded biopharmaceutical company with a diversified product portfolio that is focused on delivering innovative products for the treatment of patients with cancer. The company is developing tesetaxel, a novel, orally absorbed taxane that is in the same class of drugs as paclitaxel and docetaxel.

In the company’s news yesterday,

Genta announced that it has added the first patient to a new randomized trial of tesetaxel as initial chemotherapy for women with advanced or recurrent breast cancer.

The company expects to enroll 220 patients for the 12-month, randomized phase 2b study, which will be conducted across 15 sites in the U.S. and Western Europe.

The participating women will not have previously received chemotherapy for metastatic or recurrent disease, though eligible patients who are HER2-negative may have received adjuvant chemotherapy and hormonal therapy.

The study will compare two oral chemotherapy agents; patients will be randomized to one of three treatment groups administered twice per day for 14 consecutive days. The primary endpoint of the trial is overall response rate; secondary endpoints include progression-free survival and safety.

In the previously conducted two phase 2a studies, tesetaxel was generally well-tolerated. In the first study, 13 of 34 patients (38 percent) achieved a major objective response, and 11 patients achieved stable disease, for a disease control rate of 70 percent. In the second trial, 20 of 44 patients (45 percent) achieved major objective responses with a disease-control rate of 82 percent.

“Our preliminary results suggest that tesetaxel may compare favorably with capecitabine across a number of parameters, including response, safety, convenience, and compliance,” Dr. Loretta M. Itri, Genta’s president and chief medical officer stated in the press release. “Genta has now completed two, non-randomized, phase 2a studies comprised of more than 80 patients. The Company has been engaged in extended discussions with regulatory authorities in the U.S. and EU regarding potential registration strategies for tesetaxel in breast cancer. We believe this new study will provide a firm basis for a phase 3 trial design as first-line chemotherapy in this patient population.”

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