

Ascenta Therapeutics Presents New Clinical Data on AT-101 Monotherapy for the Treatment of Hormone-Refractory Prostate Cancer

ORLANDO, FL, February 23, 2007

Ascenta Therapeutics Inc., today announced the presentation of clinical data from a Phase 2 study of its clinical lead compound, AT-101, given as monotherapy, for the treatment of hormone-refractory prostate cancer (HRPC).

Currently in Phase 1/2 trials for the treatment of hormone refractory prostate cancer (HRPC), chronic lymphocytic leukemia (CLL), non-Hodgkin's lymphoma (NHL), and small cell lung cancer (SCLC), AT-101 is the only orally bioavailable pan-Bcl-2 inhibitor under clinical investigation. AT-101 acts to trigger programmed cell death (apoptosis) of cancer cells by inhibiting the activity of Bcl-2, Bcl-xL and Mcl-1, all proteins involved in increasing cancer cell survival. This Ascenta-sponsored Phase 2, open-label, multi-center study examined the effect of AT-101 on rising prostate-specific antigen (PSA) levels in HRPC patients who have not received prior chemotherapy.

Twenty-three patients between the ages of 52 and 86, all with rising PSA levels were enrolled from January to June 2006. Patients received AT-101 for 21/28 days until August 2006, at a starting dose of 30mg. Safety and efficacy assessments were performed at four-week intervals. A PSA response was defined as a 50 percent decrease in PSA levels which was confirmed by a second test per the published Bubley criteria standard. Radiological assessments were performed at eight-week intervals for patients with measurable or non-measurable disease.

Preliminary data from this study demonstrate that AT-101 has biological activity as a single agent in HRPC, demonstrated by observed declines in PSA slope and PSA partial responses (PR) in 3 of the patients treated (2 confirmed partial responses). GI toxicity was the most frequent serious toxicity and necessitated dose reductions to 20mg/day in several patients on this daily schedule.

"These data clearly indicate that further evaluation of AT-101 in prostate cancer is warranted", commented Ascenta Chief Medical Officer Dr. Jon T. Holmlund. "A Phase 2 study with a pulse dose schedule of AT-101 in combination with docetaxel and prednisone is ongoing to assess this regimen in HRPC patients, and we believe this regimen may optimize patient benefit for HRPC treatment regimens that include AT-101."

[Link to poster](#)

Founded in 2003, Ascenta is a privately-held biopharmaceutical company that discovers and develops targeted new medicines for the treatment of cancer. The company has offices in San Diego, California and Malvern, Pennsylvania, and has a preclinical research facility in Shanghai, China. Its technology is focused on discovering molecules that hit vulnerable targets in endogenous apoptosis pathways and shut down cell growth and proliferation in cancer cells.