

Clinical Data On Ascenta Therapeutics Lead Product AT-101 Presented At The 2006 American Society For Clinical Oncology Annual Meeting

ATLANTA, GA, June 5, 2006

Ascenta Therapeutics Inc., a privately-held, clinical stage biopharmaceutical company today announced the presentation of clinical data from an ongoing Phase 1, open label study of its clinical lead compound, AT-101, in a cohort of treatment-naïve patients with chronic lymphocytic leukemia (CLL) who are at high risk for early disease progression and inferior survival.

Currently in Phase 2 trials for the treatment of CLL, non-Hodgkin's lymphoma, and prostate cancer, 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 necessary for cancer cell survival. This study, from Dr. Thomas Kipps' group at the University of California, San Diego (UCSD) Moores Cancer Center Hematologic Malignancies Program, examined the safety and efficacy of AT-101 in CLL patients with high-risk features.

Results from this study presented by Dr. Danelle James and other researchers in Dr. Kipps' group demonstrated early evidence of single-agent activity of AT-101 in treatment-naïve CLL patients, all of whom had high risk features normally associated with poor prognosis, such as leukemia cells with deletions in the short arm of chromosome 17 (17p-), expression of unmutated immunoglobulin genes, high-level expression of CD38, and/or expression of ZAP-70. The investigators reported that all eight of the patients who received AT-101 had some evidence of drug activity as reflected in reduced lymph node size (observed in 8/8 patients), lower leukemia cell counts (6/8 patients), or reduced spleen size (6 of 6 patients with enlarged spleens at the time of treatment). The most frequent side effects observed in patients treated with AT-101 revolved around problems with the gastrointestinal tract, such as nausea, vomiting, and/or sluggish bowel function. These side effects resolved after the drug was discontinued.

[Link to poster](#)

"We are encouraged by the evidence of single-agent activity observed in this trial," said Dr. Jon T. Holmlund, Chief Medical Officer of Ascenta. "These preliminary results also point to a potential pharmacodynamic marker for AT-101, as apoptosis was detectable in cells taken from treated patients a few hours after the first dose of AT-101. This finding further confirms AT-101's biologic activity and may be useful as a biomarker in future studies of AT-101 as our clinical development program moves forward."

"Our observations suggest that AT-101 has activity in CLL," said Dr. Kipps. "The results of this trial add to the positive laboratory data that we reported last year at the American Society for Hematology meeting for the combination of AT-101 and rituximab, a combination that we currently are studying in the clinic at UCSD. Conceivably, AT-101 could have even greater activity when used in combination therapy with such anti-leukemia agents and provide for a significant advance in our treatment of CLL."

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 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. Ascenta's broad pipeline of compounds is licensed from both the National Institutes of Health and the laboratory of Dr. Shaomeng Wang at the University of Michigan.