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ASCENTA THERAPEUTICS ANNOUNCES PRESENTATION OF PROMISING RESULTS FROM CLINICAL TRIALS OF AT-101 IN PROSTATE, BRAIN, AND LUNG CANCERS AT 2009 ASCO ANNUAL MEETING

MALVERN, PENNSYLVANIA – June 1, 2009 – Ascenta Therapeutics announced today that promising results from ongoing clinical studies in prostate, brain and lung cancers were among the data presented on AT-101, an oral, pan-Bcl-2 inhibitor, at the 2009 American Society of Clinical Oncology (ASCO) Annual Meeting, May 29-June 2, in Orlando, Florida.

“We are delighted with the depth and breadth of the data available on our lead compound, AT-101, at this important scientific conference” said Mel Sorensen, MD, CEO of Ascenta Therapeutics. “The clinical utility of AT-101 is being explored in several major tumor types and treatment regimens, with prostate cancer at the most advanced stage of development.”

AT-101 in Prostate Cancer

Researchers presented updated data from an open-label, multicenter, Phase I/II study of AT-101 in combination with docetaxel and prednisone in men with castrate-resistant prostate cancer (CRPC).¹ This study enrolled 36 patients, who were treated with a standard docetaxel/prednisone regimen with the addition of AT-101 given twice a day on days 1-3 of each docetaxel treatment cycle. Thirty-six percent of patients completed at least ten 21-day cycles of treatment.

Responses to therapy were evaluated according to both PSA and RECIST (tumor shrinkage) criteria. As of last follow-up, 67 percent of patients had achieved a PSA partial response (a decrease in PSA level of at least 50 percent) and 45 percent of those with measurable disease achieved partial responses per RECIST. A reduction in circulating tumor cells was also reported after the first cycle of treatment and tended to be predictive of RECIST response. AT-101 was well tolerated in this combination as the majority of adverse events were Grade 1 or 2. Serious adverse events occurred in only 16 patients but there were no notable differences in the rates or severities of fatigue, gastrointestinal toxicities, or cytopenia compared to those generally associated with docetaxel/prednisone alone.

“The initial response rates we are seeing in this trial demonstrate strong evidence of antitumor activity in patients with metastatic CRPC,” said Gary R. MacVicar, MD, Northwestern University’s Feinberg School of Medicine. “Our data suggest that adding AT-101 to docetaxel/prednisone may improve clinical outcomes, without incremental toxicity, and we look forward to confirming this in larger studies.”

Complementing these findings from the chemotherapy-naive setting, another presentation reported data from a cohort of men with docetaxel-refractory prostate cancer who were treated with the same docetaxel/prednisone/AT-101 regimen.² A rigorous definition of refractory was

used in this trial, as the 38 patients had to have had documented disease progression during prior therapy with a docetaxel-containing regimen to qualify for enrollment. In this analysis, 41 percent of patients had a 30 percent reduction in PSA and 22 percent achieved a PSA partial response. In the group with measurable disease, 24 percent of patients achieved a partial response per RECIST. The regimen was also well tolerated, with rates and severity of toxicity comparable to those associated with the standard docetaxel/prednisone therapy. Only one reported serious adverse event, a case of small bowel obstruction (Grade 2), was considered potentially treatment-related.

AT-101 in Brain Cancer

Preliminary results from a National Cancer Institute (NCI) sponsored Phase II study of AT-101 as monotherapy for recurrent glioblastoma multiforme (GBM), the most aggressive form of brain cancer, were also presented.³ Fifty-six patients were enrolled with daily oral doses of AT-101 given for 21 of 28 days in repeated cycles. The treatment was well tolerated, with a low incidence of serious adverse events and no unique central nervous system toxicities. Responses were evaluated in 43 patients and included one confirmed partial response and 8 patients with stable disease, representing half of the patients still alive at the time of analysis. Progression-free survival (PFS) in these patients ranged from 8 to 13 months. Determination of the impact of AT-101 on overall survival (OS), the primary endpoint, is ongoing.

AT-101 in Lung Cancer

Reports from two studies in lung cancer also showed promising signals of antitumor effect. The first presentation described results from a randomized, double-blind, placebo-controlled Phase II trial in 105 patients who had received one prior chemotherapy regimen for non-small cell lung cancer (NSCLC).⁴ While the primary endpoint, a statistically significant improvement in PFS, was not met, the docetaxel plus AT-101 arm demonstrated a positive trend in OS, as reflected in the Kaplan-Meier curves (hazard ratio 0.82). This group also demonstrated a 33 percent increase in median survival and a 34 percent increase in 6-month survival compared to the docetaxel plus placebo arm. Common adverse events included fatigue (18 percent), anemia (18 percent) and dyspnea (18 percent). Using NSCLC cell lines, a genomic profile predicting response to AT-101 was developed in collaboration with Duke University. Opportunities to validate this biomarker will be pursued in future trials.

The second presentation reported on an open-label, Phase I/II study of AT-101 in combination with topotecan in patients with relapsed or refractory small cell lung cancer (SCLC) who had received prior platinum-based first line chemotherapy.⁵ The Phase II portion of the trial included 25 patients divided into chemo-sensitive (A) and chemo refractory (B) cohorts. Median time to progression was 17.4 weeks (range 5.3 – 36.1 weeks) in A and 11.7 weeks (range 1.9 – 19.4 weeks) in B, considered by the investigators to be favorable compared to historical controls. Observed toxicities with the combination were consistent with those associated with topotecan.

Abstracts of all eleven presentations or publications on AT-101 made in conjunction with the 2009 ASCO Annual Meeting are available at www.asco.org.

About AT-101

AT-101 is an orally-active, pan-Bcl-2 inhibitor (including Bcl-2, Bcl-xL, Bcl-w, and Mcl-1 inhibition) that has been shown to induce apoptosis directly by operating as a BH3 mimetic and indirectly as an independent upregulator of Noxa and Puma. By blocking the binding of Bcl-2 family members with proapoptotic proteins and upregulating specific proapoptotic factors, AT-101 lowers the threshold for cancer cells to undergo apoptosis in various tumor types.

About Ascenta Therapeutics

Ascenta Therapeutics, Inc. is a privately-held, clinical-stage biopharmaceutical company that discovers and develops new medicines for the treatment of cancer. The company is headquartered in Malvern, Pennsylvania, and has a preclinical research facility in Shanghai, China. Its technology is focused on discovering molecules that restore the natural potential for cancer cells to undergo cell death (apoptosis). Ascenta's lead agent, AT-101, is an orally-active small molecule pan Bcl-2 inhibitor (Bcl-2, Bcl-xL, and Mcl-1) currently in Phase 2 clinical trials. The Company's preclinical pipeline includes the oral multi-IAP antagonist AT-406, and an HDM2-p53 inhibitor program.

For additional information on Ascenta Therapeutics, please visit the company's website at www.ascenta.com

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1. MacVicar G, et al. An open-label, multicenter, phase I/II study of AT-101 in combination with docetaxel (D) and prednisone (P) in men with castrate resistant prostate cancer (CRPC). Abstract #5062; Poster Board #17; Poster Discussion, May 31, 8:00 a.m.-12:00 p.m.
2. Poiesz B, et al. Preliminary report of an open-label, multicenter, phase I/II study of AT-101 in combination with docetaxel (D) and prednisone (P) in men with docetaxel refractory prostate cancer. Abstract #5145; Poster Board #J13; GU General Poster Session, May 31, 2:00 p.m.-6:00 p.m.
3. Fiveash J, et al. NABT-0702: A phase II study of AT-101 in recurrent glioblastoma multiforme (GBM). Abstract #2010; Poster Board #2; Poster Discussion, May 30, 8:00 a.m.-12:00 p.m.
4. Ready N, et al. AT-101 or placebo (P) with docetaxel (D) in second line NSCLC with gene signature biomarker development. Abstract #3577; Poster Board #J19; Developmental Therapeutics, May 30, 8:00 a.m.-12:00 p.m.
5. Heist R, et al. A phase I/II study of AT-101 in combination with topotecan (T) in patients with relapsed or refractory small cell lung cancer (SCLC) after prior platinum containing first line chemotherapy. Abstract #8106; Poster Board #R14; Lung Cancer – Metastatic, May 30, 2:00 p.m.-6:00 p.m.