Atossa Therapeutics Presents Data from 40mg Cohort of Phase 2 EVANGELINE Clinical Trial Showing 100% Disease Control Rate After 24-Weeks of Treatment with (Z)-Endoxifen

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SEATTLE, April 09, 2024 (GLOBE NEWSWIRE) -- Atossa Therapeutics, Inc. (Nasdaq: ATOS) ("Atossa" or the "Company") today announced promising safety and efficacy data from the Company's Phase 2 EVANGELINE (Endoxifen Versus exemestANe GosEreLIn) clinical trial. The EVANGELINE study is evaluating (Z)-endoxifen as a neoadjuvant treatment for pre-menopausal women with Grade 1 or 2 Estrogen Receptor positive (ER+) / Human Epidermal Growth Factor Receptor 2 negative (HER2-) breast cancer. Atossa is a clinical stage biopharmaceutical company developing innovative medicines in areas of significant unmet medical need in oncology with a focus on breast cancer.

The data, which is being presented at the American Association for Cancer Research (AACR) Annual Meeting, is from the 40mg pharmacokinetic (PK) run-in cohort of the study. Seven women were enrolled in the cohort and treated daily for 28 days. At 28 days, six of the seven had Ki-67 levels below 10% and stayed on treatment for an additional five months. Per the study protocol, the seventh patient, whose Ki-67 decreased 19% but stayed above 10%, discontinued treatment and had surgery.

Among the six patients who were treated for a total of 24-weeks, magnetic resonance imaging (MRI) central review demonstrated target lesion decreases in all patients with one complete response (CR), one partial response (PR) and four stable disease (SD), per Response Evaluation Criteria In Solid Tumors (RECIST) criteria. The average target lesion decrease was 32% at 12 weeks and 37% at 24 weeks with all patients experiencing at least a 15% reduction in target lesion at 24-weeks.

Ki-67 for the 40mg cohort patients was reduced from an average of 14.5% at screening to 5.3% at 28 days and 1.2% at 24-weeks. This represents a reduction of 63% at 28 days and 92% at 24 weeks. Ki-67 is a cellular marker for proliferation and indicates how fast the tumor is growing. Less than 10% is considered low and associated with better surgical outcomes and a lower incidence of recurrence.

Treatment related toxicities included grade 3 headache (one patient), grade 2 amenorrhea (one patient), and grade 2 hot flashes (one patient). There were no grade 4 or 5 treatment related toxicities.

"The EVANGELINE study introduces a promising neoadjuvant approach for premenopausal women with ER+/HER2- breast cancer, exploring a potential treatment option that could improve clinical outcomes without the need for ovarian function suppression," said Nusayba A. Bagegni, MD, Associate Professor of Medicine, Division of Oncology, Washington University School of Medicine and EVANGELINE study investigator. "The data thus far, which shows (Z)-endoxifen is beneficial and well tolerated, suggests that this treatment could potentially help address a significant unmet need in this patient population."

"The 40mg EVANGELINE data is extremely encouraging as it shows that (Z)-endoxifen can not only stop ER+ breast cancer from growing, but it can also shrink or eliminate the tumor, as measured by MRI imaging," said Dr. Steven Quay, Atossa's President and Chief Executive Officer. "The depth of response at 40mg may even improve in the next phase of the study where we are now treating women with 80mg of (Z)-endoxifen daily. We expect this dose to deliver the optimal steady-state plasma concentrations required to fully target PKCβ1 inhibition and further enhance (Z)-endoxifen's antitumor efficacy."

About (Z)-Endoxifen
(Z)-endoxifen is the most potent Selective Estrogen Receptor Modulator (SERM) for estrogen receptor inhibition and also causes estrogen receptor degradation. It has also been shown to have efficacy in the setting of patients with tumor resistance to other hormonal treatments. In addition to its potent anti-estrogen effects, (Z)-endoxifen has been shown to target PKCβ1, a known oncogenic protein, at clinically attainable blood concentrations. Finally, (Z)-endoxifen appears to deliver similar or even greater bone agonistic effects while resulting in little or no endometrial proliferative effects compared with standard treatments, like tamoxifen.

Atossa is developing a proprietary oral formulation of (Z)-endoxifen that does not require liver metabolism to achieve therapeutic concentrations and is encapsulated to bypass the stomach, as acidic conditions in the stomach convert a significant proportion of (Z)-endoxifen to the inactive (E)-endoxifen. Atossa's (Z)-endoxifen has been shown to be well tolerated in Phase 1 studies and in a small Phase 2 study of women with breast cancer. (Z)-endoxifen is currently being studied in four Phase 2 trials: one in healthy women with measurable breast density, one in women diagnosed with ductal carcinoma in situ, and two other studies including the EVANGELINE study in women with ER+/HER2- breast cancer. Atossa's (Z)-endoxifen is protected by three issued U.S. patents and numerous pending patent applications.

About Premenopausal Patients with ER+ / HER2- Breast Cancer
Breast cancer is the most frequently diagnosed cancer in premenopausal women worldwide and accounts for almost half of the cancers that occur in women aged 15-49. An overwhelming majority (75%) of premenopausal breast cancer is estrogen receptor positive (ER+). Ovarian function suppression (OFS), when combined with either tamoxifen or an aromatase inhibitor, is the current standard of care for the endocrine management of stage 2 and 3 premenopausal ER+/HER2- breast cancer.

About EVANGELINE
Phase 2 EVANGELINE (Endoxifen Versus exemestANe GosEreLIn) study is investigating Atossa's patented (Z)-endoxifen as a possible neoadjuvant treatment for pre-menopausal women with Grade 1 or 2 Estrogen Receptor positive (ER+) / Human Epidermal Growth Factor Receptor 2 negative (HER2-) breast cancer. Participants will receive neoadjuvant treatment for up to six months, followed by surgery. The study is expected to enroll approximately 175 patients at up to 25 sites across the United States.

The primary objective of the EVANGELINE study is to determine what effect treatment with (Z)-endoxifen has on tumor cell growth and how this effect compares to treatment with current standard of care, exemestane plus goserelin. Exemestane is an aromatase inhibitor designed to block the synthesis of estrogen and slow the growth of ER+ cancers. Goserelin is a medication given to block the ovaries from making estrogen, also called ovarian function suppression (OFS). In premenopausal women, OFS is associated with significant morbidity and inadequate compliance, which compromises efficacy and increases the risk of mortality.

Clinical benefit across treatment arms will be measured by change in Ki-67 level. Ki-67 is a commonly used measure of cellular proliferation and growth in breast cancer tissue. In an earlier Phase 2 study, treatment with (Z)-endoxifen resulted in a 65.1% reduction in Ki-67. This is clinically meaningful because numerous studies have shown that reducing Ki-67 improves long term survival for ER+ breast cancer patients. Patients who experience clinical benefit after four weeks of treatment with (Z)-endoxifen are eligible to stay on treatment for up to 24 weeks. Tumor burden reduction will also be assessed by MRI.

About Atossa Therapeutics
Atossa Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing innovative medicines in areas of significant unmet medical need in oncology with a focus on using (Z)-endoxifen to prevent and treat breast cancer. For more information, please visit www.atossatherapeutics.com.

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FORWARD LOOKING STATEMENTS
This press release contains certain information that may constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We may identify these forward-looking statements by the use of words such as “expect,” “potential,” “continue,” “may,” “will,” “should,” “could,” “would,” “seek,” “intend,” “plan,” “estimate,” “anticipate,” “believe,” “future,” or other comparable words. Forward-looking statements in this press release are subject to risks and uncertainties that may cause actual results, outcomes, or the timing of actual results or outcomes, such as data related to the (Z)-endoxifen program and the potential of (Z)-endoxifen as a breast cancer prevention and treatment agent, to differ materially from those projected or anticipated, including risks and uncertainties associated with: macroeconomic conditions and increasing geopolitical instability; the expected timing of releasing data; any variation between interim and final clinical results; actions and inactions by the FDA and foreign regulatory bodies; the outcome or timing of regulatory approvals needed by Atossa, including those needed to continue our planned (Z)-endoxifen trials; our ability to satisfy regulatory requirements; our ability to remain compliant with the continued listing requirements of the Nasdaq Stock Market; our ability to successfully develop and commercialize new therapeutics; the success, costs and timing of our development activities, including our ability to successfully initiate or complete our clinical trials, including our (Z)-endoxifen trials; our anticipated rate of patient enrollment; our ability to contract with third-parties and their ability to perform adequately; our estimates on the size and characteristics of our potential markets; our ability to successfully defend litigation and other similar complaints and to establish and maintain intellectual property rights covering our products; whether we can successfully complete our clinical trial of oral (Z)-endoxifen in women with mammographic breast density and our trials of (Z)-endoxifen in women with breast cancer, and whether the studies will meet their objectives; our expectations as to future financial performance, expense levels and capital sources, including our ability to raise capital; our ability to attract and retain key personnel; our anticipated working capital needs and expectations around the sufficiency of our cash reserves; and other risks and uncertainties detailed from time to time in Atossa’s filings with the Securities and Exchange Commission, including without limitation its Annual Reports on Form 10-K and Quarterly Reports on 10-Q. Forward-looking statements are presented as of the date of this press release. Except as required by law, we do not intend to update any forward-looking statements, whether as a result of new information, future events or circumstances or otherwise.