Atossa Therapeutics Announces Updated Protocol for Clinical Trial Evaluating (Z)-Endoxifen in Combination with Abemaciclib (VERZENIO®) in Women with ER+/HER2- Breast Cancer

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SEATTLE, June 28, 2024 (GLOBE NEWSWIRE) -- Atossa Therapeutics, Inc. (Nasdaq: ATOS) ("Atossa" or the "Company") today announced protocol changes in the previously initiated study to evaluate Atossa's proprietary (Z)-endoxifen in combination with abemaciclib (VERZENIO ®), a cyclin-dependent kinase (CDK) 4/6 inhibitor marketed by Eli Lilly and Company. The study is investigating the combination as a neoadjuvant treatment in women with newly diagnosed 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.

Based on accumulating data from the ongoing Phase 2 EVANGELINE study, the dose of (Z)-endoxifen in the combination study has been increased from 40 mg to 80 mg once daily. The change in study dose was determined following a review of safety, efficacy and pharmacokinetic (PK) data from participants currently enrolled in the 80 mg PK run-in cohort of the EVANGELINE study.

The EVANGELINE study is enrolling premenopausal women with ER+/HER2- breast cancer. The study began with a 40 mg pharmacokinetic (PK) run-in cohort. Data from this cohort, which was presented at the 2024 American Association for Cancer Research (AACR) Annual Meeting, showed encouraging efficacy and an extremely favorable safety profile compared to currently approved endocrine therapies. Efficacy was measured by both reduction in Ki-67, a cellular marker for proliferation that indicates how fast the tumor is growing, and response (tumor shrinkage). Participants treated for a total of 24-weeks experienced an average reduction in Ki-67 of 92% and an average target lesion decrease of 37%. The study is now enrolling an 80 mg PK cohort, which is expected to deliver the optimal drug concentrations required to fully target PKCβ1 inhibition and further enhance (Z)-endoxifen's antitumor efficacy.

Additionally, the combination study will now enroll approximately 80 participants across two 40-participant cohorts. Both cohorts will include pre-and-menopausal women who will receive 80 mg (Z)-endoxifen once daily in combination with 150 mg abemaciclib twice daily for up to 24-weeks prior to surgery. Premenopausal women in the second cohort will also receive ovarian function suppression (OFS).

Increasing the number of study participants was done to ensure a statistically significant number of menopausal and premenopausal women are enrolled in each cohort. The addition of OFS in premenopausal women enrolled in the second cohort of the study will allow for a direct comparison of safety and efficacy among the two treatment groups. This data is expected to further validate the growing body of evidence that (Z)-endoxifen is safe and highly efficacious in premenopausal women without the need for OFS.

"We are extremely excited about the updated combination study protocol and grateful for the significantly expanded support from Eli Lilly to run the trial," said Steven Quay, M.D., Ph.D., Atossa's President and Chief Executive Officer. "As we expected, and the preliminary EVANGELINE data has confirmed, the 80 mg dose of (Z)-endoxifen has a highly favorable safety profile and delivers the desired concentration levels to optimally target PKCβ1. We also know from both the 40 mg and 80 mg EVANGELINE cohorts that premenopausal women treated with (Z)-endoxifen experience profound clinical benefit without the need for ovarian suppression. Further validating this with a head-to-head comparison of data from the two cohorts in the combination study will be extremely valuable as we continue conversations with prospective partners and regulators."

Under the terms of the study agreement, Atossa and Eli Lilly and Company are each responsible for supplying their respective study drugs.

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 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, including the timing of data related to the (Z)-endoxifen program, the potential of (Z)-endoxifen as a breast cancer prevention and treatment agent, and the potential safety and tolerability profile of (Z)-endoxifen, 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 comply 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.