Atossa Therapeutics and Quantum Leap Healthcare Collaborative Dose First Patient in I-SPY 2 Trial Combining (Z)-Endoxifen with Abemaciclib for ER+/HER2- Breast Cancer

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SEATTLE, Aug. 21, 2024 (GLOBE NEWSWIRE) -- Atossa Therapeutics, Inc. (Nasdaq: ATOS) ("Atossa" or the "Company") and Quantum Leap Healthcare Collaborative™ (QLHC), today announced the first patient has been dosed in their clinical trial evaluating Atossa's proprietary (Z)-endoxifen in combination with abemaciclib (VERZENIO®), a cyclin-dependent kinase (CDK) 4/6 inhibitor marketed by Eli Lilly and Company, as a neoadjuvant treatment in high-risk 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 oncology with a focus on breast cancer.

The study evaluating (Z)-endoxifen in combination with abemaciclib is part of the ongoing I-SPY 2 Endocrine Optimization Pilot Protocol (EOP), which focuses on patients with newly diagnosed estrogen receptor-positive (ER+) invasive breast cancer whose tumors are predicted to be sensitive to endocrine therapy but for whom chemotherapy is expected to provide little or no benefit. These patients have substantial risk for recurrence, often after five years, and need novel treatments that are more effective and tolerable than the current standard of care.

The combination study, being conducted across the I-SPY network, will enroll approximately 80 participants across two 40-participant cohorts. Both cohorts will include pre-and-post menopausal women who will receive 80 mg (Z)-endoxifen once daily in combination with 150 mg abemaciclib twice daily for 24 weeks prior to surgery. Premenopausal women in the second cohort will also receive ovarian function suppression (OFS). The addition of OFS in premenopausal women enrolled in the second cohort of the study will assess the impact of OFS with this combination. Data from the study, anticipated in 2026, is expected to further validate the growing body of evidence that (Z)-endoxifen is safe and highly efficacious in both premenopausal and postmenopausal breast cancer patients.

"Dosing the first patient in this trial marks a significant milestone for Atossa in support of our important partnership with the QLHC," said Dr. Steven Quay, Atossa's President and Chief Executive Officer. "The innovative idea of combining (Z)-endoxifen and abemaciclib in the neoadjuvant setting can open the door to the development of gentler more patient-friendly treatment options for women with invasive breast tumors. By combining these therapies, we hope to achieve improved outcomes compared to available therapies, not only in terms of safety and efficacy, but also with respect to patients' quality of life outcome measures."

"We are excited to announce that the first patient has been dosed in this clinical trial," said Dr. Jo Chien, Professor of Medicine at UCSF and PI of the sub study. "Finding better options for patients with HR+ tumors that have high clinical risk and biology that does not respond well to chemotherapy and immunotherapy is an unmet need in the field. This study is addressing this need by exploring the potential of (Z)-endoxifen combined with abemaciclib in the pre-operative setting."

Under the terms of the study agreement, QLHC will conduct the study with Atossa. 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/tissue 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 five 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.

About Quantum Leap Healthcare Collaborative
Quantum Leap Healthcare Collaborative is a 501c(3) charitable organization established in 2005 as a collaboration between medical researchers at University of California, San Francisco and Silicon Valley entrepreneurs. Our mission is to integrate care and research, and to foster high-impact trials with embedded clinical processes and systems technology and improved data management, greater access to clinical trial matching, and greater benefit to patients, providers, and researchers. Our goal is to improve and save lives. Quantum Leap provides operational, financial, and regulatory oversight to I-SPY. For more information, visit https://www.quantumleaphealth.org/

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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, the potential of (Z)-endoxifen as a breast cancer prevention and treatment agent, and potential milestones and growth opportunities for the Company, 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.