# Atossa Therapeutics and Quantum Leap Healthcare Announce I-SPY 2 Clinical Trial to Evaluate (Z)-Endoxifen in Combination with Abemaciclib (VERZENIO®) in Women with ER+/HER2- Breast Cancer

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SEATTLE, April 15, 2024 (GLOBE NEWSWIRE) -- Atossa Therapeutics, Inc. (Nasdaq: ATOS) ("Atossa" or the "Company") and Quantum Leap Healthcare Collaborative™ today announced the initiation of a new 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, in women with ER+/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 new study arm will enroll approximately 20 women with newly diagnosed Estrogen Receptor positive (ER+) / Human Epidermal Growth Factor Receptor 2 negative (HER2-) invasive breast cancer. Participants will receive 40mg (Z)-endoxifen once daily in combination with 150mg abemaciclib twice daily for a total of 24 weeks prior to surgery.

"Endocrine therapy in combination with CDK 4/6 inhibition is a widely used treatment for patients with advanced-stage ER+ breast cancer and as an adjuvant therapy for node positive, hormone positive early-stage disease, found at the time of surgical resection," said Dr. Laura Esserman, director of the University of California San Francisco Breast Care Center and founder of Quantum Leap Healthcare Collaborative. "Women with high clinical stage but less proliferative tumors (molecularly low risk or those with late recurrence risk) are challenging to treat. Late recurrence is high regardless of either endocrine or chemotherapy. Thus, we are looking for new combined treatments, which can be used in the pre-surgery (neoadjuvant) setting. We look forward to learning more about the potential of (Z)-endoxifen in combination with abemaciclib in the neoadjuvant setting in the I-SPY TRIAL."

The new study arm evaluating (Z)-endoxifen in combination with abemaciclib is part of the ongoing I-SPY 2 Endocrine Optimization Pilot Protocol (EOP), which targets 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 address the risk of recurrence and are more effective and tolerable than the current standard of care.

"Data recently presented at the American Association for Cancer Research (AACR) annual meeting was 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. "Combining this activity with a targeted therapy like CDK 4/6 inhibition, which interrupts the process through which breast cancer cells divide and multiply, has the potential to deliver efficacy beyond the sum of the two monotherapies. We look forward to seeing the results of this study as it will help us better understand which patients are best suited for mono vs. combination therapy in the neoadjuvant setting. It will also inform plans to potentially explore this combination in the advanced-stage and metastatic breast cancer settings."

Under the terms of the study agreement, Quantum Leap will conduct the study with Atossa and Eli Lilly and Company 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.

**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/

**About the I-SPY TRIALs**

The I-SPY TRIAL (Investigation of Serial studies to Predict Your Therapeutic Response with Imaging And moLecular analysis 2) (I-SPY 2 TRIAL) was designed to rapidly screen promising experimental treatments and identify those most effective in specific patient subgroups based on molecular characteristics (biomarker signatures). The Endocrine Optimization Pilot (EOP) is developing better endpoints and new endocrine targeted agents for stage 2/3 molecularly low risk breast cancer. The trial is a unique collaborative effort by a consortium that includes the Food and Drug Administration (FDA), industry, patient advocates, philanthropic sponsors, and clinicians from 30 major U.S. cancer research centers. Under the terms of the collaboration agreement, Quantum Leap Healthcare Collaborative is the trial sponsor and manages all study operations. For more information, visit www.ispytrials.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, 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.