Atossa Therapeutics Announces Support of Clinical Study Testing New, Artificial Intelligence, Breast Cancer Risk Assessment Model

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SEATTLE, May 28, 2024 (GLOBE NEWSWIRE) -- Atossa Therapeutics, Inc. (Nasdaq: ATOS) (“Atossa” or the “Company”), today announced support for a new Phase 2 study designed to validate an innovative, artificial intelligence driven, breast cancer risk assessment model. The SMART (Stockholm MAmmography Risk stratified Trial) study will test an individualized, imaging-based screening model designed to identify women with the highest risk of developing breast cancer in the next two years. If the model is validated for therapeutic use, it could serve as the foundation for a future, Phase 3, trial investigating (Z)-endoxifen in the breast cancer prevention setting. 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.

A short 'explainer' video about the SMART study can be found here: SMART Study Video Explainer.

The SMART study is expected to enroll 70,000 women who will join following their regularly scheduled bi-annual mammogram, the cost of which is covered by the nationalized healthcare system in Sweden. Mammogram results and additional assessment data will be analyzed by a proprietary algorithm known as the Profound Artificial Intelligence (AI) Risk Assessment Model (“Profound AI Model”), which will determine each participant’s risk of developing breast cancer in the next two years. The approximately 20% of women who have the highest risk of developing breast cancer in the next two years will be randomized into two arms. In the intervention arm, the approximately 7,000 women at highest risk will have a contrast enhanced mammogram (CEM). CEM has proven to better identify cancers that were missed on the regular mammogram because of dense breast tissue. Participants in the control arm will screen according to current guidelines, that is, return in two years for their next regularly scheduled mammogram. The study will measure how many women across both arms (the “high risk” population) develop breast cancer over the next two years, which will determine the predictive power of the proprietary algorithm.

“The SMART study will be the largest prospective clinical trial in the history of medicine that is intended to test if individualized, risk-based breast cancer screening is superior to current practice,” said Dr. Per Hall, Professor of Epidemiology at the Department of Medical Epidemiology and Biostatistics at Karolinska Institutet, Stockholm, Sweden, and Principal Investigator of the SMART clinical trial. “The breast cancer risk models that are widely used today are simply not effective, in large part because they fail to consider the individual woman. Our model includes imaging and other patient specific risk factors, which we think will allow us to predict, with a much higher degree of certainty, the risk a woman faces of developing breast cancer in the next two years.”

The Profound AI Model is based on an artificial intelligence algorithm that was educated by imputing the “normal” baseline mammograms from about 1,700 women who developed an interval breast cancer and comparing that to approximately 9,000 women not diagnosed with breast cancer. An interval cancer is one that is diagnosed before or at the next two-year screening mammogram. The algorithm was run to find the features on the two sets of mammograms that were most different and to assign mathematical factors to the collected features that made the algorithm most predictive. The algorithm has been validated in diverse and independent populations.

Microcalcifications, artificial intelligence generated mammographic features, the asymmetry of the left and right breast, and other factors rose to the top of importance by this process. These are factors that are currently not included in the widely used Breast Cancer Risk Assessment Tool (BCRAT), also known as The Gail Model. This model, which estimate a woman's risk of developing invasive breast cancer over the next five years and up to age 90 (lifetime risk), only considers a woman's personal medical and reproductive history and the history of breast cancer among her first-degree relatives. The Profound AI Model takes a much more individualized approach by first considering mammography features and then factoring in additional risk factors including body mass index, whether the woman has taken hormone replacement therapy, family history and alcohol and tobacco use.

"Atossa is proud to help sponsor this groundbreaking study,” said Steven Quay, M.D., Ph.D., Atossa’s President and Chief Executive Officer. "Validating the Profound AI Risk model for therapeutic purposes will allow us to leverage the algorithm for the planned SMART 2 study, which would run concurrently with the SMART trial. In SMART 2, we would use the Profound AI Risk Model to identify women at the highest risk of developing breast cancer in the next two years and randomize them into two cohorts, a treatment group who will be treated with daily (Z)-endoxifen and a control group, who will take a placebo. We can then look at the number of women who develop breast cancer over that two-year period and determine if treatment with (Z)-endoxifen prevents breast cancer.”

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.

Contact:
Eric Van Zanten
VP, Investor and Public Relations
610-529-6219
eric.vanzanten@atossainc.com

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.