Atossa Therapeutics Announces Full Enrollment of Phase 2 Karisma-Endoxifen Clinical Trial

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SEATTLE, Nov. 20, 2023 (GLOBE NEWSWIRE) -- Atossa Therapeutics, Inc. (Nasdaq: ATOS), a clinical stage biopharmaceutical company developing innovative medicines in areas of significant unmet medical need in oncology with a focus on breast cancer, today announced that it has reached full enrollment in the Company's Karisma-Endoxifen clinical trial, the 240-person Phase 2 study investigating (Z)-endoxifen in premenopausal women with measurable mammographic breast density (MBD). Participants have been randomized to placebo, 1 mg, and 2 mg daily doses of (Z)-endoxifen and will be treated for six months, over the course of which mammograms are conducted to measure reduction in MBD. MBD change is used as a proxy for therapy response.

"Many of the risk factors for breast cancer, including breast density, are known, which means treating at-risk patient populations before the disease develops could significantly lower incidence rates," 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 Karisma-Endoxifen study. "I expect the medical community and government entities to increase their focus on breast cancer prevention, which should expedite the development and availability of novel treatments like (Z)-endoxifen."

Between 40% and 50% of all women are estimated to have mammographically dense breasts, which makes mammography less sensitive and mammograms more difficult to interpret, since cancer and dense breast tissue both appear white on a mammogram. In women with the highest density, approximately 50% of all breast cancers are missed on a mammogram and diagnosed in the interval between two screening rounds. Because of this, interval cancers are often larger, more advanced, and more difficult to treat. Women with the highest density are also four to six times more likely to develop breast cancer in their lifetime compared to women with the least dense breasts.

"We are excited that the Karisma-Endoxifen study is fully enrolled and look forward to seeing data from the trial in the second half of 2024," said Dr. Steven Quay, Atossa's President and Chief Executive Officer. "While significant progress has been made in breast cancer treatment, the same cannot be said about breast cancer prevention, particularly in high-risk women. (Z)-endoxifen is currently being studied in two populations that are at high risk of developing breast cancer, women with elevated breast density and women with ductal carcinoma in situ. Both diagnoses are strong, independent predictors of breast cancer risk that we feel are modifiable with (Z)-endoxifen."

About (Z)-Endoxifen
(Z)-endoxifen is the most active metabolite of the FDA approved Selective Estrogen Receptor Modulator (SERM), tamoxifen. Studies by others have demonstrated that the therapeutic effects of tamoxifen are driven in a concentration-dependent manner by (Z)-endoxifen. In addition to its potent anti-estrogen effects, (Z)-endoxifen at higher concentrations has been shown to target PKCβ1, a known oncogenic protein.

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 greater 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 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, 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 regain compliance 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.