



Atossa Therapeutics Announces Last Patient, Last Dose in its Phase 2 Karisma-Endoxifen Clinical Trial

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SEATTLE, May 15, 2024 (GLOBE NEWSWIRE) -- Atossa Therapeutics, Inc. (Nasdaq: ATOS) ("Atossa" or the "Company") today announced that the last patient in the Company's Karisma-Endoxifen clinical trial received their final dose of study medication. 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 Karisma-Endoxifen study, which fully enrolled in November 2023, is a 240-person Phase 2 clinical trial investigating (Z)-endoxifen in premenopausal women with measurable mammographic breast density (MBD). Participants were randomized to placebo, 1 mg, and 2 mg daily doses of (Z)-endoxifen and treated for six months, over the course of which mammograms are conducted to measure reduction in MBD. Medication-induced MBD reduction has been associated with a 50% to 63% reduction in the incidence of breast cancer in a three-to-fifteen-year follow-up period.

Approximately half 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. Women with the highest density are up to six-times more likely to develop breast cancer in their lifetime compared to women with the lowest density. Additionally, in this patient population, approximately 50% of all breast cancers are missed on a mammogram and diagnosed in the interval between two screening rounds. These tumors, which are known as interval cancers, are often larger, more advanced, and more difficult to treat.

"Completing dosing of the final patient in the Karisma-Endoxifen study is an important milestone for Atossa and our robust (Z)-endoxifen development program, which includes five ongoing Phase 2 studies," said Steven Quay, M.D., Ph.D., Atossa's President and Chief Executive Officer. "We look forward to seeing the breast density reduction data in the coming months and sharing it with regulatory authorities as it will allow us to further progress plans for a potential Phase 3, registrational study."

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 PKC β 1, 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 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.

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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 and the potential of (Z)-endoxifen as a breast cancer prevention and treatment agent, 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.