Atossa Therapeutics Provides Enrollment Update for Ongoing Phase 2 Karisma-Endoxifen Clinical Trial

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SEATTLE, July 10, 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 170 patients have been enrolled in the Company's ongoing Phase 2 Karisma-Endoxifen clinical trial. Atossa expects the study to fully enroll in the fourth quarter of 2023.

The Karisma-Endoxifen trial is a randomized, double-blind, placebo-controlled efficacy study of oral (Z)-endoxifen in premenopausal women with measurable breast density. Participants receive daily doses of (Z)-endoxifen for six months, over the course of which mammograms are conducted to measure reduction in mammographic breast density (MBD). Participants will also have a mammogram at 24 months to assess the durability of the MBD changes.

Between 40% and 50% of all women are estimated to have mammographically dense breasts, which makes mammography less sensitive and more difficult to interpret, since cancer and dense breast tissue both appear white on a mammogram. Because of this, cancers are often larger, more advanced, and more difficult to treat when found in women with dense breast tissue. Additionally, mammographic breast density is a strong, independent predictor of breast cancer risk. Women with the highest density are four to six times more likely to get breast cancer than women with the least dense breasts.

"We are excited about the progress we've made in our mammographic breast density study and look forward to fully enrolling the trial later this year and seeing data in 2024," said Dr. Steven Quay, Atossa's President and Chief Executive Officer. "There are currently no approved treatments for women diagnosed with elevated breast density. We feel (Z)-endoxifen has the potential to reduce breast density in this patient population, which would make mammograms more reliable and decrease the risk that these women will develop cancer in their lifetime."

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. The Company is currently studying (Z)-endoxifen in three Phase 2 studies: one in healthy women with measurable breast density 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
Forward-looking statements in this press release, which Atossa undertakes no obligation to update, are subject to risks and uncertainties that may cause actual results to differ materially from the anticipated or estimated future results, including the risks and uncertainties associated with any variation between interim and final clinical results, actions and inactions by the FDA, the outcome or timing of regulatory approvals needed by Atossa including those needed to commence studies of (Z)-endoxifen, lower than anticipated rate of patient enrollment, estimated market size of drugs under development, the safety and efficacy of Atossa's products, performance of clinical research organizations and investigators, obstacles resulting from proprietary rights held by others such as patent rights, whether reduction in breast density or in Ki-67 or any other result from a neoadjuvant study is an approvable endpoint for (Z)-endoxifen, whether Atossa can complete acquisitions, and other risks detailed from time to time in Atossa's filings with the Securities and Exchange Commission, including without limitation its periodic reports on Form 10-K and 10-Q, each as amended and supplemented from time to time.