Atossa Completes Enrollment of Pharmacokinetic Run-In Cohort in Phase 2 EVANGELINE Clinical Trial Evaluating (Z)-Endoxifen as a Neoadjuvant Treatment for ER+ / HER2- Breast Cancer

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SEATTLE, June 12, 2023 (GLOBE NEWSWIRE) -- Atossa Therapeutics, Inc. (Nasdaq: ATOS), a clinical stage biopharmaceutical company developing innovative proprietary medicines to address significant unmet needs in oncology with a focus on breast cancer, today announces that the pharmacokinetic (PK) run-in cohort of the Phase 2 EVANGELINE (Endoxifen Versus exemestANe GosEreLIn) study has fully enrolled. EVANGELINE is a randomized non-inferiority trial of Atossa's patented Selective Estrogen Receptor Modulator (SERM), (Z)-endoxifen, and exemestane plus goserelin as a neoadjuvant treatment for pre-menopausal women with Grade 1 or 2 Estrogen Receptor positive (ER+) / Human Epidermal Growth Factor Receptor 2 negative (HER2-) breast cancer.

The PK run-in cohort consists of six patients, all of whom will be treated with (Z)-endoxifen at 40mg/day for four weeks. The goal of the PK run-in cohort is to determine if the 40mg dose delivers steady-state plasma concentrations (Css) between 500 - 1000 ng/mL, which are optimal to target PKCβ1 inhibition and enhance (Z)-endoxifen's antitumor mechanism of action.

Once the optimal dose of (Z)-endoxifen is determined, the Treatment Cohort will commence. Participants in the treatment cohort will receive neoadjuvant treatment for up to six months, followed by surgery. The study is expected to enroll approximately 175 patients at up to 25 sites across the United States.

"We are excited to fully enroll the EVANGELINE PK run-in cohort and look forward to seeing data in Q3 of this year," said Dr. Steven Quay, Atossa's President and Chief Executive Officer. "The data will show us if the 40mg dose delivers the steady-state plasma concentrations required to effectively target PKCβ1 inhibition and enhance (Z)-endoxifen's antitumor mechanism of action, or if we need to further optimize the dose. Identifying the optimal dose is an important milestone as it will allow us to activate additional sites in the US and advance plans to open sites outside of the US, which will increase the speed of recruitment for the EVANGELINE treatment cohort."

About Premenopausal Women with ER+ / HER2- Breast Cancer
Breast cancer is the most frequently diagnosed cancer in premenopausal women worldwide and accounts for almost half of the cancers that occur in women aged 15-49. An overwhelming majority (75%) of premenopausal breast cancer falls under luminal A (ER+/HER2-) or B (ER+/HER2+) subtypes. Ovarian function suppression, when combined with either tamoxifen or an aromatase inhibitor, is the standard of care for the endocrine management of stage 2 and 3 premenopausal ER+/HER2- breast cancer.

About the Phase 2 EVANGELINE Study
The Phase 2 EVANGELINE (Endoxifen Versus exemestANe GosEreLIn) study is a randomized non-inferiority trial of Atossa's patented Selective Estrogen Receptor Modulator (SERM), (Z)-endoxifen, and exemestane plus goserelin as a neoadjuvant treatment for pre-menopausal women with Grade 1 or 2 Estrogen Receptor positive (ER+) / Human Epidermal Growth Factor Receptor 2 negative (HER2-) breast cancer. The primary objective of the EVANGELINE study is to evaluate the endocrine sensitive disease (ESD) rate, measured by Ki-67 (a proliferation marker prognostic for disease free survival), after four weeks of treatment with (Z)-endoxifen compared to treatment with current standard of care, exemestane plus goserelin. Exemestane is an aromatase inhibitor designed to block the synthesis of estrogen and slow the growth of ER+ cancers. Goserelin is a medication given to block the ovaries from making estrogen, also called ovarian function suppression (OFS). In premenopausal women, OFS is associated with significant morbidity and inadequate compliance, which compromises efficacy and increases the risk of mortality.

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. We are 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.