Atossa Therapeutics Receives Approval from Health Canada to Conduct Phase 2 EVANGELINE Clinical Trial in Canada

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SEATTLE, July 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 Health Canada has issued a “No Objection Letter” following the Company’s Clinical Trial Application for its Phase 2 EVANGELINE study. This means Atossa can open sites and enroll patients in their Phase 2 EVANGELINE study throughout Canada.

The ongoing 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. Participants will receive neoadjuvant treatment for up to six months, followed by surgery. 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. The study is expected to enroll approximately 175 patients at sites across the United States and Canada.

"The authorization of our Clinical Trial Application in Canada will increase the geographic scope of our enrollment efforts for EVANGELINE and broaden the network of breast cancer specialists familiar with (Z)-endoxifen in the neoadjuvant setting,” said Dr. Steven Quay, Atossa’s President and Chief Executive Officer. "In the coming weeks, we will have data from the pharmacokinetic run-in cohort, which is designed to identify the optimal dose for the treatment arm. Once the dose is confirmed, we expect the pace of enrollment to increase as we activate additional sites in the United Sates and Canada.”

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
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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 the expected timing of releasing data, 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, anticipated progress on Atossa’s (Z)-endoxifen development program, 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, anticipated working capital needs and expectations around the sufficiency of our cash reserves, 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.