Atossa Therapeutics Begins Enrollment of Phase 2 Clinical Study of Oral Endoxifen in Sweden

SEATTLE, Dec. 22, 2021 (GLOBE NEWSWIRE) -- Atossa Therapeutics, Inc. (Nasdaq:ATOS), a clinical stage biopharmaceutical company seeking to develop innovative medicines in areas of significant unmet medical need in oncology and infectious diseases with a current focus on breast cancer and COVID-19, today announces that it has initiated enrollment of its Phase 2 clinical study of oral Z-Endoxifen in Sweden. Participants in the study will be premenopausal women with elevated mammographic breast density, which is an emerging public health issue affecting more than 10 million women in the United States and many more worldwide.

"This is an extremely important milestone as it marks the next phase of developing our proprietary Z-Endoxifen," said Steven Quay, M.D., Ph.D., Atossa's Chairman and CEO. "This study will help determine the relationship between daily doses of Endoxifen and reduction in breast density and will help us further assess safety and tolerability. We look forward to providing progress updates as they become available."

The study, known as the Karisma-Endoxifen study, is a Phase 2, randomized, double-blind, placebo-controlled, dose-response study of Atossa's proprietary oral Z-Endoxifen in healthy premenopausal women with measurable breast density. The primary objective of the study is to determine the dose-response relationship of daily oral Z-Endoxifen on breast density reduction. Secondary endpoints will assess safety and tolerability, and the trial includes an exploratory endpoint to assess durability of the breast density changes. It will be conducted at the South General Hospital in Stockholm, and will include approximately 240 participants who will receive daily doses of oral Z-Endoxifen or placebo for six months. The study is being led by principal investigator Per Hall, M.D., Ph.D., Head of the Department of Medical Epidemiology and Biostatistics at Karolinska Institutet.

About Atossa's Proprietary Endoxifen

Endoxifen is an active metabolite of an FDA-approved drug called tamoxifen, which has been widely used for over 40 years to both treat and prevent breast cancer. Tamoxifen is a "pro-drug", in that it must be metabolized into active components ("metabolites") in order to be effective. Despite the success of tamoxifen in treating estrogen-receptor-positive breast cancer, its systemic side effects have led to generally low acceptance as a therapy to reduce the risk of breast cancer.

We estimate that approximately ten million women in the U.S. have mammographic breast density (MBD), for which there is no FDA-approved treatment. Studies conducted by others have shown that MBD reduces the ability of mammograms to detect cancer and increases the risk of developing breast cancer. Although oral tamoxifen is approved to prevent breast cancer in "high-risk" women (typically based on responses to a questionnaire), it is used by less than 5% of women with an increased risk of developing breast cancer because of the actual or perceived side effects and risks of tamoxifen. We believe our Endoxifen may provide an option for women to proactively reduce the density of their breasts and may improve mammography accuracy and patient care by unmasking cancerous tumors that are otherwise hidden by breast density. Regulators may not approve Endoxifen to reduce MBD unless we can demonstrate the relationship between Endoxifen-induced reduction in MBD and reduction in incidence of breast cancer.

Legislation that has been enacted in almost all U.S. states requiring that women be notified if they have MBD. These notifications typically state that women with MBD have a higher risk of developing breast cancer, and that mammography may not be as effective in detecting breast cancer because the MBD can "mask" the detection of cancers.

Atossa has been developing its proprietary Z-Endoxifen for breast cancer and other breast conditions and has successfully completed three Phase 1 clinical studies (including a study in men) and two Phase 2 clinical studies. Atossa has also completed significant pre-clinical development and has developed clinical manufacturing capabilities through qualified third parties.

About Atossa Therapeutics

Atossa Therapeutics, Inc. is a clinical-stage biopharmaceutical company seeking to develop innovative medicines in areas of significant unmet medical need in oncology and infectious diseases with a current focus on breast cancer and COVID-19. For more information, please visit www.atossatherapeutics.com.

Forward-Looking Statements Disclaimer Statement

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, without limitation, statements regarding the satisfaction of closing conditions relating to the offering and the anticipated use of proceeds from the offering, 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 AT-H201, AT-301 and 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 Ki-67 or any other result from a neoadjuvant study is an approvable endpoint for oral Endoxifen, 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.

Company Contact:
Atossa Therapeutics, Inc.
Kyle Guse, CFO and General Counsel
Office: 866 893-4927
kyle.guse@atossainc.com

Investor Relations Contact:
Core IR
Office: (516) 222-2560
ir@atossainc.com

12/22/2021 9:30:00 AM