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Atossa Genetics Presents Additional Findings from its Phase 1 Study of Oral Endoxifen

Conference Call Today at 4:30 pm EST

SEATTLE, Feb. 01, 2018 (GLOBE NEWSWIRE) -- Atossa Genetics Inc. (NASDAQ:ATOS), a clinical-stage pharmaceutical company developing novel therapeutics and delivery methods for breast cancer and other breast conditions, today announced additional findings from its Phase 1 study of Atossa's proprietary oral Endoxifen. Endoxifen is an active metabolite of the FDA-approved drug tamoxifen, which is currently used to treat breast cancer and for breast cancer prevention in high-risk patients.

The additional findings from the oral arm of the Endoxifen Phase 1 study are summarized as follows:

- The median time for patients in the study to reach the steady-state serum levels of Endoxifen while taking daily doses of Atossa's oral Endoxifen was 7 days. Published literature indicates that it takes approximately 50-200 days for patients to reach steady-state Endoxifen levels when taking daily doses of oral tamoxifen.

- The median time for patients in the study to reach the maximum serum level of Endoxifen after taking Atossa's oral Endoxifen was ranged from 4 to 8 hours (depending on dose). The 4 mg dose of Endoxifen produced a maximum serum level of Endoxifen in 4 to 8 hours at levels above the generally accepted threshold for a therapeutic effect on estrogen-dependent breast cancer.

"These additional findings are important for several reasons," commented Steve Quay, Ph.D., MD, CEO and President of Atossa. "Breast cancer patients do not typically want to wait weeks or even months for the current standard of care, oral tamoxifen, to take effect. Our study data indicates that our proprietary oral Endoxifen reaches a steady-state in about 7 days, while the literature indicates that it can take 50-200 days for tamoxifen to reach a steady-state – keeping in mind that a breast cancer tumor can double in size in as little as 29 days. Not only does it take up to several months for oral tamoxifen to take effect, oral tamoxifen also does not benefit up to 50% of patients, partly because many patients cannot metabolize tamoxifen. For these reasons, we believe our oral Endoxifen may reduce the incidence of this deadly disease and fundamentally change the paradigm for breast cancer treatment," added Dr. Quay.

The additional findings will also be discussed during the conference call today at 4:30 pm EST. Due to expected high call attendance, participants are asked to preregister for the call through the following link: http://dpregister.com/10116753. Please note that registered participants will receive their dial in number upon registration and will dial directly into the call without delay. Those without internet access or who are unable to pre-register may dial in by calling: 1-844-824-3830 (domestic), 1-412-317-5140 (international) and Canada Toll Free: 1-855-669-9657. Callers should ask to be joined into the Atossa Genetics call.

The conference call will also be available through a live webcast at www.atossagenetics.com. Details for the webcast may be found on the Company's IR events page at http://ir.atossagenetics.com/ir-calendar.

Management will answer pre-submitted questions gathered prior to the conference call in the Question and Answer period of the call. Interested parties may submit questions for management's consideration prior to the call by submitting them in writing to Atossa Genetics' Investor Relations at scottg@coreir.com.

A replay of the call will be available approximately one hour after the end of the call through March 1, 2018. The replay can be accessed via Atossa's website or by dialing 877-344-7529 (domestic) or 412-317-0088 (international) or Canada Toll Free at 855-669-9658. The replay access code is 10116753.

The objectives of Atossa's double-blinded, placebo-controlled, Phase 1 study of 48 healthy female subjects were to assess the pharmacokinetics of proprietary formulations of both oral and topical Endoxifen dosage forms as single (oral) and repeat (oral and topical) doses, as well as to assess safety and tolerability. Preliminary results from the study, which were announced on September 14, 2017 and October 25, 2017, showed that all objectives of the study were successfully met: there were no clinically significant safety signals and no clinically significant adverse events and both the oral and topical Endoxifen were well tolerated. In the topical arm of the study, low but measurable Endoxifen levels were detected in the blood in a dose-dependent fashion. In the oral arm of the study, participants exhibited dose-dependent Endoxifen levels that met or exceeded the published therapeutic level.

Atossa is developing proprietary Endoxifen with two routes of delivery anticipated to address two distinct patient populations: oral Endoxifen for breast cancer survivors and topical Endoxifen for women with a condition called mammographic breast density (or, MBD). When a patient is treated for breast cancer, doctors typically prescribe oral tamoxifen for 5-10 years to reduce the risk of recurrent and new tumors. Tamoxifen can have uncomfortable as well as serious side effects. Perhaps more importantly, not all patients benefit from tamoxifen therapy due to their inability to effectively metabolize tamoxifen into Endoxifen. Recent research continues to confirm the key role Endoxifen plays in reducing the risk of recurrent and new breast cancer in these patients. It is estimated that more than one million breast cancer survivors in the U.S. are recommended to take tamoxifen. Atossa is developing oral Endoxifen for these patients who are "refractory" to tamoxifen meaning that they are not benefiting from tamoxifen.

There is no FDA-approved treatment for MBD, which affects more than ten million women in the U.S. It is well accepted that MBD increases the risk of breast cancer, which is why

30 states currently require that a finding of MBD be reported to the patient, physician or both. It is believed that not only does MBD make mammography less effective because MBD can hide cancerous tumors, but also the tissue itself may be more prone to develop cancer. For these reasons, Atossa is developing topical Endoxifen as a potential treatment for MBD.

Results from Atossa's Phase 1 study have paved the way for upcoming Phase 2 studies: a study using Atossa's proprietary topical Endoxifen to treat MBD which will be performed at South General Hospital in Stockholm and a study using Atossa's proprietary oral Endoxifen to treat women who are refractory to tamoxifen. We plan to open both of these studies in the first quarter of 2018.

Atossa has also started a program to deliver Chimeric Antigen Receptor Therapy, or CAR-T, cells into the ducts of the breast for the potential targeted treatment of breast cancer. This is a novel approach using Atossa's proprietary intraductal microcatheter technology for the potential transpapillary, or "TRAP," delivery of T-cells that have been genetically modified to attack breast cancer cells. We believe this method has several potential advantages including the reduction of toxicity by limiting systemic exposure of the T-cells; improved efficacy by placing the T-cells in direct contact with the target ductal epithelial cells that are undergoing malignant transformation; and, lymphatic migration of the CAR-T cells potentially extending their cytotoxic actions into the regional lymph system, which could limit tumor cell dissemination. We are also using our intraductal microcatheters in a Phase 2 study at Montefiore Medical Center in New York where we are targeting the delivery of Fulvestrant to the site of early stage breast cancer and ductal carcinoma in situ.

Atossa is developing its products to reduce the risk of developing breast cancer and to provide new approaches to effectively treat breast cancer patients in a cost-effective and safer manner. A study conducted by Defined Health, a leading market research firm, estimates that the potential market for Endoxifen exceeds $1 billion in annual sales and the potential market for Atossa's intraductal microcatheters to delivery therapeutics exceeds $800 million as a treatment and replacement for surgery.

CAR-T has been the subject of much attention recently. In October 2017, pioneer CAR-T company Kite Pharma was acquired for $11.9 billion by Gilead; in August 2017 Novartis received the first FDA approval in the CAR-T field for Kymriah for the treatment of B-cell Acute Lymphoblastic Leukemia; and in January 2018 Celgene Corporation announced the acquisition of Juno Therapeutics for $9 billion.

Atossa's 2018 potential milestones include:

- First quarter of 2018 - opening the Phase 2 Study of topical Endoxifen to treat MBD at Stockholm South General Hospital in Sweden (which we plan to complete in 2018).
- First quarter of 2018 - opening the Phase 2 Study of oral Endoxifen to treat patients who are not responding to Tamoxifen (which we plan to complete in 2018).
- Second half of 2018 - commencing one or more studies administering TRAP CAR-T with our microcatheters.
- Throughout 2018 - continuing our Phase 2 study administering Fulvestrant with our microcatheters.

The American Cancer Society (ACS) estimates that approximately 250,000 women will be diagnosed with breast cancer in the United States this year and that approximately 40,000 will die from the disease. It is the second leading cause of cancer death in American women. Although about 100 times less common than women, breast cancer also affects men. The ACS estimates that the lifetime risk of men getting breast cancer is about 1 in 1,000; 2,470 new cases of invasive breast cancer will be diagnosed; and 460 men will die from breast cancer in 2017.

About Atossa Genetics

Atossa Genetics Inc., is a clinical-stage pharmaceutical company developing novel therapeutics and delivery methods to treat breast cancer and other breast conditions. For more information, please visit www.atossagenetics.com.

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 preliminary and final clinical results, actions and inactions by the FDA, the outcome or timing of regulatory approvals needed by Atossa, lower than anticipated rate of patient enrollment, preliminary and final results of clinical studies, the safety and efficacy of Atossa's products and services, performance of clinical research organizations and investigators, obstacles resulting from proprietary rights held by others with respect to fulvestrant, such as patent rights, 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.

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