December 28, 2017

Atossa Genetics President and CEO Issues Letter to Stockholders Highlighting Key Accomplishments and Outlines Milestones for 2018

SEATTLE, Dec. 28, 2017 (GLOBE NEWSWIRE) -- Atossa Genetics Inc. (NASDAQ:ATOS) today announced it has issued the following letter by Dr. Steven C. Quay, President and CEO, to Atossa stockholders:

Dear Valued Stockholders:

Over the past two years, we have transformed Atossa into a pure play pharmaceutical company focused on the development of novel therapeutics and delivery methods aimed at both treating breast cancer as well as preventing breast cancer. We now have a remarkable opportunity to transform the field of breast cancer and substantially reduce the incidence of this deadly disease.

The current standard of care for most breast cancer patients is a 5-10 year regimen of an FDA-approved drug called Tamoxifen. Unfortunately, not all patients benefit from Tamoxifen and it can have serious side effects. For these reasons, we are developing a new drug called Endoxifen, which is the most active metabolite of Tamoxifen. We are also developing our proprietary intraductal microcatheters with the potential ability to deliver drugs and Chimeric Antigen Receptor Therapy, or CAR-T, cells directly to the site of breast cancer.

Clinical Trial Achievements. Over the past two years we have been developing two proprietary formulations of Endoxifen: oral Endoxifen for the more than one million breast cancer survivors and topical Endoxifen as a potential treatment for a conditions called mammographic breast density (or MBD). 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 now 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. Over the past year, we secured a manufacturer for Endoxifen, retained a clinical research organization for a Phase 1 study and completed this study in the last quarter of 2017.

Preliminary results of the Phase 1 study show that both arms of the study (oral and topical) were fully and successfully completed: 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.

These promising Phase 1 results have paved the way for our upcoming Phase 2 studies, which are planned to open in the first quarter of 2018. We are developing our proprietary topical Endoxifen for the treatment of women with MBD which will be conducted by Stockholm South General Hospital in Sweden. We are also planning a Phase 2 study using our proprietary oral Endoxifen to treat patients who are not responding to Tamoxifen. That study should also open in the first quarter of 2018.

We have started a new program to deliver CAR-T cells into the ducts of the breast for the potential targeted treatment of breast cancer. This is a novel approach using our 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. This approach is in the R&D stage and is currently not FDA approved. In 2018 we intend to commence studies that will help demonstrate safety and efficacy of this novel approach. 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. That study is ongoing.

Capital Raising Achievements. In 2017 we made significant improvements to our balance sheet by raising approximately $12 million in capital, which strengthened our balance sheet and improved our stockholder base with the addition of institutional biotech-focused investors. We now have sufficient capital recourses to execute on our upcoming Endoxifen Phase 2 study of MBD and our upcoming Endoxifen Phase 2 study of “refractory” patients who are not responding to Tamoxifen.

Market Opportunities. We are developing our products for large market opportunities. 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 our 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 and 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. Other companies in the clinical-stage in the field of CAR-T include Blue Bird Corporation, and Juno Therapeutics, which trades on Nasdaq with a multi-billion dollar market capitalization.

2018 Milestones. We are now well positioned to execute our strategies in 2018, which

include the following potential milestones

- First quarter of 2018 - commencing 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 - commencing 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.

Breast Cancer Statistics. 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.

We look forward to reporting our progress on these priorities throughout the year and we thank you for your continued support of Atossa.

Sincerely,

Dr. Steven C. Quay, MD, Ph.D.
President and Chief Executive Officer

About Atossa Genetics

Atossa Genetics Inc. (NASDAQ:ATOS) 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 actions and inactions by the FDA, the outcome or timing of regulatory approvals needed by Atossa, lower than anticipated rate of patient enrollment, 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, 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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