Atossa Therapeutics Issues Letter to Shareholders

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SEATTLE, Jan. 25, 2023 (GLOBE NEWSWIRE) -- Atossa Therapeutics, Inc. (Nasdaq: ATOS), a clinical stage biopharmaceutical company developing innovative proprietary medicines to address significant unmet need in cancer, today announces the issuance of the following Letter to Shareholders from Steven C. Quay, M.D., Ph.D., the Company's CEO and Chairman:

TO OUR VALUED STOCKHOLDERS:

2022 was a year of significant progress for Atossa. We focused our development efforts on advancing our breast cancer program with our patented (Z)-endoxifen, the highest potency Selective Estrogen Receptor Modifier (SERM). We currently have Phase 2 studies ongoing in the prevention and treatment settings, both focused on areas of unmet medical need. Our goal is to both help reduce the incidence of breast cancer and change the treatment paradigm for patients who are not benefiting from currently approved drugs.

In October 2022, the U.S. Food and Drug Administration (FDA) authorized the initiation of our EVANGELINE study, a Phase 2 trial of (Z)-endoxifen and Exemestane + Goserelin as neoadjuvant treatment in premenopausal women with ER+/HER2- breast cancer. While there are several FDA-approved neoadjuvant therapies for ER- breast cancers, few exist for the ER+ patients, which account for approximately 78% of breast cancers. We expect to enroll approximately 175 patients at up to 25 sites across the United States.

The EVANGELINE study marks the first time our proprietary (Z)-endoxifen is being investigated in the United States and builds on the Phase 2 "window of opportunity" study we conducted in Australia. In that study we showed treatment with (Z)-endoxifen reduced Ki-67, a commonly used measure of cellular proliferation and growth in breast cancer tissue, from an average of 25.6% at screening to 6% on the day of surgery, a 65.1% reduction. This is clinically meaningful because numerous studies by other groups have shown a reduction in Ki-67 below 25% improves long term survival for ER+ breast cancer patients.

The EVANGELINE study will help us better understand what happens to tumors when patients are treated with (Z)-endoxifen. For example, is there a pathological response or tumor shrinkage? Even a partial response in the neoadjuvant setting could change the primary treatment approach and potentially save patients from undergoing a radical mastectomy or systemic therapies including chemotherapy, hormonal therapy, and/or targeted therapy.

We are also testing the hypothesis that treatment with (Z)-endoxifen could provide clinical benefit without the need for ovarian suppression. Current treatment approaches for premenopausal women diagnosed with ER+ breast cancer include using drug therapy or surgery to prevent the ovaries from making estrogen. ER+ tumors need estrogen to grow, so lowering hormone levels can restrict growth. However, patients also experience menopausal symptoms, and in some cases, treatment induces natural menopause, which can dramatically impact a patient's quality of life. There is a critical need for new treatment approaches that provide clinical benefit without ovarian suppression.

We also continue to enroll patients in our Phase 2 study investigating (Z)-endoxifen in premenopausal women with elevated mammographic breast density (MBD). We announced last fall that the study was approximately 40% enrolled which, assuming enrollment continues at the current pace, means we should enroll all 240 study participants by the end of this year.

MBD is an emerging public health issue affecting more than 10 million women in the United States and many millions more worldwide. It's well understood that increased MBD reduces the ability of mammograms to detect cancer, but studies have also shown that women with MBD have an increased risk of developing breast cancer and that the higher the MBD, the higher the incidence of breast cancer. Importantly, we also know that reducing MBD can lead to a reduction in the incidence of breast cancer.

Our MBD study, known as the Karisma-Endoxifen study, is a randomized, double-blind, placebo-controlled trial of healthy, pre-menopausal women with increased breast density. The treatment cohort receives daily doses of (Z)-endoxifen for six months, over the course of which mammograms will be conducted to measure reduction in MBD. Patients will also be given a mammogram at 24 months to assess the durability of the MBD changes. We believe (Z)-endoxifen may provide an option for women to proactively reduce the density of their breasts, which could improve mammography accuracy and patient care by unmasking cancerous tumors that are otherwise hidden by breast density.

Given the importance of (Z)-endoxifen to the future of Atossa, and the significant impact it could have on the prevention and treatment of breast cancer, it's critical that we protect the intellectual property covering our proprietary formulation of the drug. Our position was further strengthened in March of last year when the U.S. Patent and Trademark office issued U.S. Patent No. 11,261,151 (the '151 Patent). Titled "Methods for Making and Using Endoxifen," the '151 Patent is directed to compositions of storage-stable (Z)-endoxifen and methods of treating hormone-dependent breast disorders using the storage-stable (Z)-endoxifen. The '151 Patent is estimated to expire in 2038.

Another important development in 2022 was our investment in Dynamic Cell Therapies, Inc. (DCT), a privately held, venture capital backed developer of CAR-T therapies. DCT is in the pre-clinical phase of developing controllable CAR-T cells to address difficult-to-treat cancers. Its platform technology of dynamic control of engineered T-cells is designed to improve the safety, efficacy, and durability of CAR-T cell therapies. While their initial focus is hematologic malignancies, their innovative approach could also have broad applicability in solid tumors and autoimmune diseases. Our investment, which totaled $4.7 million and resulted in Atossa owning approximately 19% of the outstanding capital stock of DCT, closed in December 2022.

Last year we also made the decision to discontinue our COVID-19 programs due to the rapidly shifting treatment landscape and the introduction of effective vaccines, which greatly reduced hospitalizations. Aligned with our sharpened focus on oncology, we expect to revisit the development of AT-H201 as an inhalation therapy for cancer patients with compromised lung-function resulting from radiation treatment in the future. This indication may fill a compelling unmet medical need because radiation-induced lung injury, which can limit the overall success of lung cancer treatment, is often irreversible and poorly treated with current therapies.

As we look forward to 2023, we are well positioned to continue accelerating the development of (Z)-endoxifen. Both of our Phase 2 trials are ongoing, and we will provide enrollment and other updates as developments warrant throughout the year. We also have a strong balance sheet with no debt and cash, cash equivalents and restricted cash of approximately $117 million as of September 30, 2022.

On behalf of the board of directors, management, and employees of Atossa Therapeutics, we thank you for your investment and continued support of our Company.

Sincerely,

Steven C. Quay, M.D., Ph.D.
Chairman of the Board of Directors and Chief Executive Officer

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 with a current focus on breast cancer and lung injury caused by cancer treatments.
For more information, please visit www.atossatherapeutics.com

Contact:
Atossa Therapeutics, Inc.
Kyle Guse, General Counsel and Chief Financial Officer
kyle.guse@atossainc.com