Atossa Therapeutics President and CEO Dr. Steven C. Quay Issues Annual Letter to Shareholders Highlighting Key Accomplishments and Strategy for 2020

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SEATTLE, Jan. 22, 2020 (GLOBE NEWSWIRE) -- Atossa Therapeutics, Inc. (Nasdaq:ATOS) today issued the following letter from Dr. Steven C. Quay, President and CEO, to Atossa shareholders:

To Our Valued Shareholders:

I begin this letter with a sense of great pride about our accomplishments at Atossa. During 2019, we focused on developing our proprietary drug Endoxifen to reduce mammographic breast density (MBD) and to treat breast cancer after a woman is diagnosed but before her surgery. We advanced our goal of developing our intraductal microcatheter technology to deliver drugs and immunotherapies to treat breast cancer. Recent highlights in advancing our goals include:

- ***Oral Endoxifen for MBD***. Our lead program is to develop our proprietary oral Endoxifen to reduce MBD. MBD is an emerging public health issue affecting over 10 million women in the United States. Studies conducted by others have shown that MBD increases the risk of developing breast cancer and that reducing MBD can reduce the incidence of breast cancer. In 2019, we completed additional Phase 1 work with our oral Endoxifen, and, in December 2019, we contracted with South General Hospital in Stockholm, Sweden to conduct a Phase 2 study of our proprietary oral Endoxifen to reduce MBD.

- ***Oral Endoxifen in the Window of Opportunity Between Diagnosis and Surgery***. In an FDA-approved, single patient, expanded access (or "compassionate use") study, a breast cancer patient receiving our oral Endoxifen experienced a significant reduction in cancer cell biological activity - the Ki-67 activity decreased by 50 percent, and the estrogen receptor content decreased by over 20 percent. The patient has continued to take oral Endoxifen in the adjuvant setting following her surgery. We also have an ongoing Phase 2 study underway in Australia administering our oral Endoxifen to women in the window of opportunity.

- ***Topical Endoxifen for MBD***. We have also been developing a topical form of Endoxifen which is applied to the skin like a lotion. In June 2019, we announced the results from our Phase 2 study using this topical formulation to reduce MBD, which indicated that our proprietary 20mg daily topical Endoxifen showed significant and rapid reduction in MBD. Because study participants experienced skin rashes and local irritation we will reevaluate the topical form once we complete the Phase 2 study of oral Endoxifen.

- ***Intraductal Microcatheter Technology.*** We recently advanced our intraductal microcatheter technology program with the IRB approval of a Phase 2 clinical study using our intraductal microcatheter technology to administer fulvestrant in patients with early-stage breast cancer or ductal carcinoma *in situ* (DCIS). The study is being conducted at a world-class teaching, research and healthcare organization based in the United States. We also advanced our intraductal R&D program by developing a model in mice using our intraductal microcatheter technology. This is an important accomplishment, as this model will enable us to identify potential immunotherapy candidates to move forward into clinical trials.

Finally, we are particularly pleased to have announced that we have changed the name of the company from Atossa Genetics to Atossa Therapeutics, which we believe more clearly reflects our focus on developing therapies and continues to honor Princess Atossa, the great queen of the Achaemenid Empire, who reigned in the fifth century BCE and who is the earliest recorded woman with breast cancer.

Moving forward in 2020, we will continue to pursue our mission with vigor and dedication:

- **Oral Endoxifen to Reduce MBD**. Our primary goal in 2020 is advancing oral Endoxifen through a Phase 2 study to reduce MBD. The primary objective of this randomized, double-blinded, placebo-controlled study is to determine if there was a change in breast density compared to placebo and among different doses, with secondary endpoints to assess and characterize safety and tolerability. South General Hospital in Stockholm will be conducting this study at multiple sites, after having recently completed our Phase 2 study of our topical form of Endoxifen. The study is being led by principal investigator Dr. Per Hall, M.D., Ph.D., Head of the Department of Medical Epidemiology and Biostatistics at Karolinska Institutet. We expected to enroll approximately 1,000 pre-menopausal participants in four groups who will be dosed for six months.

  In 2019, we completed additional Phase 1 work using our capsule Endoxifen and a new modified-release form of our oral Endoxifen. Study results showed that the capsule and tablet were safe and well-tolerated. Because the pharmacokinetics of the tablet did not appear to be significantly improved over our capsule and because the capsule is more cost-effective to manufacture, we plan to use our capsule formulation of Endoxifen in our upcoming Phase 2 study to reduce MBD.

  Upcoming 2020 milestones with this program include receiving approval to open the study from the Institutional Review Board and Medical Products Authority in the first quarter 2020. We will then begin enrolling participants in the first or second quarter of 2020 and we expect to report periodically the progress with enrollment.

- **Oral Endoxifen in the "Window of Opportunity" Between Diagnosis of Breast Cancer and Surgery**. We plan to continue enrolling participants in this Phase 2 study being conducted in Australia.

- **Intraductal Technology**. We plan to continue our Phase 2 study using our intraductal technology to administer Fulvestrant and we will be conducting additional pre-clinical work to identify potential immunotherapy candidates.

- **Gynecomastia**. Completing our Phase 2 study of MBD will help inform next steps with our program to treat and/or prevent gynecomastia with our proprietary Endoxifen. Accordingly, we don't anticipate advancing our gynecomastia program in 2020.

Atossa is an exceptional company focused on novel therapeutics and delivery methods for MBD and breast cancer. We look forward to reporting our progress on our 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 Therapeutics

Atossa Therapeutics, 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.atossatherapeutics.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.

Atossa Genetics Company Contact:

Kyle Guse
CFO and General Counsel
(206) 556-3238
kyle.guse@atossainc.com

Investor Relations Contact:

Scott Gordon
CorProminence LLC
377 Oak Street
Concourse 2
Garden City, NY 11530
Office: (516) 222-2560
scottg@coreir.com

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