Atossa Therapeutics Announces Final Data from Phase 2 Endoxifen Breast Cancer Study Primary Endpoint Met: 65.1% Reduction in Biomarker Ki-67; Secondary Endpoint Met: Endoxifen Safe and Well Tolerated

SEATTLE, June 09, 2021 -- Atossa Therapeutics, Inc. (Nasdaq:ATOS), a clinical stage biopharmaceutical company seeking to discover and develop innovative medicines in areas of significant unmet medical need with a current focus on breast cancer and COVID-19, today announced the following final data from its Phase 2 clinical study of oral Endoxifen administered in the “window of opportunity” between diagnosis of breast cancer and surgery.

- **Primary Endpoint Met: Reduction in Ki-67 was achieved.** Ki-67, a common measure of tumor cell activity, was reduced from an average of 25.6% at screening to 6% on the day of surgery, a 65.1% reduction. Ki-67 was reduced below 25% for all patients, which is potentially clinically meaningful because studies by others have shown that a reduction below 25% improves long term survival.

- **Secondary Endpoints Were as Follows:**

  **Safety and tolerability:** All adverse events were mild and considered related to the study drug. There were no abnormal laboratory findings (serum chemistry, hematologic, coagulation, urinalysis) and no differences in vital signs, physical examinations and ECGs. Based on these results, Endoxifen was considered safe and well tolerated in this study. No adverse events led to discontinuation of the study.

  **Other Results:** Estrogen receptor expression decreased from 100% at screening to 88.6% on the day of surgery and progesterone receptor expression increased from 84.3% at screening to 92.9% on the day of surgery. No correlation between Ki-67 expression and Endoxifen levels was observed.

"Based on these favorable results, we are taking a number of steps to quickly advance our development of Endoxifen," commented Steven Quay, M.D., Ph.D., Atossa's President and Chief Executive Officer. "We have begun the formal non-clinical toxicology program that will be needed for a New Drug Application to seek marketing approval for Endoxifen and plan to apply to the U.S. FDA for approval to conduct a clinical study here in the United States as soon as possible. We expect the next clinical study to measure pathological complete response in the neoadjuvant setting. Although there are several FDA-approved neoadjuvant therapies for breast cancers that are not estrogen receptor positive (ER+), currently there are very few approved therapies for the approximately 78% of breast cancers, which are ER+ that we believe creates a significant unmet need for our Endoxifen."

Atossa will hold a webinar at 8:00 am Pacific Time today to discuss the study results. To register to join the complimentary ZOOM-based webinar event, please visit Tribe Public LLC at ATOS.TribePublic.com. Registered participants may email questions for Atossa's management to Tribe Public prior to the event at research@tribepublic.com or share their questions via the ZOOM chat feature during the event. Tribe Public's Managing Member, John F. Heerdink, Jr., will host the event and relay questions to management.

The study enrolled seven newly-diagnosed patients with ER+ and human epidermal growth factor receptor 2 negative (HER2-) stage 1 or 2 invasive breast cancer, requiring mastectomy or lumpectomy. Patients received the Atossa proprietary oral Endoxifen for at least 14 days from the time of diagnosis up to the day of surgery. The primary endpoint was to determine if the administration of oral Endoxifen reduces the tumor activity as measured by Ki-67. The secondary endpoints were safety and tolerability and assessment of the study drug on expression levels of both estrogen and progesterone receptors, and correlation between Ki-67 and Endoxifen levels. The Phase 2 study was conducted on behalf of Atossa by Avance Clinical, a leading Australian CRO.

The American Cancer Society (ACS) estimates that in 2021, 281,550 women will be diagnosed with breast cancer in the U.S. and 43,600 will die. ER+ breast cancer makes up approximately 78% of all women diagnosed with breast cancer.

Atossa is evaluating a number of potential clinical benefits and potential indications for its oral Endoxifen in the window of opportunity, or neoadjuvant, setting. These may include avoidance of surgery in some patients, such as older and/or frail patients, allowing for breast conservation surgery, and use of Endoxifen in place of other neoadjuvant therapies such as chemotherapy, aromatase inhibitors and other endocrine therapies like tamoxifen.

**About Atossa Therapeutics**

Atossa Therapeutics, Inc. is a clinical-stage biopharmaceutical company seeking to discover and develop innovative medicines in areas of significant unmet medical need 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 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