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Atossa Genetics Receives Approval from Institutional Review Board for Continuation of its Fulvestrant Microcatheter Phase 2 Study

SEATTLE, WA -- (Marketwired) -- 05/09/17 -- 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 that the Institutional Review Board associated with Montefiore Medical Center (Biomedical Research Alliance of New York IRB) has approved the Fulvestrant Microcatheter Phase 2 study that was recently transferred to Montefiore.

The Fulvestrant Microcatheter Phase 2 study includes women with ductal carcinoma in-situ (DCIS) or invasive breast cancer slated for mastectomy or lumpectomy. This study will assess the safety, tolerability and distribution of fulvestrant when delivered directly into breast milk ducts of these patients compared to those who receive the same product intramuscularly. The secondary objective of the study is to determine if there are changes in the expression of Ki67 as well as estrogen and progesterone receptors between a pre-fulvestrant biopsy and post-fulvestrant surgical specimen. Digital breast imaging before and after drug administration in both groups will also be performed to determine the effect of fulvestrant on any lesions as well as breast density of the participant. Six study participants will receive the standard intramuscular fulvestrant dose of 500 mg to establish the reference drug distribution, and 24 participants will receive fulvestrant by intraductal instillation utilizing Atossa's microcatheter device.

"This study was initiated at The Columbia University Medical Center Breast Cancer Program and then transferred to Montefiore Medical Center at the beginning of 2017 when the principal investigator moved his practice to Montefiore," commented Steven Quay, CEO and President. "We are pleased that the study continues to move forward at Montefiore, which is a leading center for breast cancer treatment."

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 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 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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