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Atossa Genetics Contracts with Additional Manufacturer of Endoxifen

SEATTLE, Aug. 01, 2018 (GLOBE NEWSWIRE) -- Atossa Genetics Inc. (ATOS) ("Atossa" or the "Company"), a clinical-stage biopharmaceutical company developing novel therapeutics and delivery methods to treat breast cancer and other breast conditions, today announced that is has added Alchem Laboratories as a U.S. contract manufacturer to supply Endoxifen. Subject to successful bioequivalence and other testing, the material will be used to produce both oral and topical drug product presentations. Atossa clinical programs using its proprietary Endoxifen include:

- Phase 2 study to determine if oral Endoxifen reduces tumor activity in early stage breast cancer patients in the "window of opportunity" between diagnosis of breast cancer and surgery (now open for enrollment in Australia)
- Phase 2 study to determine if topical Endoxifen reduces mammographic breast density (now open for enrollment in Sweden)
- Phase 1 study of topical Endoxifen in men (enrollment and dosing complete; results to be announced this quarter)
- Phase 2 study of topical Endoxifen to treat gynecomastia in men being treated for prostate cancer (study targeted to open in Q4 2018)
- Phase 2 study of oral Endoxifen for patients who are "refractory" to Tamoxifen (study targeted to open in 2H 2018)

"Our needs for the ongoing clinical supply of Endoxifen are dramatically increasing as we advance our clinical studies," commented Dr. Steven Quay, Ph.D., MD, President and CEO of Atossa. "As a second Endoxifen manufacturer, Alchem will begin supplying Endoxifen for one or more of our studies slated for later this year. They will be an excellent partner, with their experience and capabilities, to ensure we are poised to move our development programs forward quickly, particularly in the U.S.," added Quay.

About Alchem Laboratories

Alchem is located in Gainesville, Florida. It has supplied APIs for 16 active clinical studies, 13 of which were led by the National Cancer Institute (NCI) and that Alchem has been supporting through multiple R&D contracts for over fifteen years. In 2018, Alchem added oral and injectable products to its topical product manufacturing capabilities in its GMP clinical manufacturing facility expansion.

Alchem provides qualified infrastructure and trained personnel for all stages of drug development including design and synthesis of novel compounds, synthesis of analogs of lead compounds, process development and optimization, analytical method development

and validation, stability studies for drugs and intermediates, cGMP manufacturing of APIs and products for clinical studies, and documentation for all stages of drug development. Its partners and collaborators include the NCI, part of the National Institutes of Health (NIH), the National Institute of Standards and Technology (NIST), the U.S. Army Medical Research Acquisition Activity (USAMRAA), the U.S. Department of Agriculture (USDA), the Dr. Margarete Fischer-Bosch-Institute of Clinical Pharmacology (ICP), Gemphire Therapeutics, Inc., Cerenis Therapeutics Holding SA, Brickell Biotech, Inc., FLUCEL LLC, Nanopharmaceutics, MRIGlobal, Pace Analytical Labs, Southern Research, and the University of Florida UF|INNOVATE - Sid Martin Biotech.

About Atossa Genetics

Atossa Genetics Inc. is a clinical-stage biopharmaceutical 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 any variation between preliminary 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, lower than anticipated rate of patient enrollment, estimated market size of drugs under development, 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, potential market sizes for Atossa’s drugs under development 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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