



Atossa Therapeutics Announces Issuance of Key U.S. Patent Covering Endoxifen

SEATTLE, March 08, 2022 (GLOBE NEWSWIRE) -- Atossa Therapeutics, Inc. (Nasdaq: ATOS), a clinical-stage biopharmaceutical company seeking to develop innovative medicines in oncology and infectious disease with a current focus on breast cancer and COVID-19, today announces that the U.S. Patent and Trademark office has issued a new patent further strengthening Atossa's intellectual property in its proprietary therapy Endoxifen, which is under development for breast cancer and other breast conditions.

U.S. Patent No. 11,261,151 (the '151 Patent) is titled "Methods for Making and Using Endoxifen" and is directed to compositions of storage-stable Endoxifen and methods of treating hormone-dependent breast disorders using the storage-stable Endoxifen.

"We are very pleased with the scope and breadth of this new key patent," said Dr. Steven Quay, Atossa's President and Chief Executive Officer. "Patents covering the composition of matter of new therapies are critical to protect markets from generic competition. The '151 Patent,' with its estimated expiration in 2038, strengthens our intellectual property estate and should create long-term stockholder value."

Atossa is developing its proprietary Endoxifen in two clinical settings: one to reduce tumor cell activity in breast cancer patients in the neoadjuvant setting, meaning prior to surgery; and another to reduce dense breast tissue in women. A Phase 2 study is currently underway in women with measurable breast density and Atossa plans to submit a request (IND) to the FDA to open other Phase 2 in the neoadjuvant setting in the next quarter.

Atossa's neoadjuvant program is focused on breast cancers that are classified as estrogen receptor positive (ER+). Although there are numerous neoadjuvant treatments for breast cancers that are not ER+, there are few neoadjuvant treatments for ER+ breast cancer which comprises about 78% of all breast cancers. We believe there is a compelling need for therapy with our Endoxifen in this setting.

An estimated ten million women in the U.S. have mammographic breast density, or MBD, for which there is no FDA-approved treatment. MBD is an emerging public health issue and 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. The American Cancer Society estimates that in the U.S. in 2022, 287,850 women will be diagnosed with breast cancer, 47,550 of which will be under the age of 50 and 43,250 of which will die from the disease.

About Atossa Therapeutics

Atossa Therapeutics, Inc. is a clinical-stage biopharmaceutical company seeking to discover and develop innovative medicines in oncology and infectious diseases with a current focus on breast cancer and COVID-19. 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 estimated patent lives, 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 and continue 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.

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