Atossa Therapeutics Completes Enrollment of Phase 1 Clinical Study of AT-301 Nasal Spray Being Developed for the Coronavirus Causing COVID

SEATTLE, Oct. 19, 2020 (GLOBE NEWSWIRE) -- 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 it has now completed enrollment in its Phase 1 clinical study using Atossa's proprietary drug candidate AT-301 administered by nasal spray.

"Completing enrollment is a significant milestone and comes at a time when we are seeing a new wave if infections in certain geographies and an increased focus on developing therapies to treat COVID-19," commented Steven Quay, M.D., Ph.D., Atossa's President and CEO. "While the virus presents significant danger overall, the vast majority of people testing positive for COVID-19 do not require hospitalization and instead quarantine at home while they manage their symptoms and attempt not to infect those around them. As there are no currently FDA-approved treatments to help these patients, we are developing AT-301 for at home use so that they can recover faster."

Atossa plans to identify potential partners who are developing COVID-19 diagnostic tests so that AT-301 nasal spray may be co-developed and commercialized with the goal of making the AT-301 therapy available at the time a person tests positive for the coronavirus. Atossa also plans to develop its nasal spray to potentially help prevent COVID-19 infection -- particularly for people in high risk environments -- including, for example, people living with a patient infected with COVID-19, healthcare workers, emergency responders and teachers. In addition to seeking a partner, next steps with this program include contracting for a commercial supply of the nasal spray devices; reporting preliminary top line results from the Phase 1 study; and completing regulatory filings and any necessary approvals to launch a Phase 2 study, which we are planning for the first half of 2021.

The ongoing Phase 1 study is a double-blinded, randomized, and placebo-controlled safety study of AT-301 nasal spray in 32 healthy adult subjects divided into two study groups. Part A consists of two single-dose cohorts receiving either active therapy, AT-301B, or the placebo comparator AT-301A at two different doses. Part B is a multiple dose arm with cohorts receiving either AT-301A or AT-301B for 14 days at two different doses. The primary objective of the study is to evaluate the safety and tolerability of single and multiple doses of AT-301 administered via nasal instillation to healthy volunteers. Secondary objectives are to assess the incidence and severity of local irritation and bronchospasm following administration of AT-301 via nasal instillation. The study is being conducted in Australia.

About Atossa Therapeutics

Atossa Therapeutics, Inc. (Nasdaq: ATOS) 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

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 development plans, 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.

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