Atossa Therapeutics Announces Preliminary Results from Phase 1 Clinical Study Showing Safety and Tolerability of AT-301 Nasal Spray Being Developed for COVID-19

SEATTLE, Nov. 10, 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 blinded preliminary results from its Phase 1 clinical study using Atossa's proprietary drug candidate AT-301 administered by nasal spray. AT-301 was found to be safe and well tolerated in this study at two different dose levels in both single and multiple dose forms over 14 days. AT-301 is being developed for at home use for patients recently diagnosed with COVID-19. There are currently no FDA-approved therapies to treat COVID-19 at home.

"We have completed all dosing in this study and we have now evaluated the blinded safety and tolerability data from all participants," commented Steven Quay, M.D., Ph.D., Atossa's President and CEO. "There we no serious adverse events, no discontinuations, and only one subject of the 32 subjects in the study experienced adverse events that were considered moderate in severity and all other adverse events were considered mild. Our preliminary assessment is that our AT-301 nasal spray was safe and well tolerated in this study. These results support advancing this program into a Phase 2 study. We are in the process of preparing a pre-IND meeting request with the U.S. FDA which we plan to submit in the next 30 days."

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.

While other companies continue to develop a vaccine for SARS-CoV-2, Atossa believes that a significant market opportunity exists for therapies like AT-301. A traditional vaccine may still take years to develop and become widely available. Surveys have shown that many people will not take a vaccine when it is initially available and a traditional vaccine will likely not be 100% effective, particularly if different strains of the Coronavirus emerge.

The Phase 1 study is a double-blinded, randomized, and placebo-controlled safety study of AT-301 nasal spray in 32 healthy adult subjects who were 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, 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 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
Office:(516) 222-2560
ir@atossainc.com

Source: Atossa Therapeutics, Inc.

11/10/2020 9:30:00 AM