Atossa Therapeutics Receives Approval to Open Clinical Study of AT-301 Nasal Spray Being Developed to Treat COVID-19

Enrollment Expected to Begin Within 30 days

SEATTLE, Aug. 03, 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 that it has received approval from the ethics committee to open a Phase 1 clinical study in Australia using Atossa's proprietary drug candidate AT-301, to be administered by nasal spray. All necessary approvals have now been obtained and enrollment is expected to begin in the next 30 days.

"The most common entry point for the coronavirus is the nasal passage where the virus can infect locally for one to three days before progressing into the lungs," commented Steven Quay, M.D., Ph.D., Atossa's President and CEO. "Our nasal spray drug is being developed with a 'vaccine-like mechanism' to help maintain a protective mucosal barrier with anti-viral properties within the nasal cavity, hopefully leading to lower infectivity and reduced symptoms in COVID-19 patients. If this can slow virus growth sufficiently to allow the patient to mount a strong, natural immune response AT-301 could be very impactful on the current public health options for controlling COVID-19. We look forward to quickly opening enrollment in this important study and reporting results before the end of the year."

AT-301 is being developed for nasal administration in patients immediately following diagnosis of COVID-19 but who have not yet exhibited symptoms severe enough to require hospitalization. It is intended for at-home use to proactively reduce symptoms of COVID-19 and to slow the infection rate so that a person's immune system can more effectively fight SARS-CoV-2 (coronavirus). Atossa also intends to conduct testing to determine whether AT-301 can be used as a prophylaxis to prevent or mitigate SARS-CoV-2; for example, as a daily preventative treatment for people at higher-risk, such as frontline workers, military, emergency medical professionals, and hospital personnel.

The 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.

"Over the years, the U.S. Food and Drug Administration has accepted well-controlled, high quality studies conducted outside the U.S. and our existing relationship with the contract research organization conducting our AT-301 trial, and their history of success with our other Phase 1 trials, expedited our ability to get the drug in the clinic, which in the case of COVID-19 is of paramount importance. Assuming a favorable outcome, we anticipate the results of this trial to be readily included in future applications with the FDA. Seeking approval in Australia, where unfortunately COVID-19 cases are rising again, is also an option," added Dr. Quay.

ABOUT ATOSSA THERAPEUTICS

Atossa Therapeutics, Inc. 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 any variation between interim and final clinical results, whether *in vitro* test results will also be achieved in *in vivo* studies, including human clinical studies, actions by and interactions with the FDA, the outcome or timing of regulatory approvals needed by Atossa including those needed to commence human clinical studies of AT-301, 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, 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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