Atossa Therapeutics Announces Enrollment and Dosing Completed in First Group of Healthy Participants in Clinical Study of AT-301 Nasal Spray Being Developed for Treatment of COVID-19

SEATTLE, Aug. 17, 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 enrolled and dosed the first cohort of healthy participants in the Phase 1 clinical study using its proprietary drug candidate AT-301, being administered by nasal spray. This group of 8 participants received a single dose of either AT-301A (placebo) or AT-301B (active).

"Advancing our COVID-19 drug candidates through clinical studies as quickly as possible is our highest priority," commented Steven Quay, M.D., Ph.D., Atossa's President and CEO. "We are very encouraged by the high level of interest in this study and the speed at which we enrolled this first group of participants. Our novel nasal spray drug candidate is being developed to provide a unique 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 proliferation sufficiently to allow the patient to mount a strong, natural immune response AT-301 could significantly impact the current public health options for controlling COVID-19. We look forward to quickly completing enrollment of all cohorts in this potentially important study."

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.

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, 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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