Atossa Therapeutics Receives Second Positive Interim Safety Assessment in Clinical Study of AT-301 Nasal Spray Being Developed for the Coronavirus Causing COVID

Safety Committee Allows Enrollment in First 14-Day, Multi-Dose Study Arm

SEATTLE, Sept. 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 a positive interim safety assessment from the second cohort of healthy participants in the Phase 1 clinical study using Atossa's proprietary drug candidate AT-301 administered by nasal spray. This second group of eight participants received a single escalated dose of either AT-301A (placebo) or AT-301B (active drug). The blinded, positive assessment by the safety committee allows the study to now enroll the next cohort, which will be the third of a total of four cohorts and the first of two multi-dose, placebo controlled cohorts.

"This second favorable safety review marks an important milestone in this study as half the participants have now been dosed and initial safety reviews have been successfully completed," commented Steven Quay, M.D., Ph.D., Atossa's President and CEO. "Based on rapid enrollment in the first half of the study, we expect to complete enrollment in the remainder of the study very quickly. Recent data from the CDC suggests that more than 90% of people testing positive for COVID-19 do not require hospitalization. With this in mind, we are developing our AT-301 nasal spray for home-use because there are no currently FDA-approved treatments to help these patients with early disease to recover faster."

Significant advances have been made in the field of COVID-19 diagnostic testing. These tests are now much more widely available and they can render results much more quickly. Atossa plans to identify potential partners who are developing these 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 communities and those working in higher-risk areas, including healthcare workers, emergency responders and teachers.

"We anticipate that our AT-301 nasal spray will complement any traditional COVID-19 vaccine that may be developed," added Dr. Quay. "A traditional COVID-19 vaccine may be effective in in as few as half of the people taking it and recent surveys indicate that as many as one-third of Americans may choose not to take any COVID-19 vaccine once one becomes available. In addition, studies of re-infection with the coronavirus suggest that the durability of immunity, whether from an actual infection or a vaccine, may not be ideal. As a result, therapies such as our nasal spray, similar to therapies working in tandem with vaccines for seasonal flu, may form an important part of a broader response to the coronavirus pandemic."

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 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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