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Avance Clinical Contracted for Atossa Therapeutics AT-301 Nasal Spray Clinical Study

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Atossa's Second COVID-19 Therapeutic Development Program

The leading Australian CRO for biotechs and Frost & Sullivan *2020 Asia-Pacific CRO Market Leadership Award* winner Avance Clinical has been contracted to conduct a clinical study of Atossa Therapeutics' proprietary drug candidate AT-301, to be administered by nasal spray. Avance has successfully completed multiple clinical studies of Atossa's proprietary Endoxifen.

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.

"Avance Clinical is very pleased to be working with Atossa Therapeutics again on their second COVID-19 Therapeutic Development Program. Atossa is a valued long-term client that clearly understands the excellence in clinical research available in Australia, and the many benefits of conducting studies in the region," says Yvonne Lungerhausen, CEO, Avance Clinical.

According to Atossa Therapeutics "AT-301 is Atossa's proprietary formula intended 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.

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. Part B is a multiple dose arm with cohorts receiving either AT-301A or AT-301B for 14

days. 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 installation".

“Our AT-301 nasal spray program is being developed for COVID-19 patients who are not hospitalized, which complements our AT-H201 program being developed for COVID-19 patients on ventilators,” commented Steven Quay, M.D., Ph.D., President and CEO of Atossa. “Many COVID-19 patients are infected via the nasal passage, which makes a nasal spray therapy potentially very attractive. Collectively, the components of AT-301 are believed to replicate a ‘vaccine-like mechanism’ to help maintain a protective mucosal barrier within the nasal cavity with anti-viral properties that may lead to lower infectivity and reduced symptoms in COVID-19 patients due to their interference with the spike protein of the virus in the nasal cavity and upper respiratory tract. We may eventually develop AT-301 as a prophylaxis to reduce risk of being infected with COVID-19. For example, it could be taken as a daily vaccine-like treatment for people at higher-risk, such as TSA workers, emergency medical professionals and hospital personnel,” concluded Dr. Quay.

An application to commence the study has been submitted to the relevant institutional review board (IRB) and local regulatory authority in Australia which must be approved before commencement of the study. Pending these approvals, Atossa expects that the study will commence this quarter.

Adequate and well-controlled studies to demonstrate safety and efficacy must be successfully completed and regulatory approvals must be obtained before AT-301 may be commercialized. Atossa has filed provisional patent applications on AT-301 to treat patients diagnosed with, or to prevent, COVID-19 via nasal spray.