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Anixa Biosciences Announces Maximum Tolerated Dose Reached in Trial of Preventative Breast Cancer Vaccine

SAN JOSE, Calif., Dec. 8, 2022 /PRNewswire/ -- [Anixa Biosciences, Inc.](#) (NASDAQ: ANIX), a biotechnology company focused on the treatment and prevention of cancer and infectious diseases, today announced the maximum tolerated dose (MTD) has been reached in the Phase 1a trial of its preventative breast cancer vaccine.

The trial is an open-label, multiple-ascending dose Phase 1a trial to evaluate safety and monitor immune response after vaccination. A critical goal was to determine the maximum tolerated dose of the vaccine. The MTD is the highest dose of a medicine or treatment that will produce the desired effect without resulting in unacceptable side effects. Higher concentrations may be effective but may induce side effects that deter use or outweigh the benefits of treatment. The MTD will guide dosing in successive Phase 2 and Phase 3 trials. Recently, a Phase 1b trial was commenced, based on the results to date of the Phase 1a trial. The Phase 1a and Phase 1b trials are currently being conducted at Cleveland Clinic and include women who have previously been diagnosed with triple negative breast cancer and are currently cancer free and at risk of recurrence, and healthy cancer free women at high risk for developing breast cancer in the future, respectively. Future trials are expected to be conducted at multiple sites.

"We are pleased to have reached this important milestone in the clinical development of our preventative breast cancer vaccine, and we look forward to completing enrollment for the Phase 1a trial," stated Dr. Amit Kumar, Chairman and CEO of Anixa. "After the last participant is vaccinated and completes all follow up tests, we will compile and analyze the data. We look forward to presenting the complete immunological data from the trial at a scientific conference or similar setting in the second quarter of 2023."

About Anixa Bioscience's Breast Cancer Vaccine

Anixa's breast cancer vaccine, currently in Phase 1 trials, takes advantage of endogenously produced proteins that have a function at certain times in life, but then become "retired" and disappear from the body. One such protein is a breast-specific lactation protein, α -lactalbumin, which is no longer found post-lactation in normal, aging tissues, but is present

in the majority of triple-negative breast cancers. Activating the immune system against this "retired" protein provides preemptive immune protection against emerging breast tumors that express α -lactalbumin. The vaccine also contains an adjuvant that activates an innate immune response, which allows the immune system to mount a response against emerging tumors to prevent them from growing. This vaccine technology was invented by Dr. Vincent Tuohy, Mort and Iris November Distinguished Chair in Innovative Breast Cancer Research in the Department of Inflammation and Immunity at Cleveland Clinic's Lerner Research Institute. Dr. Tuohy is named as inventor on the technology, which Cleveland Clinic exclusively licensed to Anixa Biosciences. Dr. Tuohy will receive a portion of commercialization revenues received by Cleveland Clinic for this technology and also holds personal equity in Anixa.

About Anixa Biosciences, Inc.

Anixa is a clinical-stage biotechnology company with programs addressing cancer and infectious disease. Anixa's portfolio of therapeutics includes a cancer immunotherapy program being developed in collaboration with Moffitt Cancer Center, which uses a novel type of CAR-T, known as chimeric endocrine receptor T-cell (CER-T) technology, and, with partner MolGenie GmbH, a COVID-19 program focused on compounds targeting the M^{pro} enzyme of SARS-CoV-2, which is largely conserved across all recently identified variants. The company's vaccine portfolio includes a novel vaccine being developed in collaboration with Cleveland Clinic to prevent breast cancer – specifically triple negative breast cancer (TNBC), the most lethal form of the disease – as well as a vaccine to prevent ovarian cancer. These vaccine technologies focus on immunizing against "retired" proteins that have been found to be expressed in certain forms of cancer. Anixa's unique business model of partnering with world-renowned research institutions on clinical development allows the company to continually examine emerging technologies in complementary fields for further development and commercialization. To learn more, visit www.anixa.com or follow Anixa on [Twitter](#), [LinkedIn](#), [Facebook](#) and [YouTube](#).

Forward-Looking Statements: Statements that are not historical fact may be considered forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are not statements of historical facts, but rather reflect Anixa's current expectations concerning future events and results. We generally use the words "believes," "expects," "intends," "plans," "anticipates," "likely," "will" and similar expressions to identify forward-looking statements. Such forward-looking statements, including those concerning our expectations, involve risks, uncertainties and other factors, some of which are beyond our control, which may cause our actual results, performance or achievements, or industry results, to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. These risks, uncertainties and factors include, but are not limited to, those factors set forth in "Item 1A - Risk Factors" and other sections of our most recent Annual Report on Form 10-K as well as in our Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. You are cautioned not to unduly rely on such forward-looking statements when evaluating the information presented in this press release.

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