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Anixa Biosciences Announces Patient Dosing of its Investigational Vaccine Candidate in a First-of-its-Kind Preventative Breast Cancer Vaccine Study

- Cleveland Clinic conducting Phase 1 trial -

SAN JOSE, Calif. and CLEVELAND, Oct. 26, 2021 /PRNewswire/ -- [Anixa Biosciences, Inc.](#) (NASDAQ: ANIX) ("Anixa") a biotechnology company focused on the treatment and prevention of cancer and infectious diseases, announced today that, in conjunction with its partner, Cleveland Clinic, it has commenced dosing of patients for a novel study of its vaccine that is being investigated for preventing triple-negative breast cancer, the most aggressive and lethal form of the disease. Anixa has a worldwide, exclusive license to the vaccine technology originating from Cleveland Clinic.

Funded by the U.S. Department of Defense, the new study is a multiple-ascending dose Phase 1 trial to determine the maximum tolerated dose of the vaccine in patients with early-stage, triple-negative breast cancer as well as monitor immune response. The study will be conducted at Cleveland Clinic and will consist of 18 to 24 patients who have completed treatment for early-stage, triple-negative breast cancer within the past three years and are currently tumor-free but at high risk for recurrence. During the course of the study, participants will receive three vaccinations, each two weeks apart, and will be closely monitored for side effects and immune response. The study is estimated to be completed in the third quarter of 2022.

"As we begin this first-of-its-kind clinical study with our partner, Cleveland Clinic, it is truly an exciting time for Anixa," stated Dr. Amit Kumar, President and CEO of Anixa Biosciences.

"Our vaccine has the potential to prevent the development of the most aggressive form of breast cancer – triple-negative breast cancer. We look forward to the prospect of advancing this promising candidate throughout later stage studies."

The study that is being conducted today is based on pre-clinical work conducted by Cleveland Clinic researchers that was originally published in [Nature Medicine](#). Plans for subsequent trials of Anixa Bioscience's vaccine would involve healthy, cancer-free study

participants at high risk for developing breast cancer who have decided to undergo voluntary bilateral mastectomy to lower their risk. Typically, those women carry mutations in the *BRCA1* or related genes and are therefore at risk of developing triple-negative breast cancer or have high familial risk for any form of breast cancer.

About Triple-Negative Breast Cancer

Despite representing only about 12-15% of all breast cancers, triple-negative breast cancer accounts for a disproportionately higher percentage of breast cancer deaths and has a higher rate of recurrence. This form of breast cancer is twice as likely to occur in African-American women, and approximately 70% to 80% of the breast tumors that occur in women with mutations in the *BRCA1* genes are triple-negative breast cancer.

About Anixa Bioscience's Breast Cancer Vaccine

Anixa's investigational vaccine 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 pre-emptive immune protection against emerging breast tumors that express α -lactalbumin. The vaccine also contains an adjuvant that activates an innate immune response that allows the immune system to mount a response against emerging tumors to prevent them from growing.

About Anixa Biosciences, Inc.

Anixa is a publicly-traded biotechnology company developing a number of programs addressing cancer and infectious disease. Anixa's therapeutics portfolio includes a cancer immunotherapy program which uses a novel type of CAR-T, known as chimeric endocrine receptor T-cell (CER-T) technology, and a Covid-19 therapeutics program focused on inhibiting certain viral protein function. The Company's vaccine portfolio includes a vaccine to prevent breast cancer – specifically triple negative breast cancer (TNBC), the most deadly form of the disease – and a vaccine to prevent ovarian cancer. These vaccine technologies focus on immunizing against specific proteins that have been found to be expressed in certain forms of cancer. Anixa continually examines emerging technologies in complementary fields for further development and commercialization. Additional information is available at www.anixa.com.

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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