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Anixa Biosciences Announces Commencement of Phase 1b Trial of its Breast Cancer Vaccine at Cleveland Clinic

SAN JOSE, Calif., Oct. 26, 2022 /PRNewswire/ -- [Anixa Biosciences, Inc.](#) (NASDAQ: ANIX), a biotechnology company focused on the treatment and prevention of cancer and infectious diseases, today announced the initiation of a Phase 1b trial for its preventative breast cancer vaccine. The study is being conducted at Cleveland Clinic and will evaluate safety and monitor immune response.

This novel study, funded by a grant from the U.S. Department of Defense, has begun recruitment of healthy, cancer-free 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. 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 by the end of 2023.

A Phase 1a trial of this vaccine is currently ongoing. The Phase 1a study includes 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.

"We are excited to commence the second stage of the Phase 1 trials for our breast cancer vaccine," stated Dr. Amit Kumar, Chairman and CEO of Anixa. "While the Phase 1a trial is ongoing, the results to date have given us the confidence to move into this next study earlier than planned." Dr. Kumar added, "This vaccine has the potential to prevent the development of triple negative breast cancer, the most lethal form of breast cancer, and we look forward to advancing this promising technology through further clinical development."

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 a number of 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](#) and [Facebook](#).

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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