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Anixa Biosciences Unveils Phase 2 Study Plan for Breast Cancer Vaccine

Announces focus on therapeutic approach; resulting in a faster and more cost-effective path to approval

SAN JOSE, Calif., Sept. 24, 2024 /PRNewswire/ -- Anixa Biosciences, Inc. ("Anixa" or the "Company") (NASDAQ: ANIX), a biotechnology company focused on the treatment and prevention of cancer, today announced its strategic plan for a Phase 2 study for its breast cancer vaccine. The Phase 1 trial is being conducted at Cleveland Clinic, funded by a grant from the U.S. Department of Defense.

The proposed Phase 2 trial will evaluate the efficacy of the vaccine administered in the neoadjuvant (before surgery) setting, in combination with chemotherapy and Keytruda (pembrolizumab). The goal of neoadjuvant therapy is to reduce tumor burden and to prevent tumor recurrence with the intent to improve survival. This clinical trial approach allows Anixa to enroll a broader range of patients, encompassing multiple types of breast cancer. The therapeutic market for breast cancer is large due to the increase in prevalence of breast cancer and an increase in screening resulting in a demand for treatment. Compared with primary prevention, the development path for breast cancer treatment is expected to have a shorter path to approval. The therapeutic market covers all stages of breast cancer, from early to advanced and metastatic cases. In 2023, the market was valued at approximately $38.35 billion and is projected to reach $89.67 billion by 2030, growing at a compound annual growth rate (CAGR) of 12.9% (Maximize Market Research).

The key objectives of the trial include evaluating the immunological response to the vaccine and comparing clinical efficacy of standard of care therapy alone with the vaccine plus standard of care therapy. A key component of this trial will be the evaluation of breast cancer tissue and the validation of the immunological mechanism of action of the vaccine.

The trial is expected to commence in 2025 and is projected to last approximately two to three years. Immunological responses to the vaccine will be made available as the trial advances, providing a faster and more cost-effective path toward potential approval and/or partnerships with pharmaceutical companies.

"We are excited to unveil our Phase 2 study plan, bringing us one step closer to a potentially

transformative therapy for breast cancer patients," said Dr. Amit Kumar, Chairman and CEO of Anixa Biosciences. "By targeting treatment rather than prevention, we can reach a broader patient population and potentially expedite the process of regulatory approval and partnerships. This trial marks a key milestone in advancing our mission to fight cancer through innovative therapies. While our Phase 2 trial focuses on the therapeutic market, with the data obtained in this trial, we expect to conduct additional, more informed studies for both recurrence prevention and primary prevention with partners in the future."

Initial Phase 1 data was presented at the San Antonio Breast Cancer Symposium in December 2023. The data showed no safety concerns, with protocol defined immune responses observed in a majority of patients. Additional data from the Phase 1 trial will be presented at the Society for Immunotherapy of Cancer (SITC) Annual Meeting in early November 2024.

The Phase 1 trial is conducted in collaboration with Cleveland Clinic and is funded by a grant from the U.S. Department of Defense. Anixa is the exclusive worldwide licensee of the novel breast cancer vaccine technology developed at Cleveland Clinic. The grant funding from the U.S. Department of Defense was provided to Cleveland Clinic.

About Anixa Bioscience's Breast Cancer Vaccine

Anixa's breast cancer 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 certain 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 the late Dr. Vincent Tuohy, who was the 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. Cleveland Clinic exclusively licensed this technology to Anixa Biosciences. Dr. Tuohy was entitled to a portion of the commercialization revenues received by Cleveland Clinic and also held equity in Anixa.

About Anixa Biosciences, Inc.

Anixa is a clinical-stage biotechnology company focused on the treatment and prevention of cancer. Anixa's therapeutic portfolio consists of an ovarian 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. The Company's vaccine portfolio includes vaccines being developed in collaboration with Cleveland Clinic to prevent breast cancer – specifically triple negative breast cancer (TNBC), the most lethal form of the disease – and ovarian cancer, as well as additional cancer vaccines to address many intractable cancers, including high incidence malignancies in lung, colon, and prostate. 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 all stages of 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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