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Anixa Biosciences Announces Opening of Enrollment for Keytruda® Arm in Ongoing Breast Cancer Vaccine Clinical Trial

SAN JOSE, Calif., Aug. 7, 2023 /PRNewswire/ -- Anixa Biosciences, Inc. ("Anixa" or the "Company") (NASDAQ: ANIX), a biotechnology company focused on the treatment and prevention of cancer, today announced that its partner, Cleveland Clinic, has begun enrolling subjects in a treatment arm evaluating the combination of the Company's breast cancer vaccine with Keytruda® (pembrolizumab). An expansion of the ongoing Phase 1 dose escalation trial of Anixa's breast cancer vaccine, this treatment arm aims to determine if the vaccine/Keytruda combination increases immune response.

Anixa's breast cancer vaccine is designed to generate T cells that target triple negative breast cancer ("TNBC"). Keytruda, a therapy marketed by Merck (NYSE: MRK), is approved for use with chemotherapy before surgery and then alone after surgery to treat both high-risk early-stage and advanced TNBC.

Keytruda is a type of immunotherapy known as a checkpoint inhibitor. T cells, a type of white blood cell involved in the body's immune system, have receptor proteins on their surface called checkpoints. These checkpoints are utilized by other immune cells to modulate the activity of T cells. Cancer cells, such as TNBC cells, have developed mechanisms to target checkpoints to inhibit the activity of T cells, as well as other immune cells. This inhibition enables the cancer cells to escape destruction by cytotoxic T cells. One of these key checkpoint receptors is known as PD-1 (Programmed Cell Death Protein-1). TNBC, like many other cancers, expresses a protein that binds to the PD-1 protein on T cells and essentially turns them "off." Keytruda is a monoclonal antibody, which blocks the ability of the cancer cells to inactivate T cells by shielding the PD-1 receptor.

Dr. Amit Kumar, Chairman and CEO of Anixa stated, "Cleveland Clinic has demonstrated in both preclinical and clinical studies that our breast cancer vaccine induces an immune response–including, we believe, production of T cells that can target TNBC–so we believe that the addition of Keytruda could have a synergistic effect. If a vaccine induces the creation of T cells targeting TNBC, and Keytruda generally maintains T cell activity, the combination could be very potent. We are grateful to the U.S. Department of Defense for providing the funding for this new arm of the trial and look forward to Cleveland Clinic's presentation of the

updated data from this trial at the San Antonio Breast Cancer Symposium (SABCS) in December."

About Anixa's Breast Cancer Vaccine Clinical Trial
The Phase 1a study is designed to evaluate the safety of the vaccine, identify the Maximum Tolerated Dose (MTD), and monitor the immune response in vaccinated women. All participants in the Phase 1a study are women who have had triple negative breast cancer (TNBC) within the last three years and have been curatively treated having undergone standard of care. At the time of vaccination, these participants are tumor-free, as determined by standard diagnostic techniques, but are at high risk of recurrence.

About Triple-Negative Breast Cancer
One in eight women in the U.S. will be diagnosed with an invasive breast cancer at some point in their lives. Approximately 10-15% of those diagnoses are TNBC, however TNBC 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 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 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 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, and Cleveland Clinic exclusively licensed the 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. The technology is currently being tested in a Phase 1 clinical trial, conducted at Cleveland Clinic and funded by a grant from the U.S. Department of Defense to Cleveland Clinic.

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 that uses a novel type of CAR-T known as chimeric endocrine receptor T-cell (CER-T) technology, and is being developed in collaboration with Moffitt Cancer Center. 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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