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Anixa Biosciences Announces Completion of Final Patient Visit in Breast Cancer Vaccine Clinical Trial

Final Clinical Visit Marks Major Milestone in First-in-Human Evaluation of Breast Cancer Vaccine

Comprehensive Immune Response and Safety Data to Be Presented at the San Antonio Breast Cancer Symposium in December

SAN JOSE, Calif., Oct. 7, 2025 /PRNewswire/ -- [Anixa Biosciences, Inc.](#) ("Anixa" or the "Company") (NASDAQ: ANIX), a biotechnology company focused on the treatment and prevention of cancer, today announced the completion of the final patient visit in its breast cancer vaccine clinical trial. This novel vaccine, invented at Cleveland Clinic, is being developed in partnership with Cleveland Clinic, and the Phase 1 trial is fully funded by a grant from the U.S. Department of Defense.

The vaccine is designed to stimulate the immune system to recognize and target breast cancer before it can recur or develop. A total of 35 women received the vaccine in the study, spanning three distinct patient cohorts:

- **TNBC Group:** Women who have completed treatment for triple-negative breast cancer, are currently cancer-free, and are at risk of recurrence.
- **Prevention Group:** Women who are cancer-free but carry genetic mutations associated with elevated breast cancer risk, and who elected to undergo preventive mastectomy.
- **Pembrolizumab (Keytruda®) Group:** Women receiving pembrolizumab in a post-operative setting who were administered the vaccine concurrently with the checkpoint inhibitor.

The trial enrolled 26 patients in the TNBC group, four in the Prevention group, and five in the Pembrolizumab group.

With the completion of all patient visits and sample collection, comprehensive data analysis can now proceed. Following analysis, a final study report will be submitted to the

Department of Defense, and a Clinical Study Report (CSR) will be filed with the U.S. Food and Drug Administration (FDA).

Cleveland Clinic will present full clinical results at the San Antonio Breast Cancer Symposium on December 11, 2025.

Dr. G. Thomas Budd, of Cleveland Clinic Cancer Institute and Principal Investigator of the study, commented, "We are pleased by the data we are seeing from this trial. Preliminary results indicate that our breast cancer vaccine is well tolerated, with more than 70% of participants demonstrating protocol-defined immune responses. We look forward to presenting the final trial data at the San Antonio Breast Cancer Symposium later this year."

Dr. Amit Kumar, Chairman and CEO of Anixa Biosciences, commented, "While cancer vaccines have historically faced considerable challenges, our approach targets a novel antigen that has not been explored in this setting. We believe this strategy could represent a new paradigm in immuno-oncology, with potential utility in both the prevention and treatment of breast cancer."

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. This technology is differentiated from other cell therapies as the natural ligand of the FSHR receptor, FSH, binds to the FSHR receptor on the tumor cell instead of an antibody fragment. Moffitt is a world leader in cancer immunotherapy treatments, pioneering next-generation cell therapies such as CAR-T, and tumor infiltrating lymphocytes (TILs) to harness the power of the immune system. The Company's vaccine portfolio includes vaccines being developed in collaboration with Cleveland Clinic to treat and prevent breast cancer 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. The breast and ovarian cancer vaccines were developed at Cleveland Clinic and exclusively licensed to Anixa. Cleveland Clinic is entitled to royalties and other commercialization revenues from the Company related to these vaccine technologies. 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 [LinkedIn](#), [X](#), [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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