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Anixa Biosciences Announces Completion of Enrollment in Phase 1 Trial of Breast Cancer Vaccine

SAN JOSE, Calif., June 2, 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 enrollment in the Phase 1 clinical trial of its breast cancer vaccine. This novel vaccine, invented at Cleveland Clinic, is also 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 (DoD).

The vaccine is designed to stimulate the immune system to target breast cancer before it can recur or develop. A total of 35 women have received the vaccine in the trial, including 26 in the triple-negative breast cancer ("TNBC") group, four in the prevention group, and five in the pembrolizumab group. These participants represent 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 that place them at high risk of developing breast cancer and have elected to undergo preventative mastectomy to lower their risk.
- **Pembrolizumab (Keytruda) Group:** Women who are receiving pembrolizumab in a post-operative setting. These women are receiving the vaccine concurrently with pembrolizumab.

The final patient visits are scheduled for August 2025. Once completed, the final study report will be submitted to the Department of Defense. A Clinical Study Report (CSR) will then be prepared for submission to the U.S. Food and Drug Administration. As part of the continued development process, the Investigational New Drug (IND) application will be transferred from Cleveland Clinic to Anixa.

Anixa and Cleveland Clinic plan to submit for presentation all trial data at a major upcoming scientific meeting.

Dr. Amit Kumar, Chairman and CEO of Anixa Biosciences, commented, "We are very

encouraged by the data we are seeing from this trial. Preliminary results show that our breast cancer vaccine is well tolerated, with more than 70% of patients demonstrating protocol-defined immune responses. These encouraging findings are guiding our planning for Phase 2 trials, which will include discussions with the FDA, protocol development, manufacturing, and clinical site selection. While cancer vaccines have traditionally faced significant hurdles, our approach is aimed at a novel target that has not been previously explored in this context. We believe this could represent a new paradigm in immuno-oncology. The breast cancer market, particularly for triple-negative breast cancer and genetically high-risk populations, continues to face a major unmet need. Our vaccine may offer a unique, immunologic pathway for both prevention and treatment."

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 [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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