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Anixa Biosciences Announces Transfer of IND for Breast Cancer Vaccine from Cleveland Clinic

SAN JOSE, Calif., Dec. 15, 2025 /PRNewswire/ -- [Anixa Biosciences, Inc.](#) ("Anixa" or the "Company") (NASDAQ: ANIX), a biotechnology company focused on the treatment and prevention of cancer, today announced that it has completed the transfer of the Investigational New Drug application ("IND") for its breast cancer vaccine from Cleveland Clinic. Anixa is now the trial sponsor for future development of its breast cancer vaccine. The transfer of the IND is a natural and planned step in the progression of the vaccine's development.

With enrollment completed and encouraging immune response and safety data observed in the Phase 1 trial, Anixa plans to advance the vaccine into a Phase 2 clinical trial and has assumed full sponsorship of the IND. Anixa plans to utilize multiple clinical sites, including Cleveland Clinic, for the Phase 2 and other clinical trials.

Anixa's breast cancer vaccine, developed in collaboration with Cleveland Clinic, targets α -lactalbumin—a lactation-associated protein that is typically expressed only in breast tissue during lactation, but which re-emerges in many forms of breast cancer. By establishing an immune response against α -lactalbumin-expressing cells, the vaccine may offer both therapeutic and preventive benefits for patients with tumors expressing this protein. The vaccine is based on preclinical research led by the late Vincent Tuohy, Ph.D., who served as the Mort and Iris November Distinguished Chair in Innovative Breast Cancer Research at Cleveland Clinic.

"We are excited about assuming sponsorship of the breast cancer vaccine IND, and we look forward to advancing this potentially game-changing cancer vaccine into future clinical trials," stated Dr. Amit Kumar, Chairman and CEO of Anixa Biosciences. "We are pleased with the progress and findings from our Phase 1 clinical trial, which were presented at the San Antonio Breast Cancer Symposium on December 11."

A discussion of the Phase 1 data can be reviewed at <https://ir.anixa.com/press-releases>.

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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