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Anixa Biosciences Announces Positive Phase 1 Data for Investigational Breast Cancer Vaccine; Primary Endpoints Were Met and Immune Response Observed in 74% of Participants

Vaccine Was Safe and Well Tolerated at the Maximum Tolerated Dose

Results Support Advancement of the Program into Phase 2 Development

Combination of Keytruda® and the vaccine generated T cell responses and showed no major additional side effects, supporting plans for a Phase 2 neoadjuvant combination study in newly diagnosed breast cancer patients

SAN JOSE, Calif., Dec. 11, 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 presentation of final data from the Phase 1 clinical trial of its investigational breast cancer vaccine (NCT04674306) at the 2025 San Antonio Breast Cancer Symposium (SABCS). The trial was conducted in collaboration with Cleveland Clinic and funded by a grant from the U.S. Department of Defense.

Final Phase 1 findings showed the investigational vaccine met all major primary endpoints, was safe and well tolerated at the maximum tolerated dose (MTD), and elicited protocol-defined immune responses in 74% of participants. The presentation, titled "Final Results of a Phase I Trial of Alpha-lactalbumin (aLA) Vaccine for Breast Cancer," was delivered by Justin Johnson, Ph.D., Program Manager at Cleveland Clinic and co-inventor of the breast cancer vaccine technology. The SABCS poster presentation is available at https://ir.anixa.com/events.

"Triple-negative breast cancer remains one of the most challenging subtypes to address, and Phase 1 trials are an important step in determining whether a new approach can be administered safely and activate the immune system as intended," said G. Thomas Budd, M.D., of Cleveland Clinic's Cancer Institute and principal investigator of the study. "In this

trial, the investigational α-lactalbumin vaccine was safe and well tolerated at the maximum tolerated dose and generated protocol-defined immune responses in 74% of participants—results that support continued clinical evaluation."

Topline Phase 1 results:

- All major primary endpoints were met
- 74% of participants demonstrated protocol-defined immune responses; α-lactalbumin (aLA)-specific T cell responses were observed per protocol-defined criteria
- Vaccine was safe and well tolerated at the MTD, with adverse events primarily injection-site irritation
- Preliminary Immunohistochemistry (IHC) of primary tumors showed aLA expression ranging from absent to strong; analyses correlating expression to immune response and clinical outcomes are ongoing
- Participants will be followed for five years after completing the study
- Combination of Keytruda and the vaccine also generated antigen-specific T cell responses and showed no major additional side effects
- Data will inform planned Phase 2 study design, including a potential Phase 2 combination study with Keytruda in the neoadjuvant setting among newly diagnosed breast cancer patients

The Phase 1 study evaluated safety and monitored immune response to an investigational vaccine targeting α-lactalbumin (aLA). The trial enrolled 35 participants across three cohorts: Cohort Ia (n=26), women who completed standard-of-care treatment, including surgery, for early-stage TNBC within three years and were tumor-free but at elevated risk of recurrence; Cohort Ib (n=4), cancer-free women with BRCA1, BRCA2, or PALB2 mutations who elected preventive mastectomy and were vaccinated prior to surgery; and Cohort Ic (n=5), women with TNBC receiving pembrolizumab (Keytruda) in the adjuvant (post-surgery) setting, with evaluation of safety of combination administration and immune responses.

In Cohort Ia, at the MTD, the vaccine was reported as safe, with no flu-like symptoms (fever and myalgias), no abnormal clinical laboratory tests, and no other observed adverse side effects in this cohort; the primary notable adverse event was injection-site irritation. Participants demonstrated aLA-specific T cell responses, including production of interferon gamma and interleukin-17.

In Cohort Ib, safety and tolerability were similar to Cohort Ia. Immunohistochemistry analyses of resected breast tissue are ongoing and will be presented in a future scientific presentation.

In Cohort Ic, a key objective was to assess whether administration of the investigational vaccine in combination with pembrolizumab could create intolerable side effects. No major adverse side effects were reported; as in other cohorts, the primary adverse event was injection-site irritation. Two participants experienced Grade 3 adverse events consisting of greater irritation at an injection site.

The investigational vaccine targets α-lactalbumin, a lactation protein generally expressed in the breast during lactation but not at other times in life or in other normal tissues. In many breast cancers, malignant cells express α-lactalbumin. The vaccine is designed to activate the immune system to direct cytotoxic T cells toward tumor cells expressing α-lactalbumin,

with the goal of providing preemptive immune protection against emerging tumors that express this antigen.

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.

"It was Dr. Tuohy's hope that this vaccine would demonstrate the potential of immunization as a new way to combat breast cancer, and that a similar approach could someday be applied to other types of malignancies," said Dr. Johnson. "Our findings that the majority of participants across all three cohorts demonstrated an immune response to α-lactalbumin is an encouraging sign."

Dr. Amit Kumar, Chairman and CEO of Anixa Biosciences, stated, "We are very encouraged that the final Phase 1 data met all major primary endpoints, with the vaccine demonstrating a favorable tolerability profile at the MTD and protocol-defined immune responses in the majority of participants. We appreciate the support provided through the U.S. Department of Defense grant that enabled this study in collaboration with Cleveland Clinic, and we look forward to engaging with regulators and advancing plans for a Phase 2 study."

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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