December 6, 2023

Anixa Biosciences and Cleveland Clinic Present Positive New Data from Phase 1 Study of Breast Cancer Vaccine

– Antigen-specific T cell responses were observed at all dose levels –

– IFNγ and IL-17, immune-mediated biomarkers of T cell activation, increased over time from baseline –

– Vaccine was safe and well tolerated –

– Conference call to commence today at 6:30 p.m. ET –

SAN JOSE, Calif., Dec. 6, 2023 /PRNewswire/ -- Anixa Biosciences, Inc. ("Anixa" or the "Company") (NASDAQ: ANIX), a biotechnology company focused on the treatment and prevention of cancer, today announced new and updated positive results from the Phase 1 clinical trial of its breast cancer vaccine. The trial is being conducted in collaboration with Cleveland Clinic with funding by a grant from the U.S. Department of Defense.

The data were presented at the 2023 San Antonio Breast Cancer Symposium by G. Thomas Budd, M.D., staff physician at Cleveland Clinic Cancer Institute and principal investigator of the study, in a poster entitled "Phase I Trial of alpha-lactalbumin vaccine in high-risk operable triple negative breast cancer (TNBC) and patients at high genetic risk for TNBC."

Patients who had been curatively treated for TNBC received three vaccinations given once every two weeks. IFNγ and IL-17, which are T cell immune response indicators (cellular immunity), and antibody production (B cell humoral immunity) were measured to evaluate the vaccination effect. Data from the 16 patients treated to date showed that:

- The majority of patients developed ELISpot (T-cell) responses that met the rigorous protocol-specified definition of an immune response, with a measurable but lesser magnitude of response noted in the remaining patients.
- 12 (75%) of the women had antigen-specific IFNγ and/or IL-17 ELISpot responses that were observed at all dose levels, while ELISA antibody responses were observed at Dose Level 2 and higher.

- A statistically significant (P = 0.03) increase in IFNγ over baseline (Day 0) was observed by Day 56; while a significant (P = 0.0001) increase in IL-17 over baseline was observed by Day 14.
- Among the doses studied, Dose Level 1 (10 mcg α-lactalbumin/10 mcg zymosan) was determined to be a usable immunologic dose as well as the maximum tolerated dose (MTD).
- No significant side effects were observed, at the MTD, besides irritation at the sites of injection. No myalgias, flu-like symptoms, or aberrant laboratory values were noted.

Anixa and Cleveland Clinic plan to investigate additional intermediate dose levels and continue studying the vaccine's safety and immunologic effects in two additional patient cohorts.

- The first cohort, which opened for enrollment in August 2023, is evaluating the combination of the Company's breast cancer vaccine with Keytruda® (pembrolizumab) in post-operative patients found to have residual disease following neoadjuvant chemo-immunotherapy.
- The second cohort will investigate the safety and immunologic effects of the vaccine in patients who are BRCA1, BRCA2, or PALB2 mutation positive and are planning prophylactic risk-reducing mastectomies.

"The data from our Phase 1 trial to date has exceeded our expectations, and we are pleased with our progress. This vaccine is designed to direct the immune system to destroy TNBC cancer cells through a mechanism that has never previously been utilized for cancer vaccine development," stated Dr. Amit Kumar, Chairman and CEO of Anixa Biosciences. "We look forward to reviewing additional data as the trial continues to completion, and we are in the planning stages of the Phase 2/3 studies of this vaccine. Our goal is to initially evaluate the vaccine's ability to prevent recurrence of cancer in survivors, and continue with extension studies to eventually determine its effectiveness in preventing the initial onset of TNBC."

"There is a large unmet need for preventing TNBC, an aggressive form of breast cancer with few targeted treatment options available," said Dr. Budd, Cleveland Clinic. "We are encouraged by the data gathered to date and look forward to determining the optimal vaccine dose in additional patient cohorts. Our hope is that future studies will demonstrate that the antigen-specific T cell responses we observed translate to the prevention of breast cancer recurrence."

Anixa is the exclusive worldwide licensee to the novel breast cancer vaccine technology invented at Cleveland Clinic, the site of the Phase 1 trial. The grant from the U.S. Department of Defense was made directly to Cleveland Clinic.

Conference Call Information

Anixa is pleased to invite all interested parties to participate in a conference call, during which this new data will be discussed.

Conference Call Details:	
Presentation host:	Anixa management, with special guest speakers
Date and time:	Today, December 6, 2023, at 6:30 p.m. ET

Phone access:	**Registration Link** to receive your dial-in number and unique PIN
Webcast:	Available at www.anixa.com under "Events & Presentations"

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. Dr. Tuohy was inventor of the technology, which Cleveland Clinic exclusively licensed to Anixa Biosciences. He was entitled to a portion of the commercialization revenues received by Cleveland Clinic and also held equity in Anixa.

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. 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.

Contacts:
Stephen Kilmer
Investor Relations
skilmer@anixa.com
646-274-3580

Mike Catelani
President, COO & CFO
mcatelani@anixa.com
408-708-9808

View original content to download multimedia:https://www.prnewswire.com/news-releases/anixa-biosciences-and-cleveland-clinic-present-positive-new-data-from-phase-1-study-of-breast-cancer-vaccine-302007568.html

SOURCE Anixa Biosciences, Inc.