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Anixa Biosciences and Cleveland Clinic Announce FDA Clearance to Initiate Clinical Trial of Breast Cancer Vaccine

Novel technology developed by Cleveland Clinic researchers

SAN JOSE, Calif., Dec. 21, 2020 /PRNewswire/ --Anixa Biosciences, Inc. (NASDAQ: ANIX), a biotechnology company focused on the treatment and prevention of cancer and infectious diseases, announced today that the U.S. Food and Drug Administration (FDA) has cleared the Investigational New Drug (IND) application for its breast cancer vaccine.

- This breast cancer vaccine technology was invented and developed by Cleveland Clinic immunologist Dr. Vincent Tuohy, and his research team.
- Oncologist, Dr. Thomas Budd, also of Cleveland Clinic, will lead the clinical trial.
- Anixa Biosciences has an exclusive worldwide license to the technology.
- The technology immunizes against a protein called alpha-lactalbumin that is expressed in the mammary glands of women, only during the latter part of gestation and during lactation. After lactation ceases, this protein is no longer expressed until a woman develops breast cancer. In a vaccinated woman, the researchers anticipate that these cancer cells will be destroyed by the immune system before they have the opportunity to grow into a mature cancer.
- The initial focus is Triple Negative Beast Cancer, but this technology is expected to potentially prevent other types of breast cancer.
- Animal studies showed notable ability to prevent breast cancer.
- The preclinical studies and two trials of this vaccine are being funded by the U.S. Department of Defense.

Dr. Amit Kumar, President and CEO of Anixa stated, "We are pleased that the FDA has authorized us to commence human clinical trials of our potentially paradigm-shifting vaccine for the prevention of breast cancer. This approval triggers a cascade of events and activities, that will eventually lead to recruitment of patients and initiation of the trial."

"This is a significant milestone for our program. Our vision has always been to prevent cancer before it arises," said Dr. Tuohy. "We are looking forward to beginning clinical trials in patients."

About Anixa Biosciences, Inc.
Anixa is a publicly-traded biotechnology company developing a number of programs addressing cancer and infectious disease. Anixa's therapeutics portfolio includes a cancer immunotherapy program which uses a novel type of CAR-T, known as chimeric endocrine receptor T-cell (CER-T) technology, and a Covid-19 therapeutics program focused on inhibiting certain viral protein function. The company's vaccine portfolio includes a vaccine to prevent breast cancer, and specifically triple negative breast cancer (TNBC), the most deadly form of the disease, and a vaccine to prevent ovarian cancer. These vaccine technologies focus on immunizing against specific proteins that have been found to be expressed in certain forms of cancer. Anixa continually examines emerging technologies in complementary fields for further development and commercialization. Additional information is available at www.anixa.com.

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, the risk that clinical trial data in humans will not be comparable to data obtained in animal studies, including as it relates to our prophylactic breast cancer vaccine, as well as 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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