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Anixa Biosciences and Cleveland Clinic File IND Application for Breast Cancer Vaccine

SAN JOSE, Calif., Nov. 23, 2020 /PRNewswire/ -- [Anixa Biosciences, Inc.](#) (NASDAQ: ANIX), a biotechnology company focused on the treatment and prevention of cancer and infectious diseases, announced today that an IND (Investigational New Drug) application for its prophylactic breast cancer vaccine has been filed with the U.S. Food and Drug Administration.

This vaccine technology was invented by a research team from Cleveland Clinic, led by Dr. Vincent Tuohy, 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. Anixa has a worldwide, exclusive license to this technology.

The technology takes advantage of self-proteins that have a function at certain times in life, but then become "retired" and disappear from the body. One such protein, alpha-lactalbumin, is expressed only in the mammary glands during lactation and then disappears once lactation ceases. Dr. Tuohy discovered that this protein is abnormally expressed again when a woman contracts breast cancer, especially Triple Negative Breast Cancer (TNBC), the most deadly form of this disease. Dr. Tuohy postulated that if women could be immunized against this protein after their childbearing years, the immune system could be trained to destroy cancer cells as they arise while ignoring normal cells that no longer express this protein, thus making it difficult for the cancer to gain critical mass. Early studies to test this theory demonstrated highly significant prevention of breast cancer in animal models.

The technology is being developed at Cleveland Clinic with funding from the U.S. Department of Defense. The funding is expected to enable completion of two Phase 1 clinical trials.

"This has the potential to be a paradigm-shifting clinical study," said Dr. Tuohy. "If our data demonstrate results similar to the pre-clinical studies, this vaccine could have a significant impact on breast cancer, the most common malignancy in women. Furthermore, the way we think about controlling breast cancer may completely change."

"We look forward to moving this novel technology into the clinical stage of development," stated Dr. Amit Kumar, President and CEO of Anixa Biosciences. "If the data in humans is comparable to the data in animals, Dr. Tuohy's 'retired' protein hypothesis will usher in a new way to prevent breast cancer, as well as other types of tumors."

"This initial clinical trial will be with women who have been diagnosed with high-risk early stage TNBC and are receiving standard of care at Cleveland Clinic," said Dr. G. Thomas Budd, Department of Medical Oncology at the Taussig Cancer Center at Cleveland Clinic, and the Clinical Investigator who will be conducting the trial. "We look forward to commencing the Phase 1 clinical trial and evaluating these 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 consists of a technology focused on the immunization against α -Lactalbumin to prevent triple negative breast cancer (TNBC). 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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