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Anixa Biosciences Breast Cancer Vaccine Technology Nearing FDA Submission

SAN JOSE, Calif., July 28, 2020 /PRNewswire/ --[Anixa Biosciences, Inc.](#) (NASDAQ: ANIX), a biotechnology company focused on the treatment and prevention of cancer and infectious diseases, today announced that its prophylactic breast cancer vaccine is making progress towards clinical trials.



Anixa and Cleveland Clinic intend to file the Investigational New Drug (IND) Application with the US Food and Drug Administration by the end of the current quarter. Despite government-mandated laboratory closures, disruptions and constraints due to the coronavirus pandemic, there has not been a significant delay in this vaccine's development timeline.

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.

The underlying 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 the age of childbirth, the immune system could be trained to destroy the cancer cells as they arise, 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.

"We are extremely excited to move forward with this technology. At the current time, the bulk of the IND application is completed. The main portion that remains to be finished is the CMC section (Chemistry, Manufacture and Control)," stated Dr. Amit Kumar, President and CEO of Anixa Biosciences. "After completion of the IND, it will be reviewed by our regulatory experts and committees and then filed with the FDA. We have already had two pre-IND meetings with the FDA as this is a novel vaccine technology."

About Anixa Biosciences, Inc.

Anixa is a publicly-traded biotechnology company developing a number of programs addressing cancer and infectious disease. Anixa's therapeutic 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, 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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