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Anixa Biosciences and Moffitt Cancer Center Receive Additional Information Request from US FDA for CAR-T IND Application

SAN JOSE, Calif., May 20, 2021 /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 (US FDA) has provided details of the additional information it is requesting regarding its Chimeric Antigen Receptor-T cell therapy (CAR-T) being developed in partnership with Moffitt Cancer Center.



The Investigational New Drug (IND) application for this study was submitted in March, and the US FDA subsequently requested additional information before approving the trial. The details of that information request have now been provided by the FDA. Anixa and Moffitt feel that the requested information can be assembled and provided to the FDA within approximately 30 days, after which the FDA will again respond within 30 days after the submission.

This technology is an autologous cell therapy that requires the manufacture of a unique drug product for each individual patient. The therapeutic product is comprised of engineered T-cells that target the follicle stimulating hormone receptor (FSHR). FSHR is found at immunological levels exclusively on the granulosa cells of the ovaries. Since the target is a hormone receptor, this technology is also known as CER-T (Chimeric Endocrine Receptor T-cell) therapy, a new type of CAR-T.

Dr. Amit Kumar, President and CEO of Anixa Biosciences, stated, "We are pleased to receive this letter with the detailed information request. While we hope to comply with the

request within 30 days, certain assays may require additional time for validation before submission. We will strive to file our submission as soon as possible and we will seek to initiate this clinical trial before the end of the year."

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, 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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