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Anixa Biosciences and Moffitt Cancer Center Report US FDA Request of Additional Information for CAR-T Therapy

SAN JOSE, Calif., April 19, 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 requested additional information regarding its Chimeric Antigen Receptor-T cell therapy (CAR-T) being developed in partnership with Moffitt Cancer Center (MCC).

The study under the Investigational New Drug (IND) application has been placed on clinical hold pending submission of additional information requested by the FDA. Within the next 30 days, it is expected that the FDA will provide a letter to MCC with detailed and specific information requested. MCC will assemble and submit information addressing the request as soon as possible thereafter. Successive to the submission, the FDA will continue its review of the IND.

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 eagerly awaiting guidance from the FDA with details about the specific information requested to clear the IND, enabling initiation of clinical trials."

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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