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Anixa Biosciences and Moffitt Cancer Center Announce FDA Clearance to Initiate Clinical Trial of Ovarian Cancer CAR-T Immunotherapy

SAN JOSE, Calif., Aug. 30, 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 (FDA) has cleared the Investigational New Drug (IND) application for its CAR-T (Chimeric Antigen Receptor-T cell) therapy, which is being developed in partnership with Moffitt Cancer Center (Moffitt).

- Dr. Robert Wenham, Chair of Gynecological Oncology at Moffitt will lead the clinical trial.
- This CAR-T therapy was developed by Dr. Jose Conejo-Garcia and his research team, when he was at the Wistar Institute. Dr. Conejo-Garcia is currently the Chairman of Immunology at Moffitt.
- Anixa Biosciences has an exclusive worldwide license to the technology.
- This technology is an autologous cell therapy. The therapeutic product is comprised of engineered T-cells that target the follicle stimulating hormone receptor (FSHR). FSHR is found at immunologically relevant levels exclusively on the granulosa cells of the ovaries. Since the target is a hormone receptor, and the target-binding domain is derived from its natural ligand, 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 stated, "We are pleased that the FDA has authorized us to commence human clinical trials of our potentially paradigm-shifting therapy. Outcomes for women with late-stage ovarian cancer are poor, so if this approach demonstrates efficacy, it would have a dramatic impact on patients for whom there are no other options."

"This is a major milestone for our program. CAR-T therapy has had major successes in B-cell malignancies, but no clinical success in other types of tumors. We feel that our technology could be the first CAR-T approach that will demonstrate efficacy in a solid tumor indication, and we are looking forward to testing and verifying that assertion in human trials,"

said Dr. Wenham.

In addition to Drs. Wenham and Conejo-Garcia, other key members of the team at Moffitt include:

- Dr. Marco Davila, Clinician and Director of the Cell Therapy Facility at Moffitt
- Dr. Daniel Abate Daga, Assistant Director of the Cell Therapy Facility at Moffitt
- Dr. Ana Marie Landin, Experimental Cell Therapy Manager at Moffitt
- Dr. Theresa Boyle, Department of Pathology at Moffitt
- Carrie Thomas, FDA Regulatory Liaison at Moffitt
- Tam Jackson, Project Management Consultant
- Scientists and Members of the Moffitt Cell Therapy Facility
- Members of the Moffitt Alliance Relations Team

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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