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Anixa Biosciences Initiates Dosing in Second Cohort of Ovarian Cancer CAR-T Clinical Trial

Dose escalation for fourth patient follows successful completion of first cohort

SAN JOSE, Calif., Feb. 12, 2024 /PRNewswire/ -- [Anixa Biosciences, Inc.](#) ("Anixa" or the "Company") (NASDAQ: ANIX), a clinical-stage biotechnology company focused on the treatment and prevention of cancer, today announced that treatment has commenced for the fourth patient in the ongoing Phase 1 clinical trial of its novel chimeric antigen receptor T-cell (CAR-T) therapy for ovarian cancer. The study is being conducted through a research partnership with Moffitt Cancer Center.

The first-in-human trial is enrolling patients with recurrent/resistant ovarian cancer who have progressed on at least two prior therapies. The CAR T was safe and tolerable in the first three patients treated. The fourth patient, the first patient enrolled in the second cohort, received triple the dose of CAR-T cells compared with the dose of the first cohort. Anixa's Follicle Stimulating Hormone Receptor (FSHR)-mediated CAR-T technology, also known as chimeric endocrine receptor T-cell (CER-T), differs from traditional CAR-T therapy by targeting FSHR, which research indicates is expressed on ovarian cells, as well as in the vasculature of tumors.

Dr. Amit Kumar, Chairman and CEO of Anixa, commented, "With no safety issues observed in the first cohort of patients, we have successfully advanced to the next cohort to evaluate a 3x higher dose. As the trial progresses, we seek to demonstrate efficacy of our cell therapy in solid tumors—a difficult challenge for traditional CAR-T therapies that have been shown to be efficacious in hematological tumors and lymphoma."

Dr. Robert Wenham, the Principal Investigator of the trial and the Chair of Gynecologic Oncology at Moffitt, stated, "First, we have the advantage of a target that is much more specific to our tumor tissue, which should minimize any on-target, off-tumor effect. Additionally, we are administering the engineered T-cells directly into the peritoneum (IP), which is the location of most of the ovarian tumor lesions. We hope that this delivery approach will enable direct trafficking of the CER-T-cells to the tumor sites and minimize adverse events such as cytokine release syndrome (CRS)".

About Anixa's CER-T Approach (Follicle Stimulating Hormone Receptor-Mediated CAR-T technology)

Anixa's chimeric antigen receptor T-cell (CAR-T) technology approach is an autologous cell therapy 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 (chimeric endocrine) receptor, and the target-binding domain is derived from its natural ligand, this technology is known as CER-T (chimeric endocrine receptor T-cell) therapy, a new type of CAR-T.

About Anixa Biosciences, Inc.

Anixa is a clinical-stage biotechnology company focused on the treatment and prevention of cancer. Anixa's therapeutic portfolio consists of an ovarian cancer immunotherapy program being developed in collaboration with Moffitt Cancer Center, which uses a novel type of CAR- T, known as chimeric endocrine receptor T-cell (CER-T) technology. The Company's vaccine portfolio includes a novel vaccine being developed in collaboration with Cleveland Clinic to prevent breast cancer – specifically triple negative breast cancer (TNBC), the most lethal form of the disease – as well as a vaccine to prevent ovarian cancer. These vaccine technologies focus on immunizing against "retired" proteins that have been found to be expressed in certain forms of cancer. Anixa's unique business model of partnering with world-renowned research institutions on clinical development allows the Company to continually examine emerging technologies in complementary fields for further development and commercialization. To learn more, visit www.anixa.com or follow Anixa on [Twitter](#), [LinkedIn](#), [Facebook](#) and [YouTube](#).

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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