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Anixa Biosciences Announces Treatment of Second Patient in its Ovarian Cancer CAR-T Clinical Trial

SAN JOSE, Calif., May 22, 2023 /PRNewswire/ -- [Anixa Biosciences, Inc.](#) (NASDAQ: ANIX), a biotechnology company focused on the treatment and prevention of cancer, today announced that, in conjunction with its partner Moffitt Cancer Center, it has commenced treatment of the second patient in the ongoing clinical trial of its novel chimeric antigen receptor T-cell (CAR-T) therapy for ovarian cancer.

This study (NCT05316129) is a dose-escalation Phase 1 trial to evaluate safety and to determine the maximum tolerated dose of follicle stimulating hormone receptor T-cells and to preliminarily assess clinical activity. The study is being conducted at Moffitt Cancer Center. All patients being enrolled in the trial have disease that is progressing and have failed at least two, but often more, therapeutic interventions. This patient received the same dose of engineered T-cells as the first patient in the trial, and the next (third) patient is expected to also receive the same dose. The successive three-patient cohort is expected to receive a higher dose of cells.

The CAR-T approach used for Anixa's therapy is known as chimeric endocrine receptor T-cell (CER-T) since the target of the engineered T-cells is an endocrine receptor. While CAR-T therapy has shown efficacy in some hematological tumors, reproducing the same results with solid tumors, such as ovarian cancer, has proven challenging. One of the reasons for this difficulty is that effective CAR-T therapy needs a specific antigen to recognize that is only present on target cancer cells in order to avoid negatively affecting healthy cells. The cell therapy being evaluated in Anixa's Phase 1 study differs from traditional CAR-T in that it targets the follicle stimulating hormone receptor (FSHR), which research indicates is exclusively expressed on ovarian cells in healthy adult females.

"We are optimistic about the potential of this therapy to impact ovarian cancer patients who are out of all other options. Our goal is to increase enrollment at a responsible rate that enables us to understand the impact that our therapy is exhibiting," stated Dr. Robert Wenham, the principal investigator of this trial at Moffitt Cancer Center.

"We are pleased to have treated the second patient in our ovarian cancer CAR-T clinical

study," stated Dr. Amit Kumar, Chairman and CEO of Anixa Biosciences. "We anticipate an increase in the rate of patient recruitment, and expect the third and potentially last patient of the current dose cohort to be treated soon. Since this is the early stage of patient enrollment, we are announcing publicly the treatment of the second patient, but it is not our intent to announce enrollment of each subsequent patient. We will make periodic announcements when warranted."

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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