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

SAN JOSE, Calif., Aug. 28, 2023 /PRNewswire/ -- Anixa Biosciences, Inc. ("Anixa" or the "Company") (NASDAQ: ANIX), a biotechnology company focused on the treatment and prevention of cancer, today announced that, in partnership with Moffitt Cancer Center, it has commenced treatment of the third patient in the ongoing clinical trial of Anixa's novel chimeric antigen receptor T-cell (CAR-T) therapy for ovarian cancer.

The study (NCT05316129), which is being conducted at Moffitt Cancer Center, is a dose-escalation Phase 1 trial to evaluate the therapy's safety; determine the maximum tolerated dose of T-cells targeting the follicle stimulating hormone receptor (FSHR); and preliminarily assess clinical activity. All patients being enrolled in the trial have disease that is progressing and have failed at least two, but often more, therapeutic interventions.

The third patient received the same dose of engineered T-cells as the first and second patients in the trial. Assuming safety is validated in the third patient, as was the case for the first two patients, Anixa expects to begin treatment of the second cohort in the fourth quarter of 2023. Patients enrolled in this second cohort will receive approximately three times the cell dose compared to the first cohort.

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 to attack a specific antigen present only on targeted cells to avoid negatively affecting healthy cells. The cell therapy being evaluated in Anixa's Phase 1 study differs from traditional CAR-T therapy in that it targets the FSHR, which research indicates is exclusively expressed on ovarian cells in healthy adult females.

Dr. Robert Wenham, Principal Investigator of the trial and Chair of the Gynecologic Oncology Program at Moffitt Cancer Center, stated, "We are pleased that the Phase 1 clinical trial evaluating this CAR-T therapy for ovarian cancer continues to progress. We are looking forward to analyzing the safety data from the first cohort, and look forward to escalating the dose in the following cohort."

"Though enrollment of patients in this trial has been slow, which is common for clinical studies of this type, we are pleased to have completed the first cohort," stated, Dr. Amit Kumar, Chairman and CEO of Anixa Biosciences. "Assuming there are no safety issues with this third patient, we look forward to advancing to the next higher dose cohort."

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.

About Moffitt Cancer Center
Moffitt is dedicated to one lifesaving mission: to contribute to the prevention and cure of cancer. The Tampa-based facility is one of only 54 National Cancer Institute-designated Comprehensive Cancer Centers, a distinction that recognizes Moffitt's scientific excellence, multidisciplinary research, and robust training and education. Moffitt's expert nursing staff is recognized by the American Nurses Credentialing Center with Magnet® status, its highest distinction. With more than 8,500 team members, Moffitt has an economic impact in the state of $2.4 billion. For more information, call 1-888-MOFFITT (1-888-663-3488), visit MOFFITT.org, and follow the momentum on Facebook, Twitter, Instagram 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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