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Anixa Biosciences Completes Treatment of First Patient Cohort in Ovarian Cancer CAR-T Clinical Trial

- With no dose-limiting toxicities observed, treatment of second dose cohort to begin

SAN JOSE, Calif., Oct. 13, 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 completed treatment of the first patient cohort in the ongoing clinical trial of Anixa's novel chimeric antigen receptor T-cell (CAR-T) therapy for ovarian cancer.

All three patients in the first cohort received the same dose of engineered T-cells, with no dose-limiting toxicities observed. Following the requisite wait time after the last patient was dosed, a comprehensive review of the safety data from this cohort, and confirmation that it is safe to escalate, the trial will begin enrolling patients in the second dose cohort immediately. Patients enrolled in this second cohort will receive three times the cell dose compared to the first cohort.

Dr. Amit Kumar, Chairman and CEO of Anixa Biosciences, stated, "We are pleased with the positive safety data from the first cohort and look forward to advancing to the next higher dose cohort. We hope to continue observing good safety results as we continue to increase dosage, and eventually objective efficacy data."

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.

Dr. Robert Wenham, the Principal Investigator of the trial, and the Head of Gynecological Oncology at Moffitt stated, "We are very pleased with the results to date. The first three patients were dosed through a peritoneal catheter and no patient has had a dose-limiting toxicity. Since most lesions in ovarian cancer are within the peritoneum, we hope the delivered CAR-T cells remain localized and active in the vicinity of the tumors. It's possible

that we may see very limited side effects due to this local, as opposed to systemic, delivery. The very selective target also gives us reason to hope that on-target, off-tumor effects will not be prevalent as in other solid tumor studies. Perhaps this delivery approach may enhance efficacy as well. However, we will also test this therapy by intravenous administration, in patients for whom peritoneal administration is not possible."

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.

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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