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Anixa Biosciences Commences Treatment of Fifth Patient in Ovarian Cancer CAR-T Clinical Trial

Novel and proprietary CAR-T approach holds potential to be first effective CAR-T therapy for solid tumors

SAN JOSE, Calif., May 21, 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 fifth patient in its 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.

Anixa's first-in-human trial ([NCT05316129](#)) is enrolling female adult patients with recurrent/progressing ovarian cancer who were unresponsive to at least two prior therapies. Safety was confirmed in the first three-patient cohort. The patients in the second cohort, including patient #5, receive triple the dose of engineered T-cells compared with the first cohort of three patients. The study will identify the maximum tolerated dose of T-cells targeting the follicle stimulating hormone receptor (FSHR), found only on ovarian cells

"With our fifth patient treated, our trial is progressing, and we continue to see that our therapy appears to be safe and well-tolerated," said Dr. Amit Kumar, Chairman and CEO of Anixa. "The technology behind our novel CAR-T therapy differs from traditional CAR-T therapies by targeting the FSHR, which research indicates is exclusively expressed on ovarian cells in healthy adult females. We developed this approach to tackle preexisting difficulties with CAR-T cell therapies in solid ovarian tumors. In our trial, we will also explore several parameters for applying our CAR-T therapy to solid tumors in general."

Anixa's FSHR-mediated CAR-T technology was developed by Jose R. Conejo-Garcia, M.D., Ph.D., Professor of Immunology in the Department of Integrative Immunobiology at the Duke University School of Medicine. Anixa holds an exclusive world-wide license to the technology from The Wistar Institute.

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 vaccines being developed in collaboration with Cleveland Clinic to prevent breast cancer – specifically triple negative breast cancer (TNBC), the most lethal form of the disease – and ovarian cancer, as well as additional cancer vaccines to address many intractable cancers, including high incidence malignancies in lung, colon, and prostate. 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 all stages of 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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