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## **Anixa Biosciences and Moffitt Cancer Center Complete Dosing of Fourth Cohort in Ovarian Cancer CAR-T Clinical Trial; Multiple Patients Surpassing Median Expected Survival**

*Continue to observe a positive safety profile—no dose limiting toxicities, cytokine release syndrome or immune effector cell-associated neurotoxicity*

SAN JOSE, Calif., Sept. 8, 2025 /PRNewswire/ -- [Anixa Biosciences, Inc.](#) ("Anixa" or the "Company") (NASDAQ: ANIX), a biotechnology company focused on the treatment and prevention of cancer, today announced it has completed dosing of the fourth cohort in its ongoing Phase 1 clinical trial ([ClinicalTrials.gov NCT05316129](#)) evaluating its novel FSHR-targeted CAR-T/CER-T therapy for recurrent ovarian cancer. The study is being conducted through a research partnership with Moffitt Cancer Center ("Moffitt"). The fifth cohort is expected to commence following a routine 30-day safety verification that no adverse effects have been observed in the fourth cohort.

To date several treated patients remain alive beyond disease-specific median survival benchmarks. Notably, one patient from the 1<sup>st</sup> cohort remains alive 28 months post-treatment. These observations are preliminary and from a small number of patients and dose levels.

The fourth cohort in the trial received  $3 \times 10^6$  CAR-positive cells per kilogram of body weight—approximately a 30-fold increase versus the first cohort ( $1 \times 10^5$  cells/kg). No dose-limiting toxicities (DLTs) have been observed to date in the fourth cohort. Pending safety review, the fifth cohort is planned at approximately  $1 \times 10^7$  cells/kg.

Anixa's FSHR-mediated CAR-T technology targets the follicle-stimulating hormone receptor (FSHR), which research indicates is exclusively expressed on ovarian cells, tumor vasculature, and certain cancer cells. This first-in-human trial is enrolling adult women with recurrent ovarian cancer who have progressed following at least two prior therapies and is designed to evaluate safety, identify the maximum tolerated dose, and explore preliminary

signals of activity.

Dr. Amit Kumar, Chairman and CEO of Anixa, stated, "With the completion of the fourth cohort, we are gaining important insights into the potential of our CAR-T therapy for ovarian cancer at higher dose levels. While this study is primarily designed to assess safety, we are encouraged by the early indications of potential efficacy, and look forward to initiating the next dose cohort following the standard safety review."

Anixa's CAR-T technology was invented 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. The ongoing clinical trial is being conducted at Moffitt under the direction of Dr. Robert Wenham, Chair of the Gynecologic Oncology Program. Anixa holds an exclusive worldwide license to the FSHR-targeting CAR-T technology from The Wistar Institute.

### **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. This technology is differentiated from other cell therapies as the natural ligand of the FSHR receptor, FSH, binds to the FSHR receptor on the tumor cell instead of an antibody fragment. Moffitt is a world leader in cancer immunotherapy treatments, pioneering next-generation cell therapies such as CAR-T, and tumor infiltrating lymphocytes (TILs) to harness the power of the immune system. The Company's vaccine portfolio includes vaccines being developed in collaboration with Cleveland Clinic to treat and prevent breast cancer 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. The breast and ovarian cancer vaccines were developed at Cleveland Clinic and exclusively licensed to Anixa. Cleveland Clinic is entitled to royalties and other commercialization revenues from the Company related to these vaccine technologies.

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](http://www.anixa.com) or follow Anixa on [LinkedIn](#), [X](#), [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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