

October 15, 2024



Anixa Biosciences Announces Second Dose Administered to Patient in Ovarian Cancer CAR-T Clinical Trial

Patient showed clinical activity after initial treatment, with necrosis, inflammation, and T cell infiltration observed in tumor biopsy from the lowest dose

SAN JOSE, Calif., Oct. 15, 2024 /PRNewswire/ -- Anixa Biosciences, Inc. ("Anixa" or the "Company") (NASDAQ: ANIX), a biotechnology company focused on the treatment and prevention of cancer, today announced that it has administered the second dose of its CAR-T therapy to an individual patient. This follows a positive response after the initial treatment in the ongoing Phase 1 clinical trial of its chimeric antigen receptor T-cell (CAR-T) therapy for ovarian cancer. The study is being conducted in collaboration with Moffitt Cancer Center.



Dr. Robert Wenham (left) and Dr. Monica Avila, with their patient

Previously, Anixa and Moffitt received approval for a single-patient IND application, allowing the administration of a second dose to a patient whose tumor biopsy revealed cellular infiltration and necrosis, indicating biological activity of the CAR-T therapy.

After the first infusion, the patient remained stable, did not require alternative treatment and her quality of life was good, leading to the decision to administer a second dose to further enhance these positive results. These findings offer promising indications that the CAR-T therapy may serve as a successful long-term treatment option, highlighting its potential effectiveness in the fight against ovarian cancer.

"While this is a single patient, the positive clinical activity observed, including necrosis and T cell infiltration, is an encouraging sign of the therapy's potential effectiveness," stated Dr. Robert Wenham, Chair of the Department of Gynecologic Oncology at Moffitt and the principal investigator of the trial. "Based on these results, we recently submitted an amendment to the current trial protocol to allow patients who may benefit to receive a second dose. We are excited to continue evaluating this treatment in our ongoing trial, and we are optimistic about the potential long-term benefits it may offer to patients with ovarian cancer."

Dr. Monica Avila, the patient's treating oncologist, stated, "My patient received her first infusion in May 2023. We are now nearly 18 months from that date, and she is doing well and is now receiving this second dose. I am thrilled with her status and look forward to observing further progress."

Dr. Amit Kumar, CEO of Anixa Biosciences, stated, "We are proud to have an outstanding team, including Dr. Wenham and Dr. Avila, and we are encouraged by the positive response seen in this patient following the initial dose of our CAR-T therapy. The continued clinical improvements reinforce our confidence in the potential of this groundbreaking treatment to provide hope for patients battling ovarian cancer. We remain committed to advancing this innovative therapy and bringing new, effective treatment options to the forefront."

The Phase 1 clinical trial at Moffitt is treating recurrent ovarian cancer patients who have failed standard-of-care therapies. To date, six patients have been treated in the dose escalation trial, three in the first cohort and three in the second cohort. Dose escalation will continue after confirming the previous dosages are safe.

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 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. 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

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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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