

February 9, 2026



Anixa Biosciences Reports Encouraging Patient Survival Observations in Ovarian Cancer CAR-T Trial; Achieves Regulatory Approval Enabling Major Dose Escalation

Multiple patients substantially exceed expected survival at low dose levels; absence of dose-limiting toxicities supports escalation to doses up to 100x higher

Trial expansion reflects growing confidence in intra-peritoneal CAR-T delivery and introduces lymphodepletion to potentially enhance efficacy

Anixa to participate in Water Tower Research fireside chat at 11:00am ET on February 10, 2026 to discuss trial observations

SAN JOSE, Calif., Feb. 9, 2026 /PRNewswire/ -- [Anixa Biosciences, Inc.](#) ("Anixa" or the "Company") (NASDAQ: ANIX), a biotechnology company focused on the treatment and prevention of cancer, today provided an update on patient outcomes observed in its ongoing Phase 1 ovarian cancer CAR-T clinical trial, following regulatory approval of a protocol amendment that enables substantial dose escalation.

The ongoing Phase 1 trial is enrolling adult women with recurrent ovarian cancer, who have failed standard of care chemotherapy, and progressed after two or more prior therapies. To date, twelve patients have been treated in the trial at four dosage levels. Of these patients, seven have lived beyond their expected median survival of approximately three to four months, based on disease stage and prior therapy history. One patient survived 28 months following treatment, three patients have survived greater than one year following treatment (17, 15 and 14 months, respectively) and three patients have survived 11, 8 and 8 months, respectively. Three patients that have reached 15, 14 and 8 months remain alive, and one additional patient who was treated more recently, is also currently alive.

While the study is designed to primarily demonstrate safety, Anixa believes this pattern of extended survival represents encouraging, albeit anecdotal, evidence of clinical activity in a

patient population with limited therapeutic options. These survival observations have been accompanied by a clean safety profile. Importantly, no dose-limiting toxicities (DLTs) have been observed to date, prompting Anixa's partner, Moffitt Cancer Center ("Moffitt"), to obtain Institutional Review Board (IRB) approval for a protocol amendment that permits significant dose escalation.

Under the amended protocol, dosing may increase from the original range of 1×10^5 to 1×10^7 CAR-positive cells per kilogram of body weight ("cells/kg") to as high as 1×10^9 cells/kg, representing a two-order-of-magnitude increase. If no DLTs are observed at this level, additional escalation may be pursued at the discretion of the principal investigator.

Anixa and Moffitt believe the favorable safety profile observed to date is partially attributable to the direct intra-peritoneal delivery of CAR-T cells, which differs from conventional intravenous administration and may reduce systemic toxicity while enhancing localized tumor targeting.

Dr. Amit Kumar, Chairman and CEO of Anixa Biosciences, stated, "Although these patients were treated at doses we believe are below the optimal therapeutic range, we are encouraged by the number of individuals who have lived far longer than expected."

As part of the amended study design, the next patient cohort will receive 1×10^7 cells/kg following treatment with cyclophosphamide and fludarabine, a preparatory regimen known as lymphodepletion. Lymphodepletion reduces competing immune cells, creating a more favorable environment for CAR-T expansion, persistence, and activity. While lymphodepletion is routinely used in CAR-T therapies for hematologic cancers, its role in solid tumors remains investigational. Anixa, Moffitt, and the U.S. Food and Drug Administration view this addition as an important opportunity to assess whether lymphodepletion can further enhance efficacy in a localized solid tumor setting, particularly when combined with intra-peritoneal CAR-T delivery.

Dr. Robert Wenham, Chair of the Gynecologic Oncology Program at Moffitt and principal investigator of the trial, added, "The absence of dose-limiting toxicities observed thus far has given us the flexibility to safely explore higher dose levels than originally planned. With regulatory approval now in place, the program is positioned to advance into higher-dose evaluation under the amended protocol. This amendment allows us to further evaluate both safety and potential therapeutic benefit as the study advances."

Dr. Kumar will further discuss the observations in the clinical trial, as well as provide updates on Anixa's plans for 2026, in the upcoming Water Tower Research Fireside Chat Series taking place on Tuesday, February 10, 2026, at 11:00am ET. Interested parties can register for the event at: [Fireside Chat Registration](#).

About Lira-cel, Anixa's CAR-T Therapy for Recurrent Ovarian Cancer

Liraltogene autoleucel, or lira-cel, uniquely targets the follicle-stimulating hormone receptor (FSHR), which is selectively expressed on ovarian cells, tumor vasculature, and certain cancer cells, but not in healthy tissue. The ongoing Phase 1 trial (ClinicalTrials.gov NCT05316129) is enrolling adult women with recurrent ovarian cancer who have progressed after at least two prior therapies.

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 liraltagene autoleucel, or lira-cel, an ovarian cancer immunotherapy 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 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.

Contact:

Mike Catelani
President, COO & CFO
mcatelani@anixa.com
408-708-9808

 View original content to download multimedia <https://www.prnewswire.com/news-releases/anixa-biosciences-reports-encouraging-patient-survival-observations-in-ovarian->

[cancer-car-t-trial-achieves-regulatory-approval-enabling-major-dose-escalation-302681799.html](https://www.fda.gov/oc/2017/cancer-car-t-trial-achieves-regulatory-approval-enabling-major-dose-escalation-302681799.html)

SOURCE Anixa Biosciences, Inc.