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Anixa Biosciences Announces Approval of Protocol Amendment for Ovarian Cancer CAR-T Clinical Trial

Amendment expands the potential benefits of CAR-T therapy allowing a second dose and includes more ovarian cancer histologies

SAN JOSE, Calif., Feb. 18, 2025 /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, along with its partner Moffitt Cancer Center ("Moffitt"), has received approval for an amendment to the protocol governing its ongoing clinical trial using CAR-T therapy for the treatment of ovarian cancer ([NCT05316129](#)).

The key changes in the protocol allows patients who may benefit from a second dose of the CAR-T therapy to receive it and expands enrollment eligibility to include patients with sex cord-stromal tumors (SCSTs) and Sertoli Leydig cell tumors (SLCTs). Previously, Anixa and Moffitt had secured a single patient IND approval for an additional dose for a patient whose biopsy showed cellular infiltration and necrosis, indicating biological activity of the CAR-T therapy. With this amendment, all eligible patients in the trial can receive a second dose of the CAR-T therapy without the need to submit individual INDs for each case.

Dr. Robert Wenham, Chair of the Department of Gynecologic Oncology at Moffitt and the principal investigator of the trial, stated, "This amendment is a crucial development in our ongoing efforts to advance the treatment of ovarian cancer with CAR-T therapy. The ability to administer a second dose to patients who show potential for additional benefit provides us with more flexibility and an opportunity to further evaluate the effectiveness of this innovative therapy."

"We are excited about the approval of this protocol amendment, as it allows us to potentially enhance the efficacy of our CAR-T therapy by providing a second dose to patients who might benefit from it and to treat additional rare types of ovarian cancer. This is a significant step in optimizing the treatment for ovarian cancer, and we look forward to continuing our work with Moffitt Cancer Center as we strive to improve outcomes for patients facing this difficult disease," stated Dr. Amit Kumar, Chairman and CEO of Anixa Biosciences.

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 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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