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Anixa Biosciences Announces Submission of Protocol Amendment for CAR-T Trial

Amendment will allow a second dose of CAR-T therapy to suitable patients

SAN JOSE, Calif., Sept. 30, 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 and partner Moffitt Cancer Center ("Moffitt") have submitted an amendment to the current protocol that governs its ongoing clinical trial utilizing a CAR-T therapy to treat ovarian cancer ([NCT05316129](#)).

A key change in the protocol provides a second dose of the therapy to patients who might benefit from an additional dose. Previously, Anixa and Moffitt sought and received approval of a single patient IND application to enable a second dose for a single patient who, upon examination of tumor obtained from a biopsy, exhibited cellular infiltration and necrosis, indicating biologic activity of the CAR-T. This amendment will permit all potential patients to receive another leukapheresis and a second dose of CAR-T, without submitting individual INDs for each patient.

Dr. Robert Wenham, Chair of the Gynecologic Oncology Department at Moffitt, and the principal investigator of the trial, stated, "In initial Phase 1 clinical trials, it is customary to begin with low, often subtherapeutic cell doses to verify safety, before increasing the dose levels. In our study, the patient approved for a second dose by the individual IND received the starting, lowest dose. While initially meeting the criteria for progression due to size of her predominate tumor, her cancer has since remained relatively stable and she has not received additional therapy since her first infusion. We are hoping a second, higher dose may improve her overall response and outcome. In general, we anticipate that higher cell doses will lead to efficacy, but for solid tumors, a second dose may be needed in a subset of patients to improve the rate and durability of responses."

"We hope to get approval from regulatory agencies shortly, to enable second doses for the appropriate patients. We are clearly enthusiastic about the progress of this trial and are looking forward to treating additional patients," 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 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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