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Anixa Biosciences Announces FDA Approval of Individual Patient IND for its Ovarian Cancer CAR-T Therapy

IND follows encouraging findings of necrosis, inflammation and T cell infiltration in tumor biopsy of patient in lowest dose cohort

SAN JOSE, Calif., July 23, 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 its collaborator, Moffitt Cancer Center (Moffitt), has received approval by the U.S. Food and Drug Administration (FDA) of an individual patient Investigational New Drug Application (IND) to allow a second dose of its CAR-T therapy for a patient that may be demonstrating clinical activity to the initial treatment.

Dr. Robert Wenham, Chair, Department of Gynecologic Oncology at Moffitt, and the principal investigator of the trial, stated, "In the first cohort and at the lowest dose administered, despite an initial increase in tumor size that met criteria for progression, one patient has remained off new therapy for many months with no new disease. Even her tumor marker that was initially elevating later began to fall. A biopsy demonstrated tumor with necrosis, inflammation and T cell infiltration by Immunohistochemistry (IHC). Based on these findings, we sought approval from the FDA to administer a second treatment to her, aiming to increase the likelihood of a partial or complete response. Recently, we received that approval from the FDA."

"I am pleased with the very long duration absent of any further disease and the possible response that my patient has exhibited with this innovative therapy, as she had no other realistic options. I look forward to evaluating her progress with successive dosing, as well as future patients who have no other alternatives," stated Dr. Monica Avila, the patient's treating oncologist.

Dr. Amit Kumar, CEO of Anixa Biosciences commented, "We were somewhat surprised and quite encouraged to see such a notable response this early, given the low dose in the first cohort. We truly hope we can help this patient, as well as all other women fighting this terrible disease."

The Phase I 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 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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