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Anixa Biosciences Announces Treatment of First Patient in its Ovarian Cancer CAR-T Clinical Trial

SAN JOSE, Calif., Aug. 15, 2022 /PRNewswire/ -- [Anixa Biosciences, Inc.](#) (NASDAQ: ANIX) ("Anixa") a biotechnology company focused on the treatment and prevention of cancer and infectious diseases, today announced that, in conjunction with its partner Moffitt Cancer Center, it has commenced treatment of the first patient in the clinical trial of its novel chimeric antigen receptor T-cell (CAR-T) therapy for ovarian cancer.

The study is a dose-escalation Phase 1 trial to determine safety and the maximum tolerated dose of follicle stimulating hormone receptor T-cells and to preliminarily assess efficacy. The study is being conducted at Moffitt Cancer Center and will consist of up to 48 patients.

The CAR-T approach used for Anixa's therapy is known as chimeric endocrine receptor T-cell (CER-T) since the target of the engineered T-cells is an endocrine receptor. While CAR-T therapy has shown efficacy in some hematological tumors, reproducing the same results with solid tumors, such as ovarian cancer, has proven challenging. One of the reasons for this difficulty is that effective CAR-T therapy needs a specific antigen to recognize that is only present on target cancer cells in order to avoid negatively affecting healthy cells. The CER-T therapy being evaluated in Anixa's Phase 1 study differs from traditional CAR-T in that it targets the follicle stimulating hormone receptor (FSHR), which research indicates is exclusively expressed on ovarian cells in healthy adult females.

"We are pleased that the first patient has been treated in our ovarian cancer CAR-T clinical study," stated Amit Kumar, Ph.D., Chairman and CEO of Anixa Biosciences. "This is truly an exciting time for Anixa, as we have now begun treating patients in our second clinical trial. With our CAR-T study, we hope to determine whether our unique targeting approach will work in solid tumors—a difficult challenge for traditional CAR-T therapies."

Robert Wenham, M.D., MS, FACOG, FACS, the trial's lead investigator and Chair of the Department of Gynecologic Oncology at Moffitt Cancer Center, added, "With limited treatment options for recurrent, chemo-resistant ovarian cancer, I am hopeful that this program can provide a unique opportunity to make a meaningful impact on patients of this devastating disease."

Jose R. Conejo-Garcia, M.D., Ph.D., Chair of the Department of Immunology at Moffitt Cancer Center and co-inventor of the CER-T technology, added, "It is exciting to see our novel FSHR-mediated CAR-T technology reaching patients, and if our unique CAR-T approach is successful, it could serve as a model for future targeted CAR-T therapies in other cancer types."

Dr. Conejo-Garcia and his research team developed the FSHR-mediated CAR-T technology when he was at the Wistar Institute where he contributed to report for the first time on the role of T-cell responses in the outcome of ovarian cancer patients. The clinical trial being conducted today is based on this pre-clinical work, originally published in [Clinical Cancer Research](#). Anixa has an exclusive, world-wide license to this technology.

About Anixa's CER-T Approach (Follicle Stimulating Hormone Receptor-Mediated CAR-T technology)

Anixa's chimeric antigen receptor T-cell (CAR-T) technology approach is an autologous cell therapy comprised of engineered T-cells that target the follicle stimulating hormone receptor (FSHR). FSHR is found at immunologically relevant levels exclusively on the granulosa cells of the ovaries. Since the target is a hormone (chimeric endocrine) receptor, and the target-binding domain is derived from its natural ligand, this technology is known as CER-T (chimeric endocrine receptor T-cell) therapy, a new type of CAR-T.

About Anixa Biosciences, Inc.

Anixa is a clinical-stage biotechnology company with a number of programs addressing cancer and infectious disease. Anixa's portfolio of therapeutics includes a 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, and, with partner MolGenie GmbH, a COVID-19 program focused on compounds targeting the M^{pro} enzyme of SARS-CoV-2, which is largely conserved across all recently identified variants. The company's vaccine portfolio includes a novel vaccine being developed in collaboration with Cleveland Clinic to prevent breast cancer – specifically triple negative breast cancer (TNBC), the most lethal form of the disease – as well as a vaccine to prevent ovarian cancer. 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 clinical 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](#) and [Facebook](#).

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.

Contacts

Company Contact:

Mike Catelani
President
mcatelani@anixa.com
408-708-9808

Investors:

Eric Ribner
LifeSci Advisors, LLC
eric@lifesciadvisors.com
646-751-4363

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