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Anixa Biosciences Announces Commencement of US FDA Approved IND Transfer to Support Upcoming Phase 2 Breast Cancer Vaccine Trial

Progress Follows Positive Immune Response Observed in Phase 1 Study

SAN JOSE, Calif., Aug. 4, 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, in collaboration with Cleveland Clinic, it has initiated the transfer of the Investigational New Drug (IND) application that supported the Phase 1 clinical trial of its breast cancer vaccine.

With enrollment completed and encouraging immune response data observed in the Phase 1 trial, Anixa plans to advance the vaccine into a Phase 2 clinical trial and will assume full sponsorship of the IND. The IND, currently held by Cleveland Clinic, is in the process of being transferred to Anixa. To oversee this process, Anixa has engaged Advyzom, a leading regulatory consulting firm specializing in strategic FDA interactions, to act as its U.S. regulatory agent regarding the assigned application.

Anixa's breast cancer vaccine, developed in collaboration with Cleveland Clinic, targets α-lactalbumin—a lactation-associated protein that is typically expressed only in breast tissue during lactation, but which re-emerges in many forms of breast cancer. By establising an immune response against α-lactalbumin-expressing cells, the vaccine may offer both therapeutic and preventive benefits for patients with tumors expressing this protein.

"We are pleased with the progress and preliminary findings from our Phase 1 clinical trial, which show that the vaccine is well tolerated, with more than 70% of patients tested to date exhibiting protocol-defined immune responses," stated Dr. Amit Kumar, Chairman and CEO of Anixa Biosciences. "The IND transfer represents a major step in advancing to a Phase 2 trial under our sponsorship. We look forward to working closely with Cleveland Clinic, Advyzom, and the FDA as we continue to move this important program forward."

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. 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.

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