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Moffitt Cancer Center and Anixa Biosciences Announce Completion of Pre-IND Meeting with FDA for CAR-T Therapy

SAN JOSE, Calif., Oct. 22, 2018 /PRNewswire/ -- Anixa Biosciences, Inc. (NASDAQ: ANIX), a biotechnology company focused on using the body's immune system to fight cancer, today announced that it, along with its partner Moffitt Cancer Center (MCC), completed a pre-IND (Investigational New Drug) meeting with the US FDA on October 16, 2018.

The meeting was focused on discussing the development of a novel CAR-T therapy that takes advantage of specific hormone–hormone receptor biology to address ovarian cancer. Approved CAR-T therapies and others in clinical trials have demonstrated dramatic results for certain hematological cancers (also known as liquid tumors), but to date there has not been any meaningful demonstration of CAR-T efficacy against solid tumors in humans. Anixa and MCC hope their therapy will demonstrate success with ovarian cancer patients due to their unique hormone–hormone receptor approach. If successful in ovarian cancer, this approach may create a new pathway for CAR-T development against many other solid tumors.

Dr. Amit Kumar, President and CEO of Anixa Biosciences said, "It is very consequential that we have begun a dialogue with the FDA. The pre-IND meeting answered a number of questions we presented to the FDA and clarified some matters, providing us with a good understanding of the design for the clinical trial in our IND application. Further, we identified the final experiments needed to complete our IND filing. We are in the process of completing these experiments, after which we will file our IND application. The IND, after review and approval by the FDA, will enable us to test our therapy in ovarian cancer patients. Assuming the FDA approves our IND, we anticipate beginning the trial as early as the summer of 2019."

Dr. Jose Conejo-Garcia, chair of the Department of Immunology at Moffitt Cancer Center, the inventor of the technology, and the Principal Investigator of the team developing the therapy added, "Our CAR-T is the first in human therapy of its kind and the feedback we received from the FDA was quite helpful. We are excited to be so close to bringing our investigational therapy to ovarian cancer patients."

About Anixa Biosciences, Inc.

[Anixa](#), a cancer-focused biotechnology company, is harnessing the body's immune system in the fight against cancer. Anixa is developing both diagnostics and therapeutics to detect cancer early, when it is most curable, and to treat those afflicted once diagnosed. It is developing the Cchek™ platform, a series of inexpensive non-invasive blood tests for the early detection of solid tumors, which is based on the body's immune response to the presence of a malignancy. It is also developing chimeric antigen receptor T-cell (CAR-T) based immuno-therapy drugs which genetically engineer a patient's own immune cells to fight cancer. Anixa also continually examines emerging technologies in complementary or related fields for further development and commercialization. Additional information is available at www.anixa.com.

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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