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Anixa Biosciences Announces Scheduling of Pre-Sub Meeting with FDA for its Cchek™ Cancer Diagnostic Test

SAN JOSE, Calif., Oct. 24, 2018 /PRNewswire/ -- Anixa Biosciences, Inc. (NASDAQ: ANIX), a biotechnology company focused on using the body's immune system to fight cancer, today announced that a Pre-Submission (Pre-Sub) meeting with the US FDA has been scheduled on Monday, December 17, 2018. The meeting is to discuss the proposed preclinical and clinical performance testing plan required to support a pre-market application, and to determine the appropriate regulatory pathway for the Cchek™ prostate cancer confirmation test.

The purpose of a Pre-Sub meeting is to permit a dialogue between the FDA and a diagnostic developer to facilitate a better understanding of the regulatory path enabling commercialization. With the Pre-Sub request, Anixa presented to the FDA a clinical trial plan and a group of questions on which it would like comment and clarification. After the meeting, and receipt of official minutes from the meeting, Anixa expects to have a better understanding of the regulatory pathway and anticipated timeline for commercialization.

"We are pleased that we were able to get our meeting with the FDA scheduled before the end of the year. We are looking forward to a productive discussion with the FDA that will help clarify the commercialization pathway for Cchek™ as a prostate cancer diagnostic test. I want to make clear that this new dialogue with the FDA is independent of and in addition to the dialogue we have already started regarding our CAR-T therapy. Both programs and corresponding interactions with the FDA will move forward independently at their own pace," stated Dr. Amit Kumar, President and CEO of Anixa Biosciences. "For Anixa Biosciences, this is an exciting time as we now have two technologies and products, regarding which we are working with regulators."

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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