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

SAN JOSE, Calif., Dec. 19, 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 completed a Pre-Submission (Pre-Sub) meeting with the US FDA on December 17, 2018.



The meeting was focused on discussing Anixa's Cchek™ test, an artificial intelligence (AI) based liquid biopsy for the early detection of cancer. Specifically, the discussion focused on using Cchek™ for prostate cancer testing, as prostate cancer will be the first commercial application.

Dr. Amit Kumar, President and CEO of Anixa Biosciences said, "The meeting was very positive and productive, with discussions that included the intended use of the test, the path for regulatory approval, and the use of AI. We are eager to move Cchek™-Prostate towards commercialization." Dr. Kumar continued, "Standard of care for screening for prostate cancer includes a prostate specific antigen (PSA) measurement, followed by a digital rectal exam (DRE). It is well known that these current tests are imperfect, and cause hundreds of thousands of men to undergo painful, expensive and risk-laden biopsies that are negative and may be unnecessary. Our preliminary data, which we presented to the FDA, demonstrates that Cchek™-Prostate could potentially eliminate a large number of these unnecessary procedures. The FDA was very supportive and appreciated us initiating the dialogue with them. As we continue through the regulatory process, we anticipate additional productive meetings and submissions with the FDA."

Anixa Biosciences expects the official minutes of the Pre-Sub meeting to be available in January. On January 24, 2019 Anixa plans to hold a conference call where it will discuss the commercialization path and timeline for Cchek™-Prostate, as well as an update on its CAR-T therapeutics program. The details of the conference call will be provided at a later date.

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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