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# Anixa Biosciences Files Pre-Submission and Requests Meeting with FDA Regarding Cchek™ Artificial Intelligence based Cancer Detection Technology

SAN JOSE, Calif., Oct. 15, 2018 /PRNewswire/ -- Anixa Biosciences, Inc. (NASDAQ: ANIX), a biotechnology company focused on using the body's immune system to fight cancer, today announced it has filed an IVD pre-submission with the US Food and Drug Administration (FDA) for use of its Cchek™ artificial intelligence based cancer detection technology, as a prostate cancer test. The FDA's Pre-Submission Program (Pre-Sub) allows medical device and *in vitro* diagnostic (IVD) manufacturers to discuss specific aspects of the regulatory process and requirements with FDA. In the submission, Anixa requested a face-to-face meeting with the FDA to discuss the agency's feedback on the proposed preclinical and clinical performance testing plan required to support a pre-market application, and to determine the appropriate regulatory path.

Dr. Amit Kumar, CEO of Anixa stated, "We are pleased to request a Pre-Sub meeting with the FDA. This meeting will be an important step in the commercialization path for Cchek™ as a prostate cancer test, which will be the first in a series of cancer detection and confirmation tests using our Cchek™ technology." Dr. Kumar continued, "This is a major milestone event for us as we begin the process of interfacing with the FDA on our diagnostic testing technology."

Dr. Kumar added, "This request for a meeting is in addition to a meeting already scheduled with the FDA regarding our CAR-T ovarian cancer therapy. I want to make clear that these are two separate and independent paths that address two different potential products. We are excited to have both of our programs ready for discussions with the FDA, and we plan on sharing the results of those meetings as appropriate."

**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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