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Moffitt Cancer Center and ITUS Corporation Request Meeting with FDA Regarding Ovarian Cancer CAR-T Therapy

SAN JOSE, Calif., Aug. 1, 2018 /PRNewswire/ -- ITUS Corporation (NASDAQ: ITUS) today announced that it and its research partner, Moffitt Cancer Center, have requested a meeting with the US FDA to review the plan for advancing their CAR-T therapy for Ovarian Cancer into human clinical trials.



This meeting, known as a pre-IND meeting, is designed to enable drug developers and the FDA to evaluate a drug's pre-clinical data and its proposed development path in anticipation of filing an Investigational New Drug (IND) application. ITUS and Moffitt have previously stated that this program is ahead of schedule. Assuming the FDA does not require additional animal studies, ITUS and Moffitt hope to file the IND application in early 2019 and begin human trials once approved by the FDA.

Dr. Amit Kumar, CEO of ITUS stated, "We are pleased to request a pre-IND meeting with the FDA. We expect to hear back from the FDA shortly, and anticipate the meeting being scheduled shortly thereafter. Our program utilizes T-cells engineered with the follicle stimulating hormone, to target ovary cells that express the follicle stimulating hormone receptor (FSHR). Due to the lack of FSHR being expressed in other tissues in healthy, adult women, and the natural affinity of follicle stimulating hormone to its cognate receptor, we believe this may be one of the first effective CAR-T applications for solid tumors."

Dr. Kumar continued, "Needless to say, this is a major milestone for ITUS as we begin the regulatory process for our ovarian cancer therapy."

Peer-reviewed and published data on this approach is available at this link: [Clin. Cancer Res. 2017 Jan 15; 23\(2\): 441-453.](#)

ITUS Corporation

[ITUS](#), a cancer-focused biotechnology company, is harnessing the body's immune system in the fight against cancer. Its wholly owned subsidiary, Anixa Diagnostics Corporation, is developing the Cchek™ platform, a series of non-invasive blood tests for the early detection of solid tumor based cancers, which is based on the body's immunological response to the presence of a malignancy. Initial focus will be prostate cancer and breast cancer. Its majority owned subsidiary, Certainty Therapeutics, Inc., is developing CAR-T based immuno-therapy drugs which genetically engineer a patient's own immune cells to fight cancer. ITUS also continually examines emerging technologies in complementary or related fields for further development and commercialization. Additional information is available at www.ITUScorp.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 ITUS Corporation'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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