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ITUS Accelerates Schedule for its CAR T Therapy and Provides Update

SAN JOSE, Calif., June 26, 2018 /PRNewswire/ -- ITUS Corporation (NASDAQ: ITUS) today provided a status update and accelerated development timeline for its CAR T therapy for Ovarian Cancer, which is in development with Moffitt Cancer Center.

Based on a number of factors, including the progress of the research discussed below, ITUS and Moffitt anticipate requesting a pre-IND meeting with the United States Food and Drug Administration (FDA) by the end of July of this year, roughly one year earlier than originally anticipated. The FDA recommends a pre-IND meeting as it enables the agency to review the development plan and provide useful recommendations. ITUS expects the meeting will be scheduled for the October/November timeframe. Assuming the FDA does not require significant additional animal studies, the Investigational New Drug (IND) application can be filed during Q1 of 2019. Should this accelerated goal be achieved, human trials could begin as early as the first half of 2019, roughly a year ahead of schedule.

ITUS initiated a Cooperative R&D Agreement (CRADA) with Moffitt to advance a proprietary CAR T therapy for ovarian cancer in November 2017. The study is led by Jose Conejo-Garcia, M.D., Ph.D., Chair of the Department of Immunology at Moffitt. The aim of this CRADA is to complete the pre-clinical studies necessary for the submission of an IND application to the FDA, seeking approval to test the therapy in human patients. The previous goal for IND submission was the end of 2019 or early 2020, now it has been accelerated dramatically.

Additionally, Robert Wenham, M.D. has joined the team to lead the clinical trial. Dr. Wenham is the Chair of Gynecological Oncology at Moffitt. He received his MD from the University of Texas, Southwestern, completed his Obstetrics and Gynecological Residency at Harvard, and his Gynecological Oncology Fellowship at Duke.

Brief R&D Results

Several groups of tumor free, female mice were intra-peritoneally infused with increasing concentrations of the murine CAR T construct, and their health status was monitored for up to 5 months. The goal of this research is to determine if the CAR T construct would specifically target the ovaries of the mice, while not disturbing other healthy organs.

- No treated mice showed any signs of pain/stress, difficulty breathing or increased respiratory rate, reduced movement, reduced grooming or feeding, dehydration, anorexia or any other sign of distress. Control mice also did not show any distress.
- Accordingly, the mice did not show any weight loss. Control mice did not show any weight loss.
- One cohort also had blood drawn periodically for measurement of multiple markers including markers for liver function (AST-Aspartate transaminase/ALT-Alanine transaminase), kidney function (creatinine), and metabolic function (glucose). No abnormal values were observed, as was the case for control mice.
- Serum IL-6 (interleukin-6) increased in the treated mice, as well as mice treated with control T-cells. This indicated that the T-cells were inducing the expected inflammatory response.
- Histological analysis of the ovaries showed that 60 percent of the treated mice had significant damage to their ovaries, while the control mice exhibited no damage. This observation confirms that the CAR T was successfully attacking the ovaries, as hoped and expected.

Additional details will be included in filings for the US FDA and will eventually be published.

Dr. Amit Kumar, CEO of ITUS stated, "We are extremely pleased with the progress of our program, and we are thrilled at the prospect of beginning human trials considerably ahead of schedule. Should our technology be the first demonstration of CAR T efficacy in humans afflicted with a solid tumor, the benefit to patients could be tremendous and the value for ITUS shareholders could be equally dramatic."

"Moffitt is committed to advancing CAR T-cell therapy so that more patients can benefit from this breakthrough treatment. Ovarian cancer is difficult to treat because most women are diagnosed at the later stages of disease progression. Consequently, outcomes are often poor and there are few treatment options. Being able to bring CAR T to patients, even in an investigational setting, is a step in the right direction," stated Dr. Wenham, Chair of Gynecological Oncology at Moffitt.

CAR T Background

Chimeric Antigen Receptor T-cell therapy is an adoptive cell therapy approach that begins with removal and isolation of certain T cells from a patient's blood. In the laboratory, these T cells are then modified by utilizing a viral vector designed to genetically engineer them to aggressively target and attack the patient's cancer. After engineering, the cells are expanded (increased in number) in the laboratory, then they are infused back into the patient where they seek out the tumor for destruction. To date this type of therapy has worked extremely well for patients suffering from B-cell malignancies (certain lymphomas and leukemias) who had failed other therapies, and for whom there were no options. These results have induced tremendous interest from the scientific and investor communities in CAR T technologies and companies. Unfortunately, to date no CAR T approach has meaningfully worked against solid tumors, for which there are many more sufferers than B-cell cancers. ITUS and Moffitt believe that certain key characteristics of their proprietary CAR T technology will enable it to work for ovarian cancer and then eventually for tumors such as breast, prostate, pancreatic and others. The peer-reviewed scientific details supporting this assertion have been discussed elsewhere and have been published in the journal, *Clinical Cancer Research*

(http://clincancerres.aacrjournals.org/content/23/2/441.article-info).

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 tumorbased cancers, which is based on the body's immunological response to the presence of a malignancy. 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.

About Moffitt Cancer Center
Moffitt is dedicated to one lifesaving mission: to contribute to the prevention and cure of cancer. The Tampa-based facility is one of only 49 National Cancer Institute-designated Comprehensive Cancer Centers, a distinction that recognizes Moffitt's scientific excellence, multidisciplinary research, and robust training and education. Moffitt is a Top 10 cancer hospital and has been nationally ranked by U.S. News & World Report since 1999. Moffitt devotes more than 2 million square feet to research and patient care. Moffitt's expert nursing staff is recognized by the American Nurses Credentialing Center with Magnet® status, its highest distinction. With more than 5,700 team members, Moffitt has an economic impact in the state of $2.1 billion. For more information, call 1-888-MOFFITT (1-888-663-3488), visit MOFFITT.org, and follow the momentum on Facebook, Twitter and YouTube.

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