T-CURE BIOSCIENCE ANNOUNCES U.S. FDA CLEARANCE OF INVESTIGATOR-INITIATED CLINICAL TRIAL FOR KK-LC-1 TCR-T AGAINST MULTIPLE SOLID TUMORS

LOS ANGELES, CA, September 15, 2021 T-Cure Bioscience, Inc., a privately held company focused on developing autologous T cell receptor therapy (TCR-T) products for the treatment of solid tumors, today announced that the U.S. Food and Drug Administration (FDA) has approved the Investigational New Drug (IND) application to initiate a Phase I clinical study evaluating a TCR-based product candidate for the treatment of tumors expressing Kita-Kyushu lung cancer antigen 1 (KK-LC-1), such as gastric, cervical, lung, breast cancers and other KK-LC-1 positive epithelial cancers (NCT05035407). T-Cure acquired the KK-LC-1 TCR therapy under an exclusive, worldwide license with the National Cancer Institute (NCI) in 2020. This Phase I Clinical Study will be conducted and sponsored by the NCI, part of the National Institutes of Health, where Dr. Scott Norberg and Dr. James Gulley will be the main PIs for this investigator-initiated trial. The trial will be done under a Cooperative Research and Development Agreement (CRADA) that T-Cure has in place with the NCI.

Last year, T-Cure entered into an exclusive, worldwide license with the NCI for intellectual property related to autologous TCR-T treatment of tumors expressing KK-LC-1, such as gastric, lung, triple negative breast and cervical cancers.

KK-LC-1 is a cancer germline (CG) antigen that has restricted expression in healthy tissues and frequent expression in epithelial cancers including lung cancer, gastric cancer, triple negative breast cancer, cervical cancer and others. Adoptive T-cell therapy is one potentially powerful treatment for cancer that genetically modifies natural T cells to make them tumor-specific and to improve their ability to destroy tumor cells. TCR-T cell therapy targeting CG antigens has been shown to induce objective responses without autoimmunity or off-target toxicity in patients with melanoma, synovial cell sarcoma and cervical carcinoma.

“TCR-T cell therapy is a promising new treatment modality that has demonstrated clinical activity in a subset of solid tumors.” stated Scott Norberg, D.O., Assistant Research Physician, Genitourinary Malignancies Branch, of NCI and Principal Investigator of the study. “Our hope is that KK-LC-1 TCR-T cell therapy can be effective against common epithelial cancers, which account for 80-90% of all human malignancies.”

“We are excited that NCI has obtained the regulatory approval from FDA to initiate a first-in-human trial against a very important target in multiple solid tumors.” stated Gang Zeng, Ph.D., Chief Executive Officer of T-Cure Bioscience. “Dr. Norberg and Dr. Gulley have extensive experiences in developing novel adoptive T-cell therapies for cancer and they will be invaluable as we advance this program.”

Of note, the TCR was isolated from the tumor-infiltrating lymphocytes of a patient who had a complete response to an immunotherapy without any toxicities. As a result, it may hold great promise for engineering patients’ immune cells to effectively target and destroy cancer cells without harming healthy tissue.

About T-Cure Bioscience, Inc.

T-Cure Bioscience, Inc. is an innovative immuno-oncology company committed to delivering effective and durable cell therapies for the treatment of cancer. The Company focuses on isolating high avidity TCR that can be used to engineer a patient's T cells to effectively target and destroy solid tumors. The Company maintains a pipeline of TCR under clinical and pre-clinical development targeting HERV-E, KK-LC-1, NY-ESO-1 and other antigens associated with solid tumors of significant unmet medical needs, including kidney cancer, breast cancer, lung cancer, gastric cancer, ovarian cancer, liver cancer, pancreatic cancer, sarcoma, and glioblastoma. More information is available at www.T-Cure.com.

Forward Looking Statements

T-Cure cautions you that all statements, other than statements of historical facts, contained in this press release, are forward-looking statements. Forward-looking statements are subject to known and unknown risks, uncertainties, and other factors that may cause our or our industry's actual results, levels or activity, performance or achievements to be materially different from those anticipated by such statements. The use of words such as "may", "might", "will", "should", "could", "expect", "plan", "anticipate", "believe", "estimate", "project", "intend", "future", "potential" or "continue", and other similar expressions are intended to identify forward looking statements. For example, all statements we make regarding (i) the initiation, timing, cost, progress and results of our preclinical and clinical studies and our research and development programs, (ii) our ability to advance product candidates into, and successfully complete, clinical studies, (iii) the timing or likelihood of regulatory filings and approvals, (iv) our ability to develop, manufacture and commercialize our product candidates and to improve the manufacturing process, (v) the rate and degree of market acceptance of our product candidates, (vi) the size and growth potential of the markets for our product candidates and our ability to serve those markets, and (vii) our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates, are forward looking. All forward-looking statements are based on current estimates, assumptions and expectations by our management that, although we believe to be reasonable, are inherently uncertain. All forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those that we expected. Any forward-looking statement speaks only as of the date on which it was made. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law.

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