

# OncoSec Receives Exclusive Licensing Rights from Dana-Farber Cancer Institute to CAR T-Cell Therapies for the Treatment of Solid Tumor Cancers

## **Development Collaboration Will Initially Focus on CAR T-Cell Therapy** for Triple-Negative Breast Cancer

SAN DIEGO and PENNINGTON, N.J., June 27, 2019 /PRNewswire/ -- OncoSec Medical Incorporated (OncoSec) (NASDAQ:ONCS), a company developing late-stage intratumoral cancer immunotherapies, today announced that it has entered into a collaboration with Dana-Farber Cancer Institute, a world-leading cancer research and treatment institution, and The Marasco Laboratory, a cutting-edge CAR T-cell research laboratory led by Wayne Marasco, M.D., Ph.D., a renowned cancer immunology researcher, to develop CAR T-cell therapies for triple-negative breast cancer and other solid tumor cancers.

Under the terms of the agreement, OncoSec has acquired an exclusive option to licensing rights to the CAR T-cell product candidates and associated IP resulting from the research being conducted at The Marasco Laboratory using engineered single-chain variable fragment (scFv) antibodies in a dual-targeted bi-specific CAR T-cell approach. Previous research conducted by The Marasco Laboratory suggests their proprietary CAR T-cell technology has the potential to be effective against numerous solid tumor indications, while minimizing the toxicity that current CAR T-cell technologies exhibit when applied beyond liquid tumor indications.

"This partnership has the potential to deliver novel, next-generation, dual-targeted CAR T-cell therapy for solid tumors, an achievement that has eluded researchers due to the toxicity of current CAR-T cell therapies. Prior research suggests that Dr. Marasco's approach may hold the key to unlocking the safe and effective use of CAR T-cell therapies in solid tumors," said Daniel J. O'Connor, President and Chief Executive Officer of OncoSec. "CAR T-cell treatment of solid tumors is an early stage market with no approved products at the present time, and thus represents a considerable unrealized market opportunity. We believe the barriers preventing the advancement of CAR T-cell technology in the solid tumor setting are surmountable by Dr. Marasco and his team's expertise. Further, combination with OncoSec's intratumoral TAVO (IL-12) by electroporation may further enhance the efficacy of CAR T-cell therapy in solid tumors."

"The structure of our agreement with Dana-Farber provides for the greatest upside for our shareholders, while significantly de-risking our modest initial investment. Our financial contribution for the research is spread over several years and coincides with the generation of product candidates and data. We also have the flexibility to cease contribution should we opt to do so," continued Mr. O'Connor.

The Company plans to begin clinical trials with the TNBC CAR T-cell therapy in 2020, both as a monotherapy and in combination with OncoSec's TAVO (IL-12).

Dr. Marasco, Professor, Department of Cancer Immunology at Dana-Farber and Professor of Medicine, Department of Medicine at Harvard Medical School, is a renowned antibody engineering expert who specializes in designing and engineering CAR T-cell therapies. Dr. Marasco and his team have a proven track record of developing monoclonal antibodies that attach to important proteins highly expressed in many common types of solid cancers, which is critical to developing an effective CAR T-cell therapy.

Importantly, the collaboration with Dana-Farber contemplates a vertically integrated development program, with the intent of conducting the CMC and clinical formulation work, as well as the clinical manufacturing of the drug product, at the Dana-Farber Core Manipulation Cell Facility (CMCF). The CMCF is an impressive GMP manufacturing facility located at Dana-Farber. Additionally, OncoSec plans to conduct the initial clinical trials within the Harvard University network of hospitals.

CAR T-cell therapies have been unable to achieve meaningful clinical results in solid tumors due to toxicity, specifically, the "on-target, off-tumor" side effects, which can trigger lethal immune pathology. The Marasco Lab has developed a proprietary strategy to limit off-tumor toxicity through the use of a bispecific CAR system in which both single-chain variable fragment (scFv) are strategically linked to drive the intracellular signaling sufficient for T cell activation/killing. Importantly, this activation/killing is triggered only if and when both targets are engaged simultaneously on a tumor.

The remarkable success of CAR T-cell therapies in hematological malignancies has propelled its development in solid tumors. However, unlike the great strides made in liquid tumors, the clinical success of CAR T-cell therapies in solid tumors has been limited in large part due to the associated immunosuppressive elements of the tumor microenvironment (TME). Intratumoral TAVO (IL-12) has a proven ability to alter the immunosuppressive TME by eliciting a productive pro-inflammatory immune response.

This TAVO induced pro-inflammatory response both limits immune suppression while driving immunogenicity, thereby providing a strong rationale for the combination of this CAR T-cell therapy with OncoSec's TAVO immunotherapy.

"We are excited to be partnering with OncoSec to work to bring new therapies to cancer patients in need," said Dr. Marasco. "The Marasco Labs are dedicated to using cutting edge science to develop new targeted CAR T therapies that can address the challenges associated with successfully treating solid tumors. This support from OncoSec will enhance our efforts."

DNA electroporation is already used as a method to make a CAR T-cell therapy. Levering OncoSec's deep expertise in electroporation, the Company also intends to investigate DNA electro-transfection for the intratumoral *in vivo* generation of functional CAR-T cells, with the goal of making CAR T-cell therapy more affordable and accessible to patients.

Dr. Marasco studied at the University of Connecticut's School of Medicine, where he received his Ph.D. in 1980. He completed his postdoctoral training at the University of Michigan Medical School, where he also earned a M.D. in 1986. He received his

subspecialty training in infectious diseases at Harvard Medical School, where he is currently a professor, and he joined the Dana- Farber Cancer Institute in 1989. In 1992, he also joined the Division of Infectious Diseases at Brigham and Women's Hospital. In 1980 and 1981, Dr. Marasco won the Biomedical Research Council Award and the National Research Service Award from the University of Connecticut School of Medicine, and the University of Michigan awarded him the United States Public Health Service Award in 1981, the Dean's Award for Research Excellence in 1986 and the Lung Immunopathology Training Grant Award in 1987 and 1988.

In 2009, U.S. News & World Report listed Dr. Marasco as a "Medical Pioneer" and a top scientist in his field. In the same year, Dr. Marasco was selected as a Distinguished Speaker by the Walter Reed Army Institute of Research. For cancer, as well as HIV/AIDS and other infectious diseases, one possible treatment involves the use of human monoclonal antibodies (Mabs) – which are proteins that are produced to bind to only one substance. For cancer treatments, Mabs bind only to cancer cells and produce immunological responses against the cancer cells. There is great promise with Mabs because their tumor-fighting effects can be less harmful to normal cells than that of traditional cancer treatments.

The Marasco Laboratory, located in the Department of Cancer Immunology and Virology at Dana-Farber Cancer Institute, conducts research in the field of targeted immunotherapy. The Lab's work has made major scientific advances in the treatment of infectious diseases and cancer. Specifically, the Lab's research interests are in human monoclonal antibody (mAb) immunotherapy.

In 2003, Dr. Marasco became the Director of the National Foundation for Cancer Research (NFCR) Center for Therapeutic Antibody Engineering to expand the use of human monoclonal antibodies in the treatment of cancer.

Dr. Marasco has had great success developing Mabs that attach to an important protein – carbonic anhydrase IX (CAIX) – that is highly expressed in renal cell carcinoma, the most common type of kidney cancer. Most recently, his team at the NFCR Center developed a combination immunotherapy treatment that holds promise for treating metastatic kidney cancer more effectively. The immunotherapy they have engineered includes not only the CAIX antibody that detects and binds to CAIX growth-promoting proteins on cancerous kidney cells, but also unblocks T cells to enable more rigorous attacks against cancer. The OncoSec / Dana- Farber collaboration will capitalize on Dr. Marasco's prior success using the double treatment approach, adapting it to triple negative breast cancer and other difficult-to-treat solid cancers using different antibodies.

#### **About OncoSec Medical Incorporated**

OncoSec is a clinical-stage biotechnology company focused on developing cytokine-based intratumoral immunotherapies to stimulate the body's immune system to target and attack cancer. OncoSec's lead immunotherapy investigational product candidate − TAVO™ (tavokinogene telseplasmid) − enables the intratumoral delivery of DNA-based interleukin-12 (IL-12), a naturally occurring protein with immune-stimulating functions. The technology, which employs electroporation, is designed to produce a controlled, localized expression of IL-12 in the tumor microenvironment, enabling the immune system to target and attack tumors throughout the body. OncoSec has built a deep and diverse clinical pipeline utilizing TAVO™ as a potential treatment for multiple cancer indications either as a monotherapy or in combination with leading checkpoint inhibitors; with the latter potentially

enabling OncoSec to address a great unmet medical need in oncology: anti-PD-1 non-responders. Results from recently completed clinical studies of TAVO™ have demonstrated a local immune response, and subsequently, a systemic effect as either a monotherapy or combination treatment approach. In addition to TAVO™, OncoSec is identifying and developing new DNA-encoded therapeutic candidates and tumor indications for use with its new Visceral Lesion Applicator (VLA), to target deep visceral lesions, such as liver, lung or pancreatic lesions. For more information, please visit www.oncosec.com.

TAVO™ trademark of OncoSec Medical Incorporated.

### **Forward Looking Statements**

Some of the statements included in this press release may be forward-looking statements that involve a number of risks and uncertainties. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. The factors that could cause our actual results to differ materially include: the status, progress and results of our clinical programs; our ability to obtain regulatory approvals for, and the level of market opportunity for our product candidates; our business plans, strategies and objectives, including plans to pursue collaboration, licensing or other similar arrangements or transactions; expectations regarding our liquidity and performance, including expense levels, sources of capital and ability to maintain operations as a going concern; the competitive landscape of our industry; and general market, economic and political conditions; and other risk factors identified from time to time in our reports filed with the Securities and Exchange Commission. Any forward-looking statements set forth in this press release speak only as of the date of this press release. We do not intend to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof.

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