

July 6, 2021



# **OncoSec Enters into a Collaboration Agreement with Merck for a Pivotal Global Phase 3 Study, KEYNOTE-C87, of TAVO™ Combined with KEYTRUDA® for Late-Stage Metastatic Melanoma**

- KEYNOTE-C87 is intended to support accelerated approval and/or a full licensure**
- Study addresses a high unmet medical need in certain patients with metastatic melanoma for whom there are no FDA approved treatment options**

PENNINGTON, N.J. and SAN DIEGO, July 6, 2021 /PRNewswire/ -- OncoSec Medical Incorporated (NASDAQ:ONCS) (the "Company" or "OncoSec") today announced it has entered into a Clinical Trial Collaboration and Supply Agreement ("Agreement") with Merck (known as MSD outside the United States and Canada) to evaluate the combination of OncoSec's DNA-plasmid interleukin-12 (IL-12) TAVO™ (tavokinogene telseplasmid) with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in a global Phase 3 randomized clinical trial, KEYNOTE-C87. The planned clinical trial will evaluate the overall survival of patients treated with the TAVO™ in combination with KEYTRUDA® versus standard of care in late-stage patients with metastatic melanoma who are refractory to immune checkpoint therapy.

TAVO™ has received Fast Track designation from the U.S. Food and Drug Administration (FDA), as a potentially first-in-class, intratumoral anti-cancer gene therapy that expresses IL-12 for the treatment of metastatic melanoma, following progression on KEYTRUDA® or OPDIVO® (nivolumab). KEYNOTE-C87 is intended to support accelerated approval by the U.S. FDA and/or serve as a pivotal study to support a full licensure. Under the terms of the Agreement, Merck will provide KEYTRUDA®, while OncoSec will provide the investigational drug, TAVO™. Each party will be responsible for its own internal costs, with OncoSec covering third party costs. Eligible patients must have Stage III or IV unresectable, metastatic melanoma, and must be refractory to prior checkpoint therapy. KEYNOTE-C87 intends to enroll approximately 400 patients and is planned to be conducted in the U.S., Canada, EU, and Australia.

"We are thrilled to enter into this collaboration and supply agreement with Merck – one of the world's leading immuno-oncology companies – to help bring TAVO™ to patients with metastatic melanoma whose disease did not respond to initial checkpoint inhibitor therapy or who have developed progressive disease and therefore do not have additional treatment

options available," said Brian Leuthner, Interim Chief Executive Officer of OncoSec. "This Phase 3 collaboration represents a crucial milestone for OncoSec as we advance TAVO™ through the clinic and toward potential approval globally, and expands upon our initial 2017 clinical collaboration and supply agreement with Merck. We look forward to our continued work and progress with Merck and its experienced team of immuno-oncology leaders as we continue to explore TAVO™ in combination with KEYTRUDA® with the goal of helping more patients with cancer."

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, N.J., U.S.A. OPDIVO® is a registered trademark of Bristol Myers Squibb.

### **About TAVO™**

OncoSec's gene therapy technology combines TAVO (tavokinogene telseplasmid), a DNA plasmid-based interleukin-12 (IL-12), with an intra-tumoral electroporation gene delivery platform to achieve endogenous IL-12 production in the tumor microenvironment that enables the immune system to target and attack tumors throughout the body. TAVO has demonstrated a local and systemic anti-tumor response in several clinical trials, including the pivotal Phase 2b trial KEYNOTE-695 for metastatic melanoma and the KEYNOTE-890 Phase 2 trial in triple negative breast cancer (TNBC). TAVO has received both Orphan Drug and Fast-Track Designation by the U.S. Food & Drug Administration for the treatment of metastatic melanoma.

### **About OncoSec Medical Incorporated**

OncoSec Medical Incorporated (the "Company," "OncoSec," "we" or "our") is a 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 along with an acceptable safety profile, warranting further development. 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](http://www.oncosec.com).

TAVO™ is a trademark of OncoSec Medical Incorporated.

### **Risk Factors and Forward-Looking Statements**

This release, as well as other information provided from time to time by the Company or its employees, may contain forward-looking statements that involve a number of risks and

uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Forward-looking statements provide the Company's current beliefs, expectations and intentions regarding future events and involve risks, uncertainties (some of which are beyond the Company's control) and assumptions. 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. You can identify forward-looking statements by the fact that they do not relate strictly to historical or current facts. These statements may include words such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "should," "will" and "would" and similar expressions (including the negative of these terms). Although we believe that expectations reflected in the forward- looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. The Company intends these forward-looking statements to speak only at the time they are published on or as otherwise specified and does not undertake to update or revise these statements as more information becomes available, except as required under federal securities laws and the rules and regulations of the Securities Exchange Commission ("SEC"). In particular, you should be aware that the success and timing of our clinical trials, including safety and efficacy of our product candidates, patient accrual, unexpected or expected safety events, the impact of COVID-19 on the supply of our candidates or the initiation or completion of clinical trials and the usability of data generated from our trials may differ and may not meet our estimated timelines. Please refer to the risk factors and other cautionary statements provided in the Company's Annual Report on Form 10-K for the fiscal year ended July 31, 2020 and subsequent periodic and current reports filed with the SEC (each of which can be found at the SEC's website [www.sec.gov](http://www.sec.gov)), as well as other factors described from time to time in the Company's filings with the SEC.

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