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# **OncoSec Announces Initiation of a Phase 2 Study at the Moffitt Cancer Center to Evaluate the Combination of TAVO plus OPDIVO® as Neoadjuvant Therapy for Melanoma**

## **Study to Assess the Potential of TAVO in Combination with Anti-PD-1 Checkpoint Inhibitors to Improve Overall Outcomes such as Operability, Pathologic Tumor Response and Long-Term Disease Control in Early Melanoma Patients**

PENNINGTON, N.J. and SAN DIEGO, Aug. 27, 2020 /PRNewswire/ -- OncoSec Medical Incorporated (NASDAQ:ONCS) (the "Company" or "OncoSec"), a company developing late-stage intratumoral cancer immunotherapies, today announced the commencement of an investigator-initiated Phase 2 study led by Senior Member and Professor Ahmad A. Tarhini, M.D., Ph.D. of the H. Lee Moffitt Cancer Center and Research Institute and the University of South Florida Morsani College of Medicine to evaluate its lead product candidate, TAVO™ (interleukin-12 or IL-12 plasmid) immunotherapy as neoadjuvant treatment (administered before surgery) in combination with intravenous OPDIVO® (nivolumab) in up to 33 patients with operable locally/regionally advanced melanoma.

Anti-PD-1 immune checkpoint therapies, such as OPDIVO®, are an established first-line treatment for advanced melanoma, and encouraging clinical data suggest that they have clinically meaningful activity in the neoadjuvant setting as well. This investigator-initiated Phase 2 study has been designed to evaluate whether the addition of TAVO can increase the published anti-tumor response observed with monotherapy OPDIVO®, an anti-PD-1 checkpoint inhibitor, in patients with locally/regionally advanced melanoma prior to surgical resection of tumors.

Recent trials with anti-PD-1 and anti-PD-1 combinations have shown significant advantages in both relapse free survival (RFS) and overall survival (OS) when administered as neoadjuvant therapy as compared to adjuvant therapy (administered after surgery) alone for metastatic melanoma. The TAVO-specific immunological signatures associated with coordinated innate and adaptive cellular responses were identified in earlier TAVO monotherapy trials and continue to be essential in driving the clinical efficacy in late-stage, anti-PD-1-refractory metastatic melanoma patients. These immunological pathways that sensitize lesions to checkpoint therapy in a late-stage setting are likely to be highly active in an earlier disease setting, which along with TAVO's excellent safety record, provides a strong rationale to leverage this therapeutic combination within the neoadjuvant setting.

"Patients with locally/regionally advanced melanoma present a major challenge for surgical and medical management," said Dr. Tarhini, who is Director, Cutaneous Clinical & Translational Research and Senior Member in the Departments of Cutaneous Oncology and Immunology at H. Lee Moffitt Cancer Center & Research Institute. "Following surgical treatment, these patients continue to have a high risk of relapse and death despite the use of standard adjuvant therapy. Neoadjuvant therapy with an effective immunotherapeutic agent, such as TAVO, combined with the anti-PD-1 checkpoint inhibitor nivolumab, has the potential to improve overall outcomes such as operability, pathologic tumor response and long-term disease control. This, combined with the excellent safety and tolerability profile TAVO has demonstrated with hundreds of patients to-date, leaves me very encouraged and eager to evaluate TAVO-nivolumab combination treatment in the neoadjuvant setting."

"This Phase 2 study will highlight the advantages of bringing TAVO into an earlier disease setting. It will be an important validation of the broad utility of TAVO, and is anticipated to build on its excellent safety and efficacy profile to date," commented Kellie Malloy Foerter, OncoSec's Chief Operating Officer. "We look forward to collaborating with Dr. Tarhini's team and to supporting other potential investigator-initiated studies that can further the understanding of TAVO's capabilities in treating cancer. We also want to express our appreciation of the patients and their families who participate in clinical trials."

For more information about the study, please visit

<https://clinicaltrials.gov/ct2/show/NCT04526730?term=NCT04526730&draw=2&rank=1>.

NCT# NCT04526730

### **About OncoSec Medical Incorporated**

OncoSec Medical Incorporated is a late-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 product candidate, TAVO™, enables the intratumoral delivery of DNA-based interleukin-12 or 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 clinical pipeline utilizing TAVO as a potential treatment for multiple cancer indications either as a monotherapy or in combination with leading checkpoint inhibitors. The company is currently evaluating TAVO in combination with the anti-PD-1 checkpoint inhibitor, KEYTRUDA® (pembrolizumab), in two KEYNOTE clinical trials, including a pivotal trial in patients with anti-PD-1 checkpoint resistant metastatic melanoma and a phase 2 trial in metastatic triple negative breast cancer. OncoSec is also identifying and developing new DNA-encoded therapeutic candidates and tumor indications for use with its novel Visceral Lesion Applicator designed to target deep internal 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.

OPDIVO® is a registered trademark of Bristol-Myers Squibb Company.

### **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, 2019 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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