OncoSec Announces First Patient Dosed in Phase 2 Trial of TAVO™ Plus OPDIVO® as Neoadjuvant Therapy for Melanoma

PENNINGTON, N.J. and SAN DIEGO, Jan. 8, 2021 /PRNewswire/ -- OncoSec Medical Incorporated (NASDAQ:ONCS) (the "Company" or "OncoSec") today announced the first patient was dosed in OMS-104, an investigator-initiated Phase 2 trial evaluating TAVO™ (tavokinogene telseplasmid), the Company's intratumoral DNA plasmid-based interleukin-12 (IL-12) therapy administered using its gene delivery platform (gene electrotransfer), in combination with the anti-PD-1 checkpoint inhibitor OPDIVO® (nivolumab) as a neoadjuvant therapy prior to surgery in patients with operable, locally or regionally advanced melanoma. The trial is designed to evaluate if the addition of TAVO can improve clinical outcomes already observed when using nivolumab alone as a neoadjuvant therapy.

Anti-PD1 checkpoint inhibitors, when administered as a neoadjuvant therapy, have shown encouraging clinical results, but rapid recurrence remains an issue for many patients. TAVO in combination with OPDIVO may drive deep anti-tumor immune responses and complete elimination of tumors prior to surgery, leading to improved long-term clinical outcomes for a significant proportion of treated patients. TAVO in combination with another anti-PD-1 checkpoint inhibitor, KEYTRUDA® (pembrolizumab), has already been shown to enhance overall response rate and partial tumor responses in patients with anti-PD-1 checkpoint-refractory metastatic melanoma in OncoSec's KEYNOTE-695 registration directed Phase 2 clinical trial.

"While studies have shown relapse and overall survival advantages when checkpoint inhibitors are given alone following surgery, there is a need to investigate novel immunotherapeutic agents such as TAVO that can be given preoperatively in order to further enhance the clinical efficacy of immunotherapy in patients with advanced melanoma," said Armad A. Tarhini, M.D., Ph.D., Leader of the OMS-104 trial and Senior Member and Professor at the H. Lee Moffitt Cancer Center and Research Institute and the University of South Florida Morsani College of Medicine. "The neoadjuvant approach utilizing TAVO in combination with checkpoint inhibitors as being tested in this study may improve operability, pathologic tumor response and long-term disease control, which is highly desirable for these patients, who continue to have a high risk of recurrence and progression despite the use of standard therapy after surgery."

OMS-104 (NCT04526730) is a Phase 2 open-label, single arm study investigating intratumoral TAVO delivered by gene electrotransfer, or short electric pulses, plus nivolumab as neoadjuvant therapy in patients with operable locally-regionally advanced melanoma. The trial aims to enroll 33 patients and consists of three phases:

1) Neoadjuvant phase, where TAVO will be administered intratumorally using gene electrotransfer in three cycles on days one and eight every four weeks and
nivolumab will be administered after TAVO on day eight of each cycle via 30-minute intravenous (IV) infusion; 2) Surgical phase consisting of a definitive surgery that will be scheduled 2-4 weeks after the last dose of nivolumab following radiologic and clinical assessment; and 3) Adjuvant phase, where nivolumab monotherapy will begin 2-4 weeks after surgery and will be administered for up to nine four-week cycles.

The primary endpoint is pathological complete response, estimated based on the proportion of participants with no viable tumor on histologic assessment at definitive surgery after the 12-week neoadjuvant period.

Daniel J. O’Connor, President and Chief Executive Officer of OncoSec, added, “TAVO delivers DNA plasmid-based IL-12 directly into the tumor using gene electrotransfer, which demonstrably enhances the immunogenicity of the treated tumors to yield productive 'in situ' vaccines. This principle has yielded striking results in post-PD-1 patients and is likely relevant in this earlier clinical setting. We look forward to exploring the utility of TAVO as a potential neoadjuvant therapy in a variety of solid tumor settings for patients in need of more effective treatment options.”

About TAVO™
OncoSec's gene delivery technology combines TAVO (tavokinogene telseplasmid), a DNA plasmid-based interleukin-12 (IL-12), with an intra-tumoral gene delivery platform (gene electrotransfer) 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 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 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 gene electrotransfer, 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.

TAVO™ is a trademark of OncoSec Medical Incorporated.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.

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, 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), as well as other factors described from time to time in the Company's filings with the SEC.

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