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OncoSec Announces Triple Combination Immunotherapy Clinical Trial Of TAVO™, Epacadostat And KEYTRUDA® In Squamous Cell Head And Neck (SCCHN) Cancer

-- Triple combination seeks to improve upon the low historical anti-PD1 monotherapy durable remissions response rate of 13-16%

SAN DIEGO and PENNINGTON, N.J., April 23, 2019 /PRNewswire/ -- OncoSec Medical Incorporated (OncoSec) (NASDAQ:ONCS), a company developing intratumoral cancer immunotherapies, today announced a triple combination clinical trial of OncoSec's TAVO™, epacadostat, and KEYTRUDA® in patients with squamous cell carcinoma head and neck (SCCHN) cancer. This study, the "TRIFECTA" study, will be conducted by the UCSF Helen Diller Family Comprehensive Cancer Center.

TRIFECTA, formally entitled, "The Trifecta Study: Optimizing Antitumor Immunity Using Tavokinogene Telseplasmid with Electroporation, Pembrolizumab, and Epacadostat in Squamous Cell Carcinoma of the Head and Neck," will evaluate the combination use of OncoSec's TAVO™ (intratumoral IL-12 tavokinogene telseplasmid), epacadostat (IDO inhibitor), and KEYTRUDA® (pembrolizumab, an anti-PD1 monoclonal antibody) in patients with SCCHN cancer.

TRIFECTA will be an investigator-initiated clinical trial by UCSF otolaryngologist, Dr. Chase Heaton, to determine whether the triple combination can increase the overall response rate (ORR) in SCCHN compared with historical data for KEYTRUDA® as a monotherapy. The costs of this clinical trial will be shared with others and will require minimal financial commitment from OncoSec.

The response rate in patients with unresectable SCCHN is very low when treated with anti-PD1 antibodies as a monotherapy, with only 13-16%^{1 2} durable remissions. Treatment failures are more common in patients whose tumors either lack anti-tumor immune cells or have an overabundance of regulatory immune cells that suppress effective anti-tumor immune responses. TAVO™ has previously demonstrated the ability to reverse this type of anti-PD-1 resistance in patients with metastatic melanoma.

"Effective anticancer immune responses require three steps, including immune priming and tumor infiltration with T cells; activation of partially exhausted TILs; and selective modulation of T cell populations to maximize the ratio of effector to regulatory immune cells," said Dr. Alain Algazi, Associate Professor of Clinical Medicine at UCSF and Clinical Strategic Advisor

to OncoSec. "Based on this framework, we hypothesize that the combination of TAVO's tumor infiltration mechanism, with pembrolizumab's TIL technology and epacadostat's T cell modulating capabilities will substantially increase the ORR to pembrolizumab in patients with SCCHN and that the combination will be well tolerated in this population."

TRIFECTA is a single-arm open-label clinical trial in which 35 evaluable patients will receive TAVO™, pembrolizumab, and epacadostat. The primary endpoint of the study is overall response rate (ORR) by RECIST v1.1 and will be compared to historical data for pembrolizumab monotherapy in SCCHN and to existing data regarding the combination of pembrolizumab and epacadostat.

Melanoma patients in the anti-PD-1 refractory setting have found renewed clinical responses with the combination of KEYTRUDA® with TAVO™ in the KEYNOTE-695 trial. TAVO's mechanism of action may also enhance the activity of epacadostat as expression of IDO is driven by IFN-g, which, in TAVO-treated patients may create a broader target and therefore opportunity to limit this suppressive IDO axis. Due to its favorable safety profile, clinical activity and ability to trigger adaptive resistance (increases in both IDO and PD-L1 expression) via a robust IFN-g response, TAVO™ is a strong backbone for a combination strategy with epacadostat and Merck's anti-PD-1 antibody, pembrolizumab.

"Supporting this investigator-initiated clinical is a very cost-effective way to learn if the three-way combination of TAVO™, epacadostat and pembrolizumab can significantly improve the historical anti-PD-1 monotherapy durable remission response rate of 13-16%," said Daniel O'Connor, President and Chief Executive Officer of OncoSec. "Studies such as these continue to build on the body of clinical evidence in support of TAVO™ in a variety of combination therapies. We believe it is important to support investigator led studies such as this one, especially considering the prestige of the medical institution and the oncologists involved."

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 platform – 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 ImmunoPulse® platform. For more information, please visit www.oncosec.com

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

ImmunoPulse® is a registered trademark of OncoSec Medical Incorporated, San Diego, CA, USA.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as "can," "may," "will," "suggest," "look forward to," "potential," "understand," "anticipate," "believe," "estimate," "may," "expect" and similar references to future periods.

Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on management's current preliminary expectations and are subject to risks and uncertainties, which may cause our results to differ materially and adversely from the statements contained herein. Potential risks and uncertainties that could cause actual results to differ from those predicted include, among others, the following: uncertainties inherent in pre-clinical studies and clinical trials, such as the ability to enroll patients in clinical trials and the risk of adverse events; unexpected new data, safety and technical issues; our ability to raise additional funding necessary to fund continued operations; the success and timing of our clinical trials; the success and timing of our IND submission to the FDA; our ability to obtain and maintain marketing approval from regulatory agencies for our products in the U.S. and foreign countries; our ability to successfully implement our strategy; and the other factors discussed in OncoSec's filings with the Securities and Exchange Commission.

Undue reliance should not be placed on forward-looking statements, which speak only as of the date they are made. OncoSec disclaims any obligation to update any forward-looking statements to reflect new information, events or circumstances after the date they are made, or to reflect the occurrence of unanticipated events.

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¹ Seiwert, T. Y. et al. Safety and clinical activity of pembrolizumab for treatment of recurrent or metastatic squamous cell carcinoma of the head and neck (KEYNOTE-012): an open-

label, multicentre, phase 1b trial. *Lancet Oncol.* **17**, 956–965 (2016).

² Ferris, R. L. *et al.* Nivolumab for Recurrent Squamous-Cell Carcinoma of the Head and Neck. *N. Engl. J. Med.* (2016). doi:10.1056/NEJMoa1602252



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