

# **UCSF Doses First Patient in Triple Combination Clinical Trial of OncoSec's TAVO<sup>™</sup>, Epacadostat and KEYTRUDA<sup>®</sup> for the Treatment of Unresectable Squamous Cell Head and Neck Cancer**

**First-of-its-kind study seeking to evaluate the potential anti-tumor effect of the IL-12, IDO1 and anti-PD-1 triple combination**

SAN DIEGO and PENNINGTON, N.J., May 23, 2019 /PRNewswire/ -- OncoSec Medical Incorporated (OncoSec) (NASDAQ: ONCS), a late-stage cancer biotechnology company developing intratumoral gene-delivery immunotherapies, today announced that the first patient has been dosed in TRIFECTA, a triple combination clinical trial of OncoSec's TAVO<sup>™</sup>, an IDO1 drug (epacadostat) and KEYTRUDA<sup>®</sup> in patients with unresectable squamous cell carcinoma head and neck (SCCHN) cancer. The study is being led by Dr. Chase Heaton, M.D., a leading oncologic head and neck surgeon at UCSF, and was developed in collaboration with Dr. Alain Algazi, leader of the Head and Neck Medical Oncology Program at UCSF and Clinical Strategic Advisor to OncoSec. Preliminary data from the TRIFECTA study is anticipated later this year.

The TRIFECTA study capitalizes on findings from a 2017 pilot study of TAVO in head and neck cancer patients, which demonstrated impressive clinical and biological results including evidence of synergy between TAVO<sup>™</sup>, and PD-1 antibodies in the disease. One of the patients in the 2017 pilot study, who experienced a remarkable tumor response following TAVO<sup>™</sup> treatment, was featured in a LA Times in an article entitled, "*I have terminal cancer and I know my friends want to ask, 'Aren't you dead yet?'*"

A link to the LA Times article can be found here: <https://www.latimes.com/opinion/op-ed/la-oe-welsh-cancer-immunotherapy-20160717-snap-story.html>.

The triple combination of IL-12, IDO1 and anti-PD-1 monoclonal antibody is a first-of-its-kind clinical trial and is seeking to exploit individual anti-tumor properties of each modality. The goal of the study is to evaluate this three-way combination in SCCHN cancer and, if promising, to potentially evaluate the triple combination in other tumor types.

TRIFECTA is an investigator-initiated, single-arm, open-label clinical trial in which 35 evaluable SCCHN patients will receive TAVO<sup>™</sup>, 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. The study is being conducted by the UCSF Helen Diller Family Comprehensive Cancer Center.

"Despite advancements in the field of immunotherapy, patients with unresectable SCCHN have had limited success when treated with anti-PD-1 antibodies as a monotherapy. Given TAVO's ability to reverse anti-PD-1 resistance in patients with a variety of tumor types, we are hopeful this triplet combination will benefit this vulnerable patient population," said Daniel O'Connor, President and CEO of OncoSec. "The start of this investigator-initiated clinical trial marks an important milestone for OncoSec and we look forward to reporting preliminary data from this study later this year."

### **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](http://www.oncosec.com).

TAVO™ trademark of OncoSec Medical Incorporated.

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

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