

OncoSec Reports Preliminary Data from KEYNOTE-695 Phase 2b Registration-Directed Clinical Trial of TAVO[™] in Combination with KEYTRUDA[®] for Metastatic Melanoma at Society for Immunotherapy of Cancer's 33rd Annual Meeting

TAVO[™] in combination with KEYTRUDA[®] has shown early signals of reversing resistance in refractory metastatic melanoma patients previously treated and definitively progressed on either KEYTRUDA[®] (pembrolizumab) or OPDIVO[®] (nivolumab)

Of the first nine patients to complete 12 weeks of treatment and reach initial tumor evaluation (by RECIST v1.1), two patients had a partial response, one patient had stable disease (22% BORR and 33% DCR) and tumor responses occurred in both TAVO[™] treated and untreated lesions

SAN DIEGO and PENNINGTON, N.J., Nov. 6, 2018 /PRNewswire/ -- OncoSec Medical Incorporated (OncoSec) (NASDAQ: ONCS), a company developing novel cancer immunotherapies based on its proprietary technology generating sustained intratumoral IL-12 levels, today reported preliminary data from KEYNOTE-695, a global, multicenter Phase 2b, open-label trial of intratumoral delivery of TAVO[™] (tavokinogene telseplasmid / IL-12) with intravenous KEYTRUDA[®] (pembrolizumab) in patients with unresectable, advanced melanoma. Eligible patients had refractory, locally advanced or metastatic disease defined as unresectable Stage III/IV metastatic melanoma that had definitively progressed on a full-course of anti-PD-1 treatment with KEYTRUDA[®] (pembrolizumab) or OPDIVO[®] (nivolumab).

As of September 1, 2018, 21 patients had been enrolled in the study. Out of the 21 patients, nine patients had completed 12 weeks of treatment and reached the first tumor evaluation point at approximately 12 weeks, while the remaining 12 patients had not yet reached the first tumor evaluation. All nine patients were previously treated and definitively progressed on anti-PD-1 therapies with 56% (5/9) having had more than one prior line of therapy. All enrolled patients had exceedingly low frequencies of intratumoral CD8+ peCTL (PD-1+/CTLA-4+) at screening with a notable increase in TIL density following treatment.

Two of the nine patients experienced a partial response and one patient had stable disease (22% BORR and 33% DCR) by RECIST v1.1. Tumor responses were noted in both treated and untreated lesions. Of the two responding patients, both had multiple prior rounds of anti-PD-1 therapy, with no response, and one had also progressed after 4 cycles of OPDIVO[®] and YERVOY[®] (ipilimumab), an FDA-approved anti-CTLA4 / anti-PD-1 antibody combination. Tumor responses were associated with treatment-related upregulation of immune-based transcripts in the tumor microenvironment, as well as increased frequencies of intratumoral T cells within three weeks of therapy.

"There is currently no approved therapy for the KEYNOTE-695 patient population. A 10% response rate is considered meaningful in this cohort, since this is about what we expect with additional chemotherapy, however, such responses lack durability. The preliminary tumor responses (22% BORR and 33% DCR) and supporting immune data observed here for the first time are important," said Adil Daud, MD, HS Clinical Professor, Department of Medicine (Hematology/Oncology), UCSF; Director, Melanoma Clinical Research, UCSF Helen Diller Family Comprehensive Cancer Center.

KEYNOTE-695 enrollment criteria with respect to anti-PD-1 checkpoint failure is highly restrictive. In order to be considered an anti-PD-1 checkpoint failure, all patients must have Stage III/IV metastatic melanoma progressive disease after at least four prior cycles of either KEYTRUDA[®] or OPDIVO[®]. Disease progression is determined according to RECIST v1.1, measured by radiologic assessment, with confirmation of progression by second assessment. All patients must receive their first TAVO[™] / KEYTRUDA[®] combination treatment within 24 weeks of the last dose of an FDA approved anti-PD-1 therapy, with no intervening therapies between such failure and KEYNOTE-695 enrollment. Patients that were BRAF eligible must have received and progressed following BRAF treatment.

"Although several clinical studies have reported late-stage melanoma data in anti-PD-1 failures, such failures are inconsistently defined. This is a critical point," continued Dr. Daud. "Since patients in KEYNOTE-695 have unequivocally failed approved anti-PD-1 therapies, these preliminary data, viewed in this context, carry weight."

TAVO[™] was well-tolerated, with Grade 1 adverse events associated with injection site or procedural pain. One TAVO[™] related Grade 3 SAE of cellulitis was reported and resolved.

KEYNOTE-695 is a registration-enabled clinical trial. In order to be eligible for accelerated approval, a product candidate must treat a serious condition and provide a meaningful advantage over available therapies. In early 2017 and prior to the commencement of the study, the Company reviewed the patient inclusion criteria with FDA so that KEYNOTE-695 could be submitted to FDA for accelerated approval. KEYNOTE-695 is expected to be completed in 2019. Based on the outcome of the study and feedback from FDA, the Company plans to file for accelerated approval by end of 2019 or early 2020.

TAVO[™] has received both Orphan Drug and Fast-Track Designation by the U.S. Food & Drug Administration.

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.

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

Cautionary Note Regarding 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," 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; 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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