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OncoSec Announces Clinical Data of the KEYNOTE-695 Trial Assessing TAVO™-EP in Combination with KEYTRUDA® (pembrolizumab) in Patients with Advanced Melanoma Refractory to anti-PD-1 Treatment

EWING, N.J. and SAN DIEGO, April 3, 2023 /PRNewswire/ -- OncoSec Medical Incorporated (NASDAQ: ONCS) (the Company or OncoSec), a clinical-stage biotechnology company developing intratumoral immunotherapies to stimulate the patient's immune system to target cancer cells and eradicate disease, today announced primary endpoint data from the Phase 2 KEYNOTE-695 clinical trial. This global, open-label single-arm trial is evaluating TAVO™-EP, OncoSec's proprietary interleukin 12 (IL–12) encoding plasmid delivered by intratumoral electroporation, in combination with KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy, in patients with unresectable or metastatic (Stage III/IV) melanoma who had confirmed disease progression after at least 12 weeks exposure to immediate prior anti-PD-1 antibody therapy (pembrolizumab or nivolumab). The last patient started treatment in December 2020; clinical database lock occurred in October 2022. The primary endpoint of overall response rate (ORR) per RECIST v1.1 assessed by blinded independent central review (BICR) was not met.

Among 98 efficacy evaluable patients with at least one post-baseline tumor assessment, the confirmed ORR per RECIST v1.1 by BICR assessment is 10.2% (95% confidence interval: 5.00, 17.97), which did not achieve the pre-specified clinically meaningful ORR of ≥17% (95% CI: 10.2, 25.8). The BICR results for 98 efficacy evaluable patients are lower than the ORR per RECIST v1.1 by investigator assessment of 18.8% for the 101 patients previously reported as the key secondary endpoint of the KEYNOTE–695 trial.

BICR assessment, i.e., review of the available images of treated and non-treated lesions by radiologists and oncologists, blinded to investigator assessments, showed that 4 patients had a complete response (CR), 6 patients had a partial response (PR), and 25 patients had stable disease (SD) as a best response, for a disease control rate (CR + PR + SD) of 35.7%. The durable response rate of ≥24 weeks is 8.2% and the median duration of response is 25.5 months (range: 6.83-not reached).

As previously reported, the median overall survival for all enrolled 105 patients was 22.7 months (95% CI: 14.4, 35.5), after a median follow-up period of 33.4 months. The combination therapy of TAVO™-EP and pembrolizumab was generally well tolerated with Grade 3 treatment-related adverse events (TRAEs) in 4.8% of all enrolled patients. No patients in the KEYNOTE-695 trial or any other clinical trials evaluating TAVO™-EP alone or

in combination experienced Grade 4 or Grade 5 TRAEs.

The Company plans to pursue TAVO™-EP in combination with anti-PD-1 therapy in the neoadjuvant melanoma setting

Advancing TAVO™-EP in neoadjuvant melanoma is supported by data from an investigator-sponsored trial (IST) led by Dr. Ahmad Tarhini at H. Lee Moffit Cancer Center & Research Institute evaluating TAVO™ in combination with intravenous nivolumab (Neoadjuvant Immunotherapy With Tavo + Electroporation in Combination With Nivo. in Melanoma Patients - Full Text View - ClinicalTrials.gov). Interim data, presented in November 2022 as a poster (abstract #617) at the 37th Annual Meeting of the Society of Immunotherapy of Cancer, showed high clinical (70% ORR by RECIST v1.1) and pathological response rates (88.9% major pathological response, including 66.7% complete pathological response). Of note, several patients predicted to be non-responders to immune checkpoint blockade by biomarker analysis prior to treatment appear to respond to TAVO™ in combination with nivolumab, supporting further the mechanism of action of IL-12. A meeting with the FDA to discuss a phase 2 randomized trial design and future development plans in the melanoma neoadjuvant setting is scheduled in May 2023.

"Treatment of patients with anti-PD-1 refractory melanoma remains difficult with limited success for immune checkpoint inhibitor combinations and exploratory therapeutic approaches. It is disappointing that review by blinded central readers did not confirm the previously reported results by investigator assessment of the KEYNOTE-695 Phase 2 clinical trial in this patient population. However, we remain optimistic that the observed long duration of response and overall survival of 22.7 months in this heavily pre-treated patient population, together with previously reported preliminary results from Dr. Tarhini's IST in the neoadjuvant melanoma setting, provide rationale for further development of TAVO™-EP in combination with anti-PD-1 therapy. We plan to discuss these data and a draft protocol for TAVO™-EP in combination with pembrolizumab for a randomized Phase 2 trial in the neoadjuvant setting at the upcoming meeting with the FDA to potentially initiate the trial in the second half of 2023," said Robert Arch, Ph.D., Chief Executive Officer of OncoSec. "I want to thank all patients who participated in the KEYNOTE-695 trial, the clinical teams who conducted this trial, and everybody at OncoSec who remain focused on developing TAVO™-EP as a novel intratumoral treatment approach for cancer patients with unmet medical needs."

About OncoSec Medical Incorporated

OncoSec Medical Incorporated (the "Company," "OncoSec," "we" or "our") is a biotechnology company focused on developing intratumoral immunotherapies to stimulate the patient's immune system to target cancer cells and eradicate disease. 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 therapeutic approach TAVO™-EP, which employs electroporation, is designed to produce a localized expression of IL-12 in the tumor microenvironment and, thereby, stimulate the immune system to target and attack tumors. OncoSec's clinical pipeline is utilizing TAVO™ as a potential treatment for multiple cancer indications either as a monotherapy or in combination with checkpoint inhibitors; with the latter potentially enabling OncoSec to address a great unmet medical need in oncology: anti-PD-1 non-responders. Results from completed clinical trials of TAVO™ have demonstrated a local immune response, and subsequently, a systemic effect as either a monotherapy or

combination treatment approach along with a well-tolerated safety profile, warranting further development of TAVO™-EP. 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 LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

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). Examples of forward-looking statements include, among other things, statements regarding the future development of TAVO™ and TAVO™-EP and the Company's plans to seek regulatory approval for its clinical products and OncoSec's continued focus on developing TAVO™-EP as a novel intratumoral treatment, including in the neoadjuvant melanoma space. 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").

Forward-looking statements included in this release involve substantial risks and uncertainties that could cause our clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, our limited working capital, history of losses, and ability to continue as a going concern; the success and timing of our clinical trials, including safety and efficacy of our product candidates; the ability to achieve the clinical and operational objectives; our ability to adhere to ongoing compliance requirements of all health authorities, in the U.S. and foreign countries; capital requirements and needs for additional financing; our ability to obtain additional funding; the ability of our product candidates to successfully perform and advance in clinical trials; our ability to obtain and maintain authorization from regulatory authorities for use of our product candidates for initiation and conduct of clinical trials; the performance of our clinical research organizations, clinical trial sponsors, and clinical trial investigators; and our ability to successfully implement our strategy. 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, 2022 and any 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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