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OncoSec's TAVO™ Receives ATMP Certification from European Medicines Agency to Support Marketing Authorization Application in Metastatic Melanoma

PENNINGTON, N.J. and SAN DIEGO, May 13, 2020 /PRNewswire/ -- OncoSec Medical Incorporated (Nasdaq:ONCS) (the "Company" or "OncoSec"), a company developing late-stage intratumoral cancer immunotherapies, today announced the European Medicines Agency (EMA) issued an advanced therapy medicinal product (ATMP) certificate for chemistry manufacturing controls (CMC) data covering its lead product candidate, TAVO™ (interleukin-12 or "IL-12" plasmid), for the treatment of metastatic melanoma. Following TAVO's classification as an ATMP last year, the certification procedure involved a thorough scientific evaluation over several months of CMC data for TAVO by the EMA's Committee for Advanced Therapies (CAT). The CAT assessment of the TAVO CMC data provides valuable regulatory feedback to help ensure a successful marketing authorization application prior to submission. After a positive opinion from CAT, EMA issued a certificate confirming that the CMC data comply with the standards that apply for evaluating the Marketing Authorization Application (MAA).

"Certification of TAVO as an ATMP allows us to leverage a specific EU regulatory framework, akin to fast-track in the United States, designed to facilitate the review, approval, and access of TAVO in the EU market," said Robert Ashworth, PhD, Senior Vice President, Regulatory, Quality and CMC at OncoSec. "With the CMC portion of the MAA now reviewed and certified, we are preparing to commence process validation activities for TAVO as we work to bring this innovative immunotherapy to patients with metastatic melanoma who have limited treatment options."

The Committee for Advanced Therapies is the committee at the European Medicines Agency that is responsible for classifying and assessing the quality, safety and efficacy of advanced-therapy medicinal products and following scientific developments in the field. It is a multidisciplinary committee, gathering together some of the best available experts in Europe.

The ATMP designation is a classification for certain medicines for human use that are gene-, cell-, or tissue-based. The main responsibility of the CAT is to prepare a draft opinion on each ATMP application submitted to the European Medicines Agency, before the Committee for Medicinal Products for Human Use (CHMP) adopts a final opinion on granting a marketing authorization for the product. During drug development, CAT also reviews and certifies the acceptability of quality and non-clinical data.

OncoSec has expanded its pivotal KEYNOTE-695 study of TAVO to Europe, laying the

foundation for a MAA submission within the EU. The KEYNOTE-695 study is a pivotal, global, open-label trial evaluating TAVO in combination with the checkpoint inhibitor, KEYTRUDA® (pembrolizumab) in patients with anti-PD-1 checkpoint resistant metastatic melanoma. TAVO currently has orphan drug designation and fast track status in the United States.

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 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 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.

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, the allowance by FDA of the clinical use of CORVax12 and our next-generation APOLLO generator in this or any future 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, 2019 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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