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OncoSec and Gynecologic Oncology Group (GOG) Foundation, Inc. to Conduct a Pivotal Study of TAVO™ with Standard of Care KEYTRUDA® for Treatment of Late Stage Cervical Cancer

Registration-Enabled Study Expected to Begin Patient Enrollment in First Half 2019

GOG Foundation is a World-Renowned Non-Profit Organization with the Purpose of Conducting Clinical Research for the Prevention and Treatment of all Gynecologic Cancers

SAN DIEGO and PENNINGTON, N.J., Jan. 7, 2019 /PRNewswire/ -- OncoSec Medical Incorporated (OncoSec) (NASDAQ:ONCS), a company developing novel cancer immunotherapies, today announced it has established a collaboration with the GOG Foundation, Inc., (GOG Foundation), to conduct a registration-enabled study of TAVO™ (tavokinogene telseplasmid) in women with recurrent/persistent cervical cancer (OMS-150).

In June, 2018, KEYTRUDA® (pembrolizumab) received accelerated approval from the FDA for the treatment of advanced cervical cancer with disease progression during or after chemotherapy based on data from a single-arm 98 patient study that showed a 14% overall response rate (ORR). Previous data in other advanced solid tumors demonstrate that TAVO combined with KEYTRUDA can induce objective responses in patients who do not respond to anti-PD-1 antibody monotherapy.

In this registration-directed clinical trial, OncoSec and GOG will evaluate the combination of TAVO and commercially available KEYTRUDA with the goal of achieving a clinically meaningful response rate greater than what has already been demonstrated with KEYTRUDA alone (14%). OncoSec and the GOG Foundation plan to enroll approximately 80 to 100 patients, who qualify for standard of care treatment with KEYTRUDA, in this single-arm study with TAVO. The trial will be open to patients with surface or subcutaneous lesions that are accessible via TAVO's current delivery system. Patient enrollment is expected to begin in the first half of 2019. Importantly, should a clinically meaningful increase be observed in patients receiving the TAVO beyond that which they receive from KEYTRUDA alone, OncoSec plans to seek accelerated approval of TAVO in this patient population.

"KEYTRUDA is only the second drug in 30 years to be approved for the treatment of cervical cancer and, though it represents significant progress, the number of patients who can benefit is limited. Our goal is to improve upon the 14% KEYTRUDA response rate with the addition of TAVO," said Daniel J. O'Connor, President and Chief Executive Officer of OncoSec. "We believe that TAVO, our proprietary intratumoral plasmid-based IL-12, is an excellent complement for expanding the clinical benefit of anti-PD-1 therapies, especially for those patients that are resistant to anti-PD-1 therapies. Given that KEYTRUDA is already approved and reimbursed for this indication, this study fits perfectly with our strategy of identifying opportunities to conduct small, relatively low-cost single-arm clinical studies that have the potential to offer a rapid path to drug approval and commercialization."

The study will be conducted within GOG Foundation's network under OncoSec's investigational new drug (IND) application for TAVO. The GOG Foundation is a world-renowned non-profit organization with the purpose of conducting clinical research for the prevention and treatment of all gynecologic cancers, such as ovarian cancer, cervical cancer, endometrial cancer, vulvar cancer, and vaginal cancer. Its members make up a multi-disciplinary group, consisting of gynecologic oncologists, medical oncologists, pathologists, radiation oncologists, nurses, statisticians, and basic scientists.

"Conducting research that can lead to promising new therapies for women facing cervical cancer and other gynecological malignancies is central to our mission, and this collaboration is an exciting opportunity to bring our esteemed network and expertise in quality scientific research to the table," said Larry J. Copeland, MD, GOG Foundation President. "We're grateful to play a role in this trial and look forward to advancing this therapy through the clinic."

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.

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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