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OncoSec Announces Positive Phase II Data Demonstrating Company's ImmunoPulse® IL-12 in Combination with Pembrolizumab Increased Response Rates in Anti-PD-1 Non-Responder Melanoma Patients

New Data Showed 48% Best Overall Response Rate

Comprehensive Immune Monitoring Data Demonstrated Combination of ImmunoPulse® IL-12 and Pembrolizumab Can Convert "Cold" Tumors to "Hot" Tumors

SAN DIEGO, Feb. 23, 2017 /PRNewswire/ -- OncoSec Medical Incorporated ("OncoSec") (NASDAQ: ONCS), a company developing DNA-based intratumoral cancer immunotherapies, today reported new positive clinical data from a Phase II Investigator Sponsored Trial assessing the combination of OncoSec's investigational intratumoral therapy, ImmunoPulse® IL-12, and the approved anti-PD- 1 therapy (pembrolizumab), in patients with unresectable metastatic melanoma. The results of this single-arm, open-label trial, which was led by the University of California, San Francisco (UCSF), indicated that ImmunoPulse® IL-12 can increase response rates in patients who are not expected to respond to anti-PD-1 therapy alone.

The trial is evaluating the following key endpoints: best overall response rate (BORR) by Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 and immune-related Response Criteria; safety and tolerability; duration of response; 24-week landmark progression-free survival (PFS); median PFS; and overall survival (OS). The study results showed an overall response rate (ORR) at 24 weeks of 43% (9/21), and BORR of 48% by RECIST v1.1. There were 24% (5/21) complete responders (CR), 19% (4/22) partial responders (PR), and 9% (2/21) stable disease (SD) for a total disease control rate of 52% (11/21). These data are consistent with, and expand upon, previously reported preclinical and clinical data that provide a strong rationale for combining ImmunoPulse® IL-12 with anti-PD-1 blockade.

"Collectively, these data suggest that intratumoral IL-12 DNA with electroporation in combination with pembrolizumab can effectively alter the tumor microenvironment by triggering adaptive resistance," said Alain Algazi, M.D., the study's lead investigator, and skin cancer specialist in the Melanoma Center at the UCSF Helen Diller Family Comprehensive Cancer Center. "This increases the substrate for a therapeutic PD-1/PD-L1 blockade while driving systemic anti-tumor immunity and concordant clinical responses in patients unlikely to benefit from anti-PD-1 monotherapy."

Dr. Algazi presented the study findings today in an oral presentation titled, "Immune monitoring outcomes of patients with stage III/IV melanoma treated with a combination of pembrolizumab and intratumoral plasmid interleukin 12 (pIL-12)" (Abstract #78), at the ASCO-SITC Clinical Immuno-Oncology Symposium in Orlando, FL.

In this trial, a biomarker that has previously been shown to be predictive of response to checkpoint inhibitor therapy was used to enroll 22 patients who have a low likelihood of responding to an anti-PD-1 therapy. These patients were treated with the combination of intravenous pembrolizumab and ImmunoPulse® IL-12 for more than 24 weeks.

The combination therapy continued to demonstrate a favorable safety profile and was well tolerated. Importantly, of the 22 patients enrolled, nine had previous checkpoint inhibitor therapy; ORR for this subset of patients was 33% (3/9).

Comprehensive immune monitoring of blood and tissue samples showed that the combination of ImmunoPulse® IL-12 with pembrolizumab produces a safe and powerful systemic immune response. This response leads to an increase in tumor-specific CD8+ T-cells and an "adaptive immune resistance" that broadly supports an immune-directed mechanism that is differentiated between responders and non-responders. Analysis of the biomarker data suggests that the combination of ImmunoPulse® IL-12 with pembrolizumab is transforming "cold" tumors, which would be predicted to not respond to anti-PD-1 therapy, into "hot" tumors, thus increasing the potential for a meaningful clinical response to the checkpoint inhibitor therapy. Moreover, an analysis of pre-treatment samples using various analytical methods that have also been demonstrated to predict response to anti-PD-1 therapy, including immunohistochemistry (IHC) and RNA expression of critical immune-related genes by NanoString®, correlate with the predictive biomarker used to enroll patients for this study.

"OncoSec's vision to bring intratumoral gene therapies to the oncology market continues to advance with these positive, impactful data, which hold immense promise for cancer patients who are unlikely to benefit from immunotherapy," said Punit Dhillon, OncoSec President and CEO. "These results provide a strong foundation for our planned Phase II registration trial, which will evaluate the combination of ImmunoPulse® IL-12 and an anti-PD-1 therapy in melanoma patients who have previously failed an approved anti-PD-1 therapy alone. We expect to initiate this study later in 2017."

The full-text abstract is available and can be viewed on ASCO-SITC's website at www.immunosym.org. The presentation is available in the Publications section of OncoSec's website.

About the ASCO-SITC Clinical Immuno-Oncology Symposium
The ASCO-SITC Clinical Immuno-Oncology Symposium is a three-day meeting focused on clinical and translational research in immuno-oncology and the implications for clinical care. This is a new meeting, one that will address the high level of need for clinical education in a field where all aspects of care are fundamentally different from traditional therapies. For more information, please visit www.immunosym.org.

About OncoSec Medical Incorporated
OncoSec is a biotechnology company developing DNA-based intratumoral immunotherapies with an investigational technology, ImmunoPulse®, for the treatment of cancer.

ImmunoPulse® is designed to enhance the local delivery and uptake of DNA-based immune-targeting agents, such as IL-12. In Phase I and II clinical trials, ImmunoPulse® IL-12 has demonstrated a favorable safety profile and evidence of anti-tumor activity in the treatment of various solid tumors as well as a systemic immune response. OncoSec's lead program, ImmunoPulse® IL-12, is currently in clinical development for several indications, including metastatic melanoma and triple-negative breast cancer. The program's current focus is on the significant unmet medical need in patients with melanoma who are refractory or non-responsive to anti-PD-1/PD-L1 therapies. In addition to ImmunoPulse® IL-12, the Company is also identifying and developing new immune-targeting agents for use with the ImmunoPulse® platform. For more information, please visit www.oncosec.com.

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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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