

August 15, 2016



OncoSec Announces Peer-Reviewed Publication of T-Cell Exhaustion Marker to Predict Response to Anti-PD-1 Therapy in Melanoma

SAN DIEGO, Aug. 15, 2016 /PRNewswire/ -- OncoSec Medical Incorporated ("OncoSec") (NASDAQ: ONCS), a company developing DNA-based intratumoral cancer immunotherapies, today announced the publication of research showing that partially exhausted CD8+ cells infiltrating melanoma tumors accurately predicted most patients' responses to anti-PD-1 therapies. The findings, published in the *Journal of Clinical Investigation*, show that the response to pembrolizumab strongly correlated to the percent of CD8+ tumor-infiltrating lymphocytes (TILs) that expressed high levels of both PD-1 and CTLA-4. The study was led by University of California, San Francisco (UCSF) researchers and physicians. This exhaustion marker is currently being used to select patients for the ongoing Phase II investigator-sponsored clinical trial evaluating the combination of OncoSec's investigational therapy, ImmunoPulse® IL-12, and the approved anti-PD-1 therapy, pembrolizumab, in patients with unresectable metastatic melanoma.

With tumor samples from a discovery cohort of 20 patients who had received anti-PD-1 therapy, researchers used multiparameter flow cytometry to sort cells according to immune biomarker expression in the study. Researchers examined CD8+ cells to see whether they expressed PD-1, CTLA-4, and other proteins. The number of partially exhausted CD8+ cells in tumors that expressed high levels of both PD-1 and CTLA-4 was a reliable biomarker of response to anti-PD-1 therapy, with response defined by standard RECISTv1.1 criteria. This observation was confirmed in a separate validation cohort of 20 patients.

"This paper supports the concept that the 'target cell' of anti-PD-1 monoclonal antibodies (mAb) is the partially exhausted CD8+ T-cell within the tumor, which can be readily quantified using flow cytometry," said Robert H. Pierce, MD, OncoSec Chief Scientific Strategist and co-author of the paper. "We've taken advantage of this assay's ability to strongly predict patients, who are unlikely to respond to anti-PD-1 mAb monotherapy, and select these patients in our ongoing Phase II trial, where we are combining intratumoral electroporation of plasmid IL-12 and pembrolizumab."

"These findings represent an advance in the field of cancer immunotherapy," said Adil Daud, MD, director of Melanoma Clinical Research at the UCSF Helen Diller Family Comprehensive Cancer Center. "Many tests examining PD-L1 levels in tumor tissue can only modestly discriminate between responders and non-responders. This analysis accurately predicts response to anti-PD-1 therapy and can be utilized in the clinic to appropriately select patients with a high likelihood of achieving a clinical response to PD-1 pathway inhibition."

OncoSec is assessing the anti-tumor activity, safety, and tolerability of the combination of ImmunoPulse® IL-12 and pembrolizumab in melanoma patients in a Phase II clinical trial sponsored by UCSF. This multi-center, open-label, single-arm trial is the first study to use UCSF's T-cell exhaustion marker assay. The study will test the hypothesis as to whether the addition of ImmunoPulse® IL-12 to pembrolizumab can increase the response rate in melanoma patients, who have a low likelihood of responding to monotherapy with anti-PD-1 blockade. The key endpoints of the study include: best overall response rate (BORR) by RECIST v1.1 and immune-related Response Criteria (irRC); safety and tolerability; duration of response; 24-week landmark progression-free survival; median progression-free survival; and overall survival. OncoSec expects to present data from this trial in the second half of 2016.

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 and has shown the potential to reach beyond the site of local treatment to initiate a systemic immune response. ImmunoPulse® IL-12, OncoSec's lead program, 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," "predict," "likelihood," "will," "hypothesis," "expect," "potential," "designed," "may," "could," 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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