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OncoSec Collaborators Present Results of Novel T-Cell Exhaustion Marker to Predict Response to Anti-PD-1 Monotherapy

The combination of OncoSec's ImmunoPulse™ IL-12 and pembrolizumab is the first clinical trial to use this assay to select specific patients, who are unlikely to respond to monotherapy with anti-PD-1 agents

SAN DIEGO, June 6, 2016 /PRNewswire/ --OncoSec Medical Incorporated ("OncoSec") (NASDAQ: ONCS), a company developing DNA-based intratumoral cancer immunotherapies, today announced that its collaborators at the University of California San Francisco (UCSF) presented results at the American Society of Clinical Oncology (ASCO) Annual Meeting, demonstrating the utility of a T-cell exhaustion marker to predict response to anti-PD-1 monotherapies. Authors of this poster discussion session from UCSF include Adil Daud, MD, Alain Algazi, MD, and Michael Rosenblum, MD, PhD. This "low-tumor infiltrating lymphocyte" (TIL) 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.

Using samples from prior trials, authors presented results from a total of 53 patients evaluable for both response and the T-cell exhaustion marker (TEx). Fifteen patients were treated with a combination of ipilimumab and nivolumab, and 38 with monotherapy anti-PD-1. Patients determined to be "low-TIL" (TEx ≤20%) had 0/12 (0%) responses to anti-PD-1 therapy, while patients who were "high-TIL" (TEx >20%) had 21/26 (81%) responses. Median TEx was 40.3% for responders and 16% for non-responders. Using a threshold of TEx at 20%, the negative predictive value for response was 100% and the positive predictive value was 81%. For patients treated with the combination of ipilimumab and nivolumab, the TEx threshold predictive of response was much lower. The authors concluded that this novel T-cell exhaustion marker (% TEx) is an accurate predictor of response to monotherapy, but not response to combination therapy with ipilimumab and nivolumab.

OncoSec is currently enrolling patients into the Phase II clinical trial led by UCSF to assess the anti-tumor activity, safety, and tolerability of the combination of ImmunoPulse™ IL-12 and pembrolizumab. This multi-center, open-label, single-arm trial is the first study to select patients for "low-TIL" status using 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 low-TIL 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.

"We are delighted that our collaborators are presenting data at ASCO demonstrating the utility of the flow cytometric TIL assay," said Robert H. Pierce, MD, Chief Scientific Officer at OncoSec. "Our ongoing investigator-sponsored combination trial of ImmunoPulse™ IL-12 and pembrolizumab hinges on the strong predictive value for poor treatment outcomes from this assay. Given these data, we are confident that we will be able to robustly identify a combination efficacy signal in our ongoing single-arm trial."

For more information about this trial, please visit:http://oncosec.com/clinical-pipeline/.

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 skin cancers as well as the potential to initiate 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. 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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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," "hypothesis," "look forward to," "potential," 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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To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/oncosec-collaborators-present-results-of-novel-t-cell-exhaustion-marker-to-predict-response-to-anti-pd-1-monotherapy-300279866.html

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