

OncoSec Presents Positive Melanoma Clinical Data at American Association for Cancer Research (AACR) Annual Meeting 2016

SAN DIEGO, April 19, 2016 /PRNewswire/ -- OncoSec Medical Incorporated ("OncoSec") (NASDAQ: ONCS), a company developing DNA-based intratumoral cancer immunotherapies, today presented long-term, follow-up data of patients who were treated with its investigational therapy ImmunoPulse[™] IL-12 and later went on to receive an anti-PD-1/PD-L1 therapy. These data suggest that ImmunoPulse[™] IL-12 may prime and enhance response rates to PD-1/PD-L1 blockade. Alain Algazi, MD, skin cancer specialist in the Melanoma Center at the UCSF Helen Diller Family Comprehensive Cancer Center, presented the findings in an oral presentation entitled "Intratumoral electroporation of plasmid IL-12 can prime response to anti-PD1/PD-L1 blockade in patients with Stage III/IV-M1a melanoma" (Abstract #CT134) at the American Association of Cancer Research (AACR) Annual Meeting in New Orleans, LA.

"We are encouraged by the data from this analysis, which show that intratumoral IL-12 DNA with electroporation can prime the immune system and help improve patient response to anti-PD-1," said Dr. Algazi. "These results are being validated prospectively in a Phase II clinical trial and they could make a clinically meaningful impact on patient outcomes and address a great unmet need in immuno-oncology."

These new data were generated from a single-site retrospective analysis of the Company's Phase II monotherapy clinical study of ImmunoPulse[™] IL-12, which employs intratumoral electroporation to enhance delivery of DNA-based interleukin-12 (IL-12), in patients with advanced melanoma. After completing treatment with ImmunoPulse[™] IL-12, a subset of patients subsequently received an anti-PD-1/PD-L1 therapy either as their next line of treatment or a later line of treatment. Patients with documented follow-up history and evaluable for anti-PD-1/PD-L1 response were included in this analysis.

In this study, 34 patients were enrolled and treated with ImmunoPulse[™] IL-12 alone. Fourteen of these 34 patients went on to receive a systemic anti-PD-1/PD-L1 therapy and were evaluable for PD-1/PD-L1 overall response rate ("ORR") using immune-related response criteria. The PD-1/PD-L1-associated ORR among patients was **64%** (9/14). The analysis showed 36% of patients (5/14) had a complete response (CR), 29% of patients (4/14) had a partial response (PR), 14% percent of patients (2/14) experienced stable disease, and 21% of patients (3/14) had progressive disease. Furthermore, 8 of these 14 evaluable patients received a systemic anti-PD-1/PD-L1 antibody with no intervening therapy after treatment with ImmunoPulse[™] IL-12. Of these 8 patients, an ORR of **75%** was observed (50% CR and 25% PR).

Additionally, multiple biomarker analyses demonstrate that ImmunoPulse[™] IL-12 therapy

promotes the generation of activated natural killer and functional T cell immune subsets in the periphery as well as CD8⁺ tumor infiltrating lymphocytes (TIL), which may help trigger the PD-1 immune checkpoint (i.e. "adaptive immune resistance") to provide the "substrate" for effective anti-PD-1/PD-L1 therapy.

"Although one always needs to be cautious regarding the interpretation of retrospective analyses, these data are consistent with our hypothesis that ImmunoPulse™ IL-12 is driving a specific anti-tumor TIL response, which primes the patient for an enhanced response to PD-1 blockade," said Robert H. Pierce, MD, Chief Scientific Officer. "We look forward to following up on these observations with interim data from our ongoing combination trial in patients with melanoma investigating ImmunoPulse™ IL-12 and the anti-PD-1 therapy, pembrolizumab, later this year."

The full-text abstract is available and can be viewed on AACR's website at www.aacr.org. The presentation is available in the [Publications](#) section of OncoSec's website.

About Melanoma

Melanoma is one of the most dangerous forms of skin cancer and accounts for the vast majority of skin cancer deaths.¹ When melanoma is caught early enough, surgical excision can be curative in the majority of Stage I and II melanomas. The overall 5-year survival rate for patients with localized melanoma is 98% in the United States.¹ At later stages, malignant melanoma remains a deadly and frequently difficult to treat cancer. The overall 5-year survival rate for patients falls to 17% when the disease metastasizes to distant sites or organs.¹ Approximately 8,780 patients are diagnosed with Stage III and IV melanoma in the United States each year.²

Melanoma that has spread to distant sites may be treated with surgery, immunotherapy, chemotherapy and/or radiation therapy.¹ Numerous chemotherapy regimens have been tested in melanoma with only modest success and limited overall survival benefit.³ Immunotherapies, such as checkpoint inhibitors, have demonstrated improvement in overall survival of patients compared to chemotherapy.³

While immunotherapy can be extremely effective, the majority of patients will not respond to anti-PD-1 therapy alone, representing a great unmet need in oncology. However, researchers are focusing efforts on targeting pathways of T cell activation.⁴ The presence of CD8⁺ T cells seems to correlate with improved prognosis and long-term survival in solid malignancies, such as melanoma,^{5,6} thus many emerging experimental immunotherapies seek to enhance the tumor's immunogenicity and increase the anti-tumor CD8⁺ T cell response.

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, squamous cell carcinoma of the head and neck, 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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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," "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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