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# OncoSec Announces First Patient Enrolled in Phase II Clinical Trial Evaluating Combination of ImmunoPulse™ IL-12 and Anti-PD-1 Treatment

SAN DIEGO, Aug. 18, 2015 /PRNewswire/ -- OncoSec Medical Incorporated ("OncoSec") (NASDAQ: ONCS), a company developing DNA-based intratumoral cancer immunotherapies, today announced enrollment of the first patient into the Phase II Investigator Sponsored Trial led by the University of California, San Francisco (UCSF) to assess the anti-tumor activity, safety, and tolerability of the combination of OncoSec's investigational therapy, ImmunoPulse™ IL-12, and Merck's approved anti-PD-1 agent, KEYTRUDA® (pembrolizumab), in patients with unresectable metastatic melanoma. The primary endpoint is the best Overall Response Rate (bORR) of the combination regimen in patients whose tumors are characterized by low numbers of tumor-infiltrating lymphocytes (TILs).

"There is increasing evidence that tumors need to be inflamed and have TILs in order for anti-PD-1 therapies to be most effective," said Mai H. Le, MD, Chief Medical Officer of OncoSec. "Both preclinical and clinical evidence suggest that ImmunoPulse™ IL-12 can promote tumor immunogenicity. We anticipate that ImmunoPulse™ IL-12 will increase the proportion of patients who will respond to immune checkpoint inhibitors like KEYTRUDA® and that the combination will have synergistic anti-tumor activity."

"This is the first study in the field of immuno-oncology to evaluate the combination of DNA-based interleukin-12 with electroporation and an anti-PD-1/PD-L1 inhibitor," said Punit Dhillon, CEO and President of OncoSec. "We believe the combination of OncoSec's intratumoral cancer immunotherapy and checkpoint inhibitors has the potential to be a powerful approach in the fight against cancer."

This multi-center, open label, single-arm trial will enroll approximately 42 patients with unresectable, "low-TIL" metastatic melanoma. Alain Algazi, MD, a skin cancer specialist in the Melanoma Center at the UCSF Helen Diller Family Comprehensive Cancer Center, is the study's sponsor and principal investigator. The key endpoints of the study include: best Overall Response Rate 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.

The treatment schedule for the trial follows the standard schedule for pembrolizumab. Pembrolizumab will be administered systematically once every three weeks and ImmunoPulse™ IL-12 will be administered on three separate days every six weeks. ImmunoPulse™ IL-12 employs intratumoral delivery of DNA-based IL-12 followed by electroporation. Merck will supply pembrolizumab, and OncoSec will provide

ImmunoPulse™ IL-12.

To learn more about the trial, visit www.oncosec.com. Additional details can also be found at www.clinicaltrials.gov.

**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 percent 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 63 percent when the disease reaches the lymph nodes and 16 percent when the disease metastasizes to distant organs.[1]

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.[2] Two approaches – checkpoint inhibitors and targeted kinase inhibitors – have demonstrated improvement in overall survival of patients compared to chemotherapy. [2]

While immunotherapy can be extremely effective, the currently approved regimens do not benefit the majority of patients. However, early data of combination approaches with immunotherapies are promising.[2] Researchers also continue to focus efforts on targeting pathways of T cell activation.[3] The presence of CD8+ T cells seems to correlate with improved prognosis and long-term survival in solid malignancies, such as melanoma,[4,5] 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 biopharmaceutical 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 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 Phase II development for several indications, including metastatic melanoma, squamous cell carcinoma of the head and neck (HNSCC), and triple-negative breast cancer (TNBC). 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.

**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 "anticipate," "intend," "estimate," "believe," "expect," "future," "may," "should," "will," 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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**References**
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