

# UC San Francisco and OncoSec Medical Collaborate to Evaluate Investigational Combination of ImmunoPulse and Anti-PD-1 Treatment

*Investigator Sponsored Trial Led by Dr. Alain Algazi and Supported by OncoSec and Merck Will Evaluate Combination of KEYTRUDA<sup>®</sup> and ImmunoPulse in Metastatic Melanoma*

SAN DIEGO-- OncoSec Medical Inc. (OTCQB: [ONCS](#)), a company developing DNA-based intratumoral cancer immunotherapies, has entered a clinical collaboration with the University of California, San Francisco (UCSF), to evaluate the safety, tolerability and efficacy of the combination of KEYTRUDA<sup>®</sup> (pembrolizumab), Merck's anti-PD-1 therapy, and OncoSec's ImmunoPulse (intratumoral IL-12) in metastatic melanoma.

Recent data suggest that patients who are PD-L1 positive and have increased tumor-infiltrating lymphocytes (TILs) are more likely to respond to anti-PD-1/PD-L1 mAbs compared to patients who are PD-L1 negative. Therefore, therapies that promote TIL generation and PD-L1 positivity may play an important role in augmenting the clinical efficacy of these agents.

Interleukin-12 (IL-12) is an inflammatory cytokine believed to be a master regulator of the immune system, promoting up-regulation of both the innate and adaptive immune responses. More specifically, IL-12 stimulates the production of another cytokine, interferon gamma (IFN- $\gamma$ ), which results in the stimulation of antigen processing and presentation machinery, leading to increased TILs and anti-tumor cytotoxic T-cell (CTL) activity.

ImmunoPulse, an investigational intratumoral immunotherapy, uses plasmid DNA that encodes for IL-12 and delivers it directly into the tumor using a proprietary electroporation device. Preclinical and clinical data suggest that local delivery and expression of IL-12 with ImmunoPulse promotes tumor immunogenicity and increases TILs without the toxicities associated with systemic IL-12 administration. Recent interim data from OncoSec's ongoing Phase II study have demonstrated that plasmid IL-12 electroporation treatment increases IFN- $\gamma$  production and increased expression of genes related to antigen processing and presentation, including the expression of PD-L1.

Punit Dhillon, President and CEO of OncoSec, said, "This collaboration with Dr. Algazi and UCSF with support from Merck marks the first clinical trial to evaluate the combination of an anti-PD-1 antibody with an intratumoral therapy using electroporation. Over the course of the last year, OncoSec has continually stated the need to evaluate intratumoral therapies that have the ability to convert the anti-PD-1 non-responder population to responders. The design of this clinical trial will assess this hypothesis, and we believe the combination of OncoSec's intratumoral immunotherapies and checkpoint inhibitors holds significant promise

for the treatment of melanoma and other cancers. We look forward to sharing the results from this clinical trial in the future."

Dr. Robert Pierce, Chief Scientific Officer of OncoSec, said, "There is a strong rationale for combining a treatment like ImmunoPulse, which increases TILs, with a T cell checkpoint therapy like pembrolizumab, which then acts on those TILs. This study is designed to test whether this combination increases patients' TILs and improves anti-tumor efficacy in low-TIL melanoma patients."

Dr. Alain Algazi, principal investigator at UCSF, said, "The PD-1 antibody pembrolizumab takes the brakes off of the anti-melanoma immune responses. ImmunoPulse with IL-12 has the potential to bring immune cells and signals into the tumor so that, when pembrolizumab takes the brakes off the immune response, the results could be devastating for the tumor and great for our patients."

This Phase II clinical trial will be conducted as a multicenter Investigator Sponsored Trial (IST), with UCSF and Dr. Alain Algazi as the sponsor. Merck will supply pembrolizumab, and OncoSec will provide electroporation devices and plasmid IL-12. Enrollment is expected to begin in Q1 2015.

## **About OncoSec Medical**

OncoSec Medical Inc. is a biopharmaceutical company developing its investigational ImmunoPulse intratumoral cancer immunotherapy. OncoSec Medical's core technology is designed to enhance the local delivery and uptake of DNA IL-12 and other DNA-based immune-targeting agents. Clinical studies of ImmunoPulse have demonstrated an acceptable safety profile and preliminary evidence of anti-tumor activity in the treatment of various skin cancers, as well as the potential to initiate a systemic immune response without the systemic toxicities associated with other treatments. OncoSec's lead program evaluating ImmunoPulse for the treatment of metastatic melanoma is currently in Phase 2 development, and is being conducted in collaboration with several prominent academic medical centers. As the company continues to evaluate ImmunoPulse in its current indications, it is also focused on identifying and developing new immune-targeting agents, investigating additional tumor indications, and evaluating combination-based immunotherapy approaches. For more information, please visit [www.oncosec.com](http://www.oncosec.com).

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