

# OncoSec Reports Positive Top-Line Six-Month Primary Endpoint Data from Phase II Melanoma Trial of ImmunoPulse Monotherapy

*Best Overall Response Rate of 31 Percent*

*Complete Response Rate of 14 Percent*

*Disease Control Rate of 48 Percent*

SAN DIEGO-- OncoSec Medical Inc. (OTCQB: [ONCS](#)), a company developing DNA-based intratumoral cancer immunotherapies, released top-line six-month data from the first Phase II trial of its investigational intratumoral plasmid IL-12 electroporation (pIL-12 EP) monotherapy (ImmunoPulse IL-12) in patients with Stage III and IV metastatic melanoma. Dr. Robert H. Pierce, Chief Scientific Officer at OncoSec, a co-author of the study, presented these data today in an abstract at the Melanoma Bridge 2014 conference in Naples, Italy.

In this Phase II study, 30 patients with stage III-IV melanoma received up to four cycles of pIL-12 EP into superficial cutaneous, subcutaneous and nodal lesions on Days 1, 5 and 8 of each 12-week cycle. Tumor responses were evaluated using modified RECIST criteria for cutaneous lesions. The primary endpoint of the study was best overall response rate (bORR) by modified RECIST. In the 29 response-evaluable patients, bORR was 31 percent (9/29), with 14 percent (4/29) of patients achieving a complete response (CR). Regression of at least one non-injected, non-electroporated lesion was observed in 50 percent (13/26) of patients.

Dr. Mai H. Le, Chief Medical Officer, stated, "Along with the Phase I long-term survival analysis presented yesterday, these data continue to support the use of pIL-12 EP as a treatment for metastatic melanoma. Importantly, our observation that non-treated lesions regress in approximately half of the patients suggests that local, intratumoral pIL-12 EP successfully induces a more global anti-tumor immune-mediated response."

The most common treatment-related adverse event (AE) reported was transient Grade 1/2 pain at the treatment site, reported in 87 percent (26/30) of patients. The reports of pain were directly associated with the procedure and the median duration of pain was one minute. Only one Grade 3 adverse event of pain was reported. No other Grade 3 or worse adverse events were observed and there were no reports of any treatment-related serious adverse events (SAEs).

Analysis of tissue samples from patients treated with pIL-12 EP showed a gene expression pattern consistent with generation of an inflammatory response with increased CD8<sup>+</sup> TILs (tumor-infiltrating lymphocytes) and the induction of key immune co-stimulatory molecules.

These findings were corroborated by the results of preliminary preclinical experiments testing pIL-12 EP in the B16.F10 mouse melanoma model, which also indicated the presence of CD8+ TILs (tumor-infiltrating lymphocytes) and the induction of adaptive resistance mechanisms in distant tumors.

Dr. Pierce said, "We are pleased to see such good concordance between our findings from patient biopsy samples and the B16.F10 mouse model. This gives us confidence that we can use this experimental model to deepen our understanding of how ImmunoPulse re-programs the immune system to drive a systemic anti-cancer immune response. Taken together, these clinical and preclinical data provide further evidence for combining this approach with checkpoint inhibitors such as anti-PD-1."

Punit Dhillon, President and Chief Executive Officer, added, "Induction of systemic anti-tumor immune responses in metastatic melanoma with a local IL-12 therapy, like ImmunoPulse, may provide an important and convenient therapeutic option for treating this devastating disease, particularly with other therapies that block immune checkpoints. In light of this data, we are excited about our recently announced combination trial of ImmunoPulse IL-12 with Merck's recently approved PD-1 inhibitor, Keytruda<sup>®</sup>, in a Phase IIb study."

### **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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