

# OncoSec Medical Presents Positive Phase 2 Interim Data Evaluating ImmunoPulse in Melanoma

*Data Presented at 2014 ASCO Annual Meeting Suggest ImmunoPulse is Well-Tolerated and Has a Systemic Anti-Tumor Response*

SAN DIEGO-- OncoSec Medical Inc. (OTCQB: [ONCS](#)), a company developing its ImmunoPulse DNA-based intratumoral cancer immunotherapy, announced interim data from its Phase 2 melanoma study at the American Society of Clinical Oncology's (ASCO) 50<sup>th</sup> Annual Meeting in Chicago. The abstract, titled "Systemic anti-tumor effect and clinical response in a Phase 2 trial of intratumoral electroporation of plasmid interleukin-12 in patients with advanced melanoma" (ASCO Abstract #9025), was presented by Adil Daud, M.D., OncoSec's Chief Clinical Strategist and Principal Investigator of the Phase 2 melanoma study, and selected for discussion during a poster highlights session for melanoma/skin cancers led by Axel Hauschild, M.D., Ph.D.

Data from the multicenter, open-label, single-arm study confirmed the safety of OncoSec's lead product candidate, ImmunoPulse, which delivers the anti-tumor agent pIL-12 directly into the tumor via *in-vivo* electroporation (EP), with no treatment-related serious adverse events or deaths having been reported. Regression of treated and non-treated tumors suggests successful induction of systemic anti-tumor response.

To date, 30 patients have been enrolled and have received at least one cycle of treatment. At the time of this interim analysis, 28 patients were evaluable for objective response rate (ORR) at 24-week primary time point. Best ORR was evaluated per modified RECIST1.1 criteria, and provided in Table 1 below.

**Table 1: Best ORR at 24 Weeks of First Treatment (Modified RECIST)**

Number of Evaluable Patients	Objective Response (%)	Complete Response (%)
28	9/28 (32%)	3/28 (11%)

In addition to best overall response, an assessment of best local response in treated lesions was conducted (Table 2). Complete response was defined as complete regression of a treated lesion. Partial response was defined as >30 percent reduction in the longest diameter of the tumor, while stable disease was defined as ≤30 percent reduction and <20 percent increase in the longest diameter of the tumor.

**Table 2: Treated Lesion Best Local Response**

Number of Evaluable Treated Lesions	Stable Disease (%)	Partial Response (%)	Complete Response (%)
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Importantly, intratumoral treatment with IL-12 EP resulted in the development of a systemic anti-tumor effect in the majority of patients. Twenty-two of the enrolled patients presented with baseline lesions that were left untreated in order to evaluate the induction of a systemic response. Regression was documented in at least one non-injected tumor in 59 percent (13/22) of patients (Table 3). These results suggest that intratumoral therapy with IL-12 can induce systemic anti-tumor responses while avoiding the toxicities observed with systemic recombinant IL-12 therapy.

**Table 3: Systemic Anti-tumor Response (Untreated lesions)**

<b>Number of Evaluable Patients</b>	<b>Response (at least 30% decrease) in at least 1 untreated lesion</b>
22	13/22 (59%)

Correlative data were also presented, including gene expression in a subset of eight patients, where adequate paired pre- and post-treatment biopsy samples were available. Utilizing NanoString®'s nCounter technology, a focused analysis of immunomodulatory cell types and pathways supported the hypothesis that IL-12 electroporation leads to induction of interferon- $\gamma$  and downstream interferon- $\gamma$ -inducible genes, including key modulators of antigen presentation and processing machinery and chemokines. Additional genes of interest were also up-regulated, including PD-1, PD-L1 and T cell markers, confirming the Phase 1 data, indicating that treatment results in T cell infiltration.

OncoSec's Chief Medical Officer, Robert H. Pierce, M.D., commented: "Taken together, these data—the systemic clinical responses, the gene expression pattern in the treated lesions in patients and our analysis of treated and untreated tumors in B16 mouse model—form a coherent picture of IL-12's mechanism of action as a potent enhancer of tumor immunogenicity. In summary, intratumoral IL-12 appears to 'de-cloak' the tumor, allowing the immune system to see the tumor as 'foreign' and generate the CD8 T cells needed to mount an attack. These findings are incredibly important given the emerging understanding that a prerequisite for response to T cell checkpoint therapies such as anti-PD-1 mAbs is the presence of the PD-1+ CD8 T cells."

"To establish our leadership, we have been strongly investing in our R&D infrastructure and these efforts are paying off, and we expect OncoSec to be the most innovative and scientifically driven intratumoral immunotherapy company in the industry" said Punit Dhillon, President and CEO of OncoSec. "The more we understand IL-12's mechanism of action, the better positioned we are to expand our development into other targets as well as drive rational combinations in the clinic, and that's OncoSec's development path forward."

### **About OncoSec Medical Inc.**

OncoSec Medical Inc. is a biopharmaceutical company developing its ImmunoPulse DNA-based intratumoral cancer immunotherapy. OncoSec Medical's core technology leverages a proprietary electroporation platform to enhance the local delivery and uptake of IL-12 and

other DNA-based immune-modulating 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 for a systemic immune response without the systemic toxicities associated with other treatments. OncoSec's clinical programs currently include three Phase 2 trials targeting metastatic melanoma, Merkel cell carcinoma and cutaneous T-cell lymphoma respectively (<http://clinicaltrials.gov/ct2/results?term=oncosec&Search=Search>). As the company continues to evaluate ImmunoPulse in these indications, it is also investigating additional indications and combination-based approaches. For more information, please visit [www.oncosec.com](http://www.oncosec.com).

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