

OncoSec Medical Enrolls First Patient in Squamous Cell Carcinoma of the Head and Neck Phase II Clinical Trial

SAN DIEGO, June 16, 2015 /PRNewswire/ -- OncoSec Medical Inc. ("OncoSec") (NASDAQ: ONCS), a company developing DNA-based intratumoral cancer immunotherapies, announced today that the company has enrolled the first patient into OMS-I130, a Phase II clinical trial of ImmunoPulse™ IL-12 in patients with treatment-refractory, metastatic and unresectable squamous cell carcinoma of the head and neck (HNSCC). ImmunoPulse™ IL-12, which employs intratumoral electroporation to enhance delivery of DNA-based interleukin-12 (IL-12), is designed to promote an anti-tumor immune response.

"This study will address one of the great unmet medical needs in oncology today: the number of patients who do not respond to anti-PD-1 treatment," said Mai H. Le, MD, Chief Medical Officer of OncoSec. "As we expand the application of ImmunoPulse™ IL-12 beyond cutaneous cancer indications, we anticipate that it will augment the anti-tumor immune response in HNSCC and increase the number of patients who will respond to anti-PD-1 therapy."

Robert H. Pierce, MD, Chief Scientific Officer of Oncosec and a member of the anti-PD-1 Biomarker Team while at Merck, added, "Key biomarker data was recently presented at the 2015 American Society of Clinical Oncology (ASCO) annual meeting, showing that a specific NanoString®-based gene expression profile characterizes anti-PD-1 response in HNSCC. Importantly, at OncoSec, we have observed the ability of ImmunoPulse™ IL-12 to promote this NanoString® gene expression signature in melanoma, and we anticipate that this will be observed in HNSCC as well."

The lead investigators for OMS-I130 are Tanguy Seiwert, MD, from the University of Chicago and lead author of the presentation outlining the key gene signature for anti-PD-1 responders with HNSCC, and Alain Algazi, MD, from the University of California, San Francisco.

"Median overall survival in recurrent and metastatic HNSCC is less than one year even with aggressive, multi-agent chemotherapy. Immune checkpoint inhibitors, including anti-PD-1 antibodies, can achieve durable remissions in some patients, but these therapies are ineffective in the majority of patients because tumor-fighting immune cells and signals are missing from the tumor," said Dr. Algazi. "ImmunoPulse™ IL-12 allows tumors to produce key immune signals and attract these immune cells, which can potentially provide the missing link that will allow the majority of patients to achieve long-term remission."

OMS-I130 is a single-arm, open-label study evaluating the safety and anti-tumor activity of intratumoral DNA-based IL-12 with electroporation in approximately 30 patients with treatment-refractory metastatic and unresectable HNSCC. The key endpoints include:

objective response evaluations by RECIST v1.1 and immune-related Response Criteria (irRC); biomarker comparisons of pre- and post-treatment tumor biopsies, including NanoString® gene expression profiling and immunohistochemistry for tumor-infiltrating lymphocytes (TILs); duration of response to treatment; overall survival; progression-free survival; and safety.

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

About Squamous Cell Carcinoma of the Head and Neck

Squamous cell carcinoma (SCC) of the head and neck is one of most common causes of cancer-associated mortality worldwide. While the incidence of SCC of the head and neck (HNSCC) that is attributable to traditional risk factors, smoking and alcohol abuse, is declining, the incidence of SCC of the oropharynx due to HPV infection is on the rise.¹

HNSCC can be treated with surgery, radiation, or chemoradiation in 60-90 percent of patients, but a substantial number of patients will develop recurrent or distant metastatic disease after locoregional therapy. These recurrences are associated with a poor overall prognosis², and the median overall survival in patients with metastatic HNSCC is under a year even with intensive combination chemotherapy.³

The limited efficacy of standard of care treatment options means that 11,500 patients die every year from squamous cell carcinoma of the oral cavity and the oropharynx in the United States alone.¹ There is a clear medical need in head and neck cancers for more effective treatment options to minimize toxicity and improve efficacy.

About OncoSec Medical Inc.

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 limiting the systemic toxicities associated with other treatments. OncoSec's lead program evaluating ImmunoPulse™ for the treatment of metastatic melanoma is currently in Phase II 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.

This press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Any statements in this release that are not historical facts may be considered such "forward-looking statements." Forward-looking statements 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. Some of the potential risks and uncertainties that could cause actual results to differ from those predicted include our ability to raise additional funding, our ability to acquire, develop or commercialize new products, uncertainties inherent

in pre-clinical studies and clinical trials, unexpected new data, safety and technical issues, competition, and market conditions. These and additional risks and uncertainties are more fully described in OncoSec Medical'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 Medical 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.

References:

1. Davies, L., et al. (2006). "Epidemiology of head and neck cancer in the United States." *Off J Am Acad Otolaryngol-Head Neck Surg* 135: 451–457.
2. Kowalski, L. P., et al. (2000). "Natural history of untreated head and neck cancer." *Eur J Cancer Oxf Engl* 1990 36: 1032–1037.
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