

# OncoSec Presents Update on PISCES/KEYNOTE-695 Phase 2b Registration-Directed Clinical Trial in Combination with Merck's KEYTRUDA® for Metastatic Melanoma at the ASCO 2018 Annual Meeting

SAN DIEGO, June 4, 2018 /PRNewswire/ -- OncoSec Medical Incorporated (OncoSec) (NASDAQ:ONCS), a company developing intratumoral cancer immunotherapies, today announced the presentation of a Trials in Progress poster at the American Society of Clinical Oncology (ASCO) 2018 Annual Meeting taking place in Chicago, IL.

Titled, *Trial in Progress, A Phase 2 Study of Intratumoral pIL-12 Plus Electroporation In Combination With Intravenous Pembrolizumab In Patients With Stage III/IV Melanoma Progressing on Either Pembrolizumab or Nivolumab Treatments (PISCES/KEYNOTE-695)*, the poster provides an update on OncoSec's global, multi-center, registration-directed openlabel Phase 2b clinical trial, assessing the Company's investigational therapy, (intratumoral pIL-12 [tavokinogene telseplasmid] delivered with electroporation) ("tavo" or "ImmunoPulse® IL-12"), and the approved anti-PD-1 therapy pembrolizumab, in patients with unresectable metastatic melanoma who have progressed or are progressing on an anti-PD-1 therapy.

PISCES/KEYNOTE-695, a phase 2b, Simon 2-stage multicenter study of tavo in combination with intravenous KEYTRUDA, will enroll approximately 48 patients with histological diagnosis of melanoma with progressive locally advanced or metastatic disease defined as Stage III or Stage IV. Stage 1 of the study will enroll 23 patients. The primary endpoint will be the Best Overall Response Rate (BORR).

Numerous sites in the U.S., Australia, and Canada are open and enrolling patients. The Company anticipates that enrollment in stage 1 will be completed by the third quarter 2018.

"Despite the addition of immunotherapy and targeted therapies, disease progression continues to occur in a significant percentage of advanced melanoma patients," said OncoSec Chief Clinical and Regulatory Officer, Sharron Gargosky, Ph.D. "We are pleased with our progress as we continue to enroll patients in the KEYNOTE-695 trial, which is evaluating the tolerability and efficacy of pembrolizumab plus tavo in Stage III/IV melanoma patients who have progressed or are progressing on approved checkpoint inhibitors."

The Company's prior Phase 2 combination study of tavo and pembrolizumab (OMS-102) in 22 patients unlikely to respond to anti-PD-1 therapy demonstrated a 50% best overall response rate and a 41% complete response rate. In addition, the trial showed a 57% progression free survival (PFS) rate at 15 months (median PFS not yet reached) and 100%

(11/11) duration of response. In clinical studies to date, tavo has demonstrated a favorable safety profile and has been well tolerated.

PISCES/KEYNOTE-695 is the second combination study conducted with tavo and pembrolizumab and, if successful, could form the basis for a BLA under the accelerated approval pathway.

Tavo has received both Orphan Drug and Fast-Track Designation by the U.S. Food & Drug Administration.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.

ImmunoPulse® is a registered trademark of OncoSec Medical Incorporated.

To learn more about the trial, visit<u>www.oncosec.com</u>. Additional details can also be found at <u>www.clinicaltrials.gov</u> via NCT03132675.

# About PISCES/KEYNOTE-695 (Anti-PD-1 IL-12 Stage III/IV Combination Electroporation Study)

PISCES/KEYNOTE-695 is a global, multicenter phase 2b, open-label trial of intratumoral plasma encoded IL-12 (tavokinogene telseplasmid or "tavo") delivered by electroporation in combination with intravenous pembrolizumab in patients with stage III/IV melanoma who have progressed or are progressing on either pembrolizumab or nivolumab treatment. The Simon 2-stage study of intratumoral tavo plus electroporation in combination with pembrolizumab will enroll approximately 48 patients with histological diagnosis of melanoma with progressive locally advanced or metastatic disease defined as Stage III or Stage IV. The primary endpoint will be the Best Overall Response Rate (BORR).

# About Metastatic Melanoma<sup>1</sup>

Melanoma is a type of skin cancer that begins in skin cells called melanocytes. As the cancer progresses, melanoma becomes more difficult to treat once it spreads beyond the skin, such as the lymphatic system (metastatic disease). Given its occurrence young individuals, the potential years of life lost to melanoma can be higher when compared with other cancers. Although melanoma is a rare form of skin cancer, it accounts for over 75% of skin cancer deaths. The American Cancer Society estimates that approximately 87,000 new melanoma cases and 10,000 deaths from the disease will occur in the United States in 2017. Additionally, the World Health Organization estimates that approximately 132,000 new cases of melanoma are diagnosed around the world every year.

## **About OncoSec Medical Incorporated**

OncoSec is a biotechnology company developing DNA-based intratumoral immunotherapies with an investigational technology, ImmunoPulse<sup>®</sup>, for the treatment of cancer. ImmunoPulse is designed to enhance the local delivery and uptake of DNA-based immunetargeting agents, such as plasmid encoded IL-12 (tavokinogene telseplasmid or "tavo"). In Phase 1 and 2 clinical trials, ImmunoPulse<sup>®</sup> IL-12 has demonstrated a favorable safety

<sup>&</sup>lt;sup>1</sup> American Cancer Society (<a href="https://www.cancer.org/cancer/melanoma-skincancer/about/key-statistics.html">https://www.cancer.org/cancer/melanoma-skincancer/about/key-statistics.html</a>); World Health Organization (<a href="http://www.who.int/uv/fag/skincancer/en/index1.html">http://www.who.int/uv/fag/skincancer/en/index1.html</a>)

profile, evidence of anti-tumor activity in the treatment of various solid tumors, and the potential to reach beyond the site of local treatment to initiate a systemic immune response. OncoSec's lead program, ImmunoPulse IL-12, is currently in clinical development for metastatic melanoma and triple-negative breast cancer. The program's current focus is on the significant unmet medical need in patients with melanoma who are refractory or have relapsed on anti-PD-1 therapies. In addition to tavo, the Company is also identifying and developing new immune-targeting agents for use with the ImmunoPulse platform. For more information, please visit <a href="https://www.oncosec.com">www.oncosec.com</a>.

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