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# **OncoSec Initiates Registration Directed Clinical Trial, KEYNOTE-695, of ImmunoPulse® IL-12 in Combination with Merck's KEYTRUDA® (pembrolizumab)**

**Enrolling patients with unresectable metastatic melanoma who have progressed or are progressing on an anti-PD-1 therapy**

**Global study in the U.S. and Australia**

**ImmunoPulse® IL-12 granted Fast Track and Orphan Drug Designation in the U.S.**

SAN DIEGO, Oct. 10, 2017 /PRNewswire/ -- OncoSec Medical Incorporated ("OncoSec" or the "Company") (NASDAQ:ONCS), a company developing intratumoral cancer immunotherapies, today announced that it has initiated its phase 2b registration directed trial, PISCES/KEYNOTE-695. The PISCES/KEYNOTE-695 study is a global, multicenter phase 2b trial of OncoSec's investigational therapy, ImmunoPulse® IL-12 (intratumoral pIL-12 [tavokinogene telseplasmid or "tavo"] with electroporation), combined with KEYTRUDA® (pembrolizumab), an anti-PD-1 therapy marketed by Merck (known as MSD outside the US and Canada), in patients with unresectable metastatic melanoma who have progressed or are progressing on an anti-PD-1 therapy.

"Patients with metastatic melanoma who are progressing or have progressed on anti-PD-1 therapy have limited treatment options. We believe the combination of ImmunoPulse IL-12 and pembrolizumab offers a potentially transformative approach for these patients given the absence of approved therapies," said Punit Dhillon, CEO and President at OncoSec. "The advancement of the PISCES trial marks an important milestone for the Company."

The phase 2b, Simon 2-stage multicenter study of intratumoral tavo with electroporation 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. The primary endpoint will be the Best Overall Response Rate (BORR).

"ImmunoPulse IL-12 and pembrolizumab are immunotherapies designed to modulate the patient's own immune response to fight cancer," said Sharron Gargosky Ph.D., Chief Clinical and Regulatory Officer at OncoSec. "We are pleased with the progress of the ongoing PISCES trial, which has benefitted from our clinical trial collaboration and supply agreement with Merck."

The collaboration agreement, which was announced in May 2017, is between OncoSec

Medical Incorporated and Merck, through a subsidiary. Under the agreement, OncoSec will sponsor and fund the study and Merck will provide KEYTRUDA.

To learn more about the trial, visit [www.oncosec.com](http://www.oncosec.com). Additional details can also be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) via NCT03132675.

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

ImmunoPulse® is a registered trademark of OncoSec Medical Incorporated, San Diego, CA, USA.

## **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.

<sup>1</sup> American Cancer Society (<https://www.cancer.org/cancer/melanoma-skin-cancer/about/key-statistics.html>); World Health Organization (<http://www.who.int/uv/faq/skincancer/en/index1.html>)

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

PISCES 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 OncoSec Medical Incorporated**

OncoSec is a biotechnology company developing DNA-based intratumoral immunotherapies with an investigational technology, ImmunoPulse®, for the treatment of cancer. ImmunoPulse is designed to enhance the local delivery and uptake of DNA-based immune-targeting agents, such as IL-12 (tavokinogene telseplasmid [pIL-12] or "tavo"). In Phase 1 and 2 clinical trials, ImmunoPulse® IL-12 has demonstrated a favorable safety 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 [www.oncosec.com](http://www.oncosec.com).

### **Cautionary Note Regarding Forward-Looking Statements**

This press release contains "forward-looking statements" within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, including statements about OncoSec's business strategies, including advancement of its lead melanoma program and its broader clinical portfolio and plans to pursue collaborations with industry partners, as well as the potential contributions and impact of new directors on these strategies. Forward-looking statements can be identified by words such as "can," "may," "will," "suggest," "look forward to," "potential," "understand," and similar references to future periods.

Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on management's current preliminary expectations and are subject to risks and uncertainties, which may cause OncoSec's results to differ materially and adversely from the statements contained herein. Potential risks and uncertainties that could cause actual results to differ from those predicted include, among others, the following: uncertainties inherent in pre-clinical studies and clinical trials, such as the substantial time, costs and unpredictability of such studies and trials, the ability to enroll patients in clinical trials and the risk of adverse events; unexpected new data, safety and technical issues; OncoSec's ability to raise additional funding necessary to fund continued operations; and the other factors discussed in OncoSec's filings with the Securities and Exchange Commission, including its quarterly report on Form 10-Q for the quarter ended April 30, 2017.

Undue reliance should not be placed on forward-looking statements, which speak only as of the date they are made. OncoSec 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.

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