

# OncoSec Presents Positive Phase 2 Data for ImmunoPulse® IL-12 in Combination with Pembrolizumab Demonstrating a Best Overall Response Rate (BORR) of 50% in Predicted Anti-PD-1 Non-Responder Melanoma Patients

Data from Recently Completed Phase 2 Monotherapy and Combination Therapy Studies Presented at the 2017 9th World Congress of Melanoma - A Joint Meeting with the Society for Melanoma Research

8 of 21 (38.1%) Achieved RECIST v1.1 Durable Complete Response (CR) in Predicted Anti-PD-1 Non-Responder Melanoma Patients at 24 Weeks

Comprehensive Immune Monitoring Data Demonstrated Combination of ImmunoPulse® IL-12 and Pembrolizumab Can Convert "Cold" Tumors to "Hot" Tumors

# Favorable Safety Profile with <10% SAE as ImmunoPulse IL-12 Monotherapy or in Combination with Pembrolizumab

SAN DIEGO, Oct. 19, 2017 /PRNewswire/ -- OncoSec Medical Incorporated ("OncoSec" or "Company") (NASDAQ:ONCS), a company developing DNA-based intratumoral cancer immunotherapies, today announced updated Phase 2 clinical and immune monitoring data from patients treated with its investigational therapy, ImmunoPulse® IL-12 as a monotherapy versus the combination of ImmunoPulse IL-12 and the approved anti-PD-1 therapy pembrolizumab. These data were presented today in an oral presentation at the 2017 9th World Congress of Melanoma – A Joint Meeting with the Society for Melanoma Research, and continue to support the rationale for the Company's recently initiated global, open-label, Phase 2b registration directed trial, PISCES/KEYNOTE-695.

The Phase 2 OMS-I100 monotherapy and Phase 2 OMS-I102 combination with pembrolizumab studies included 51 and 22<sup>\*</sup> patients, respectively, with metastatic melanoma. The combination study patients were selected based on their baseline biomarker data, which predicted that patients would not respond to anti-PD-1 therapy. Monotherapy patients were treated with ImmunoPulse IL-12 alone and patients in the combination study also received pembrolizumab every 3 weeks per protocol. Fewer than 10% of patients in both studies reported treatment related serious adverse events (9.8% in the monotherapy

and 8.7% in the combination studies). Data also demonstrate that ImmunoPulse IL-12 can trigger key immunologic events driving a cellular response leading to an inflamed tumor with increased TIL frequency whether as a monotherapy or combined with pembrolizumab, converting "cold" tumors to "hot", which were further enhanced with the addition of an anti-PD1 antibody.

\*Includes one CR with non-evaluable RECIST lesions

### **Key Findings**

OMS-I102 Combination with Pembrolizumab

50% (11/22) BORR observed at 24 weeks (42.9% [9/21] achieved RECIST v1.1 BORR).

41% (9/22) complete responders (CR), 9% (2/22) partial responders (PR), and 9% (2/22) stable disease (SD) for a total disease control rate of 59% (38.1% [8/21] achieved RECIST v1.1 durable CR).

Data demonstrate that the combination of ImmunoPulse IL-12 and pembrolizumab prime a coordinated innate and adaptive immune response, suggesting a synergistic relationship with anti-PD-1.

OMS-I100 Monotherapy

25-34.6% best overall response rate (BORR) by a modified "skin" RECIST.

Favorable safety profile (no life threatening or grade 4 AE).

In patients (n=26) treated with ImmunoPulse IL-12 on a 90-day cycle, there were 19.2% (5/26) complete responders (CR), 15.4% (4/26) partial responders (PR), and 34.6% (9/26) stable disease (SD) for a total disease control rate of 69.2%.

In the protocol addendum where patients (n=20) were treated with ImmunoPulse IL-12 on a 6-week cycle, there were 0 complete responders (CR), 25% (5/20) partial responders (PR), and 40% (8/20) stable disease (SD) for a total disease control rate of 65%.

"We are encouraged by the data from these analyses, which continue to show that ImmunoPulse IL-12 can prime the immune system to help improve patient response to anti-PD-1," said Dr. Alain Algazi, Lead Trial Investigator, Associate Professor, Department of Medicine (Hematology/Oncology), at the University of California San Francisco (UCSF) Helen Diller Family Comprehensive Cancer Center. "The complete response rates observed in the Phase 2 study assessing the combination of ImmunoPulse IL-12 and pembrolizumab in the predicted anti-PD-1 non-responder patient population provide compelling early evidence that the combination could lead to a clinically meaningful impact on patient outcomes."

"Collectively, these study findings reinforce the combination of ImmunoPulse IL-12 and pembrolizumab to address a significant unmet medical need in melanoma patients who are unlikely to respond to anti-PD-1 therapies," said Punit Dhillon, CEO and President of OncoSec. "We look forward to presenting additional data from our ongoing Phase 2 combination study at the upcoming 2017 Society for Immunotherapy of Cancer Annual

Meeting, in addition to our global, open-label, registration directed phase 2b clinical trial, PISCES/KEYNOTE-695, which we anticipate reporting initial data in mid-2018."

The full-text abstract is available and can be viewed on the World Melanoma Congress – Joint Meeting with the Society of Melanoma Research website at <a href="https://worldmelanoma2017.com/">https://worldmelanoma2017.com/</a>. The presentation is available in the Publications section of OncoSec's website.

### 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 immunetargeting 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 <a href="https://www.oncosec.com">www.oncosec.com</a>.

## **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.

### **CONTACT:**

Investor Relations:
OncoSec Medical Incorporated

Phone: 855-662-6732 investors@oncosec.com

Media Relations:

OncoSec Medical Incorporated

Phone: 855-662-6732 media@oncosec.com





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<u>demonstrating-a-best-overall-response-rate-borr-of-50-in-predicted-anti-pd-1-non-responder-melanoma-patients-300539506.html</u>

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