

# OncoSec Provides Highlights from Research Reception at AACR Annual Meeting 2018

SAN DIEGO, April 16, 2018 /PRNewswire/ -- OncoSec Medical Incorporated (OncoSec) (NASDAQ: ONCS), a company developing intratumoral cancer immunotherapies, today provided highlights from its Research Reception held on Sunday, April 15, 2018, during the American Association of Cancer Research (AACR) Annual Meeting 2018.

The Research Reception was organized to provide industry experts gathered at the AACR with a comprehensive overview of OncoSec's ongoing and anticipated clinical programs involving ImmunoPulse<sup>®</sup> IL-12 (or Intratumoral tavo-EP) in metastatic melanoma and triple-negative breast cancer (TNBC), including an overview of a poster presented at AACR regarding a Phase 1 pilot study of ImmunoPulse IL-12 in TNBC ("***Intratumoral plasmid IL-12 and electroporation in pre-treated inoperable locally advanced or recurrent triple-negative breast cancer (TNBC)***") - Poster 055 / Abstract CT022).

ImmunoPulse IL-12 is currently being used in several ongoing clinical trials, with the technology demonstrating evidence of anti-tumor activity in the treatment of various solid tumors, the potential to initiate a systemic immune response, and a favorable safety profile. ImmunoPulse IL-12 combines intratumoral plasmid IL-12 with electroporation to produce a controlled, localized expression of IL-12 in the tumor microenvironment, which in turn, enables the immune system to target and attack tumors throughout the body.

The full webcast and presentation slides from the Research Reception can be accessed via OncoSec's website: <http://www.oncosec.com>.

The following is a recap of key highlights from the event:

## **Melanoma Data Update: OMS-I100 Monotherapy Study & OMS-I102 Pembrolizumab Combination Study**

Led by Alain Algazi, MD of the UCSF Helen Diller Family Comprehensive Cancer Center, the first presentation provided data from the OMS-I100 Phase 2 clinical trial, which demonstrated that ImmunoPulse IL-12 delivered as a monotherapy promoted innate and adaptive immune responses, importantly driving increased CD8<sup>+</sup> TIL frequency.

- Updated clinical data from the OMS-I100 study demonstrated that, in addition to peripheral immune responses, regression of distal, non-treated lesions were observed on average in 45% of the patients
- Also, the treatment-related reshaping of the tumor microenvironment points to amplification of the IFN- $\gamma$ /IL-12 feedforward loop, which in addition to supporting anti-tumor immunity, triggers adaptive immune resistance (PD-L1 expression) and provides the basis for a combination with IL-12 and anti-PD-1 therapy
- Updated data from the OMS-I102 Phase 2 clinical trial (ImmunoPulse IL-12 in

combination with pembrolizumab) demonstrated a 57% progression free survival (PFS) rate at 21 months with 100% (11/11) duration of response and median PFS/OS not yet reached

#### **OMS-I140 Protocol; Review of Intratumoral IL-12 Data in TNBC Presented at AACR**

Led by Melinda Telli, MD of the Stanford University Medical Center, the following presentation provided a review of the OMS-I140 Phase 1 pilot study of ImmunoPulse IL-12 in TNBC, including an analysis of initial findings from the study, which were presented as a poster during AACR. The Phase 1 pilot study was designed to determine whether intratumoral plasmid IL-12 with electroporation (ImmunoPulse IL-12) would elicit a pro-inflammatory molecular and histological signature in treated as well untreated sites. Following administration of ImmunoPulse IL-12 on Days 1, 5 and 8 of a single 28-day cycle, data was obtained from five patients of the 10-patient study.

- Treatment-related increase in CD8<sup>+</sup> TIL density was observed by intratumoral chromogenic staining in 2 of 5 patient tumors (1 treated /1 untreated tumor)
- NanoString analysis suggests that 1 cycle of Intratumoral tavo-EP did not globally impact intratumoral immune-related gene expression
- Evidence of a treatment-related productive systemic immune response was seen in reduced gMDSCs and increased SLECs in the peripheral blood
- Reported treatment-related adverse events included transient pain associated with electroporation and fatigue (both grade 1)
- These results suggest that Intratumoral tavo-EP is a safe and tolerable TIL-stimulating therapy of skin and subcutaneous TNBC tumors
- Further study of this therapy in combination with anti-PD-1 antibody therapy is warranted

#### **OMS-I141 Protocol; Upcoming Anti-PD-1 Combination Clinical Trial in TNBC**

A presentation given by Pamela Munster, MD of the UCSF Helen Diller Family Comprehensive Cancer Center, provided a review of OncoSec's proposed Phase 2 trial in TNBC involving a combination of ImmunoPulse IL-12 (intratumoral tavo-EP) and an anti-PD-1 antibody therapy. The future Phase 2 trial will be a Simon 2-stage minimax design, non-comparative, open-label, single-arm, multicenter study of ImmunoPulse IL-12 plus an anti-PD-1 antibody therapy.

- The study is expected to enroll approximately 25 patients (15 in Stage 1, and, if appropriate, 10 in Stage 2) with TNBC and electroporation accessible cutaneous / subcutaneous tumors
- The proposed primary endpoint is to assess efficacy as measured by objective response rate (ORR) by independent central review (ICR) based on Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 of intratumoral tavo-EP in combination with an anti-PD-1 antibody therapy in subjects with inoperable locally advanced or metastatic TNBC
- OncoSec expects to initiate this proposed study in 2018

#### **PISCES/KEYNOTE-695 Operational Update**

Led by OncoSec's Chief Clinical and Regulatory Officer, Sharron Gargosky, PhD, the final presentation offered an operational assessment of PISCES/KEYNOTE-695, a global, multicenter Phase 2b, open-label trial of ImmunoPulse IL-12 in combination with

pembrolizumab in patients with stage III/IV melanoma who have progressed or are progressing on either pembrolizumab or nivolumab treatment. OncoSec expects to report preliminary data at an upcoming medical meeting in 2018.

### **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 plasmid encoded IL-12 (tavokinogene telseplasmid 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. 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 our 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 ability to enroll patients in clinical trials and the

risk of adverse events; unexpected new data, safety and technical issues; our 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.

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:  
Stern Investor Relations  
Will O'Connor  
Phone: (212) 362-1200  
[will@sternir.com](mailto:will@sternir.com)

Media Relations:

Janine McCargo / David Schemelia

Tiberend Strategic Advisors, Inc.

Phone: 212-827-0020

[jmccargo@tiberend.com](mailto:jmccargo@tiberend.com) [dschemelia@tiberend.com](mailto:dschemelia@tiberend.com)



View original content with multimedia <http://www.prnewswire.com/news-releases/oncosec-provides-highlights-from-research-reception-at-aacr-annual-meeting-2018-300630165.html>

SOURCE OncoSec Medical Incorporated