

# **OncoSec Presents New Data Showing A Single Cycle Of Monotherapy TAVO<sup>™</sup> Can Generate Productive Immune Responses In Triple Negative Breast Cancers (TNBC)**

**TAVO<sup>™</sup> converted 4 of 10 poorly immunogenic "salvage setting" TNBC tumors into immunologically active lesions**

**A second TNBC study, KEYNOTE-890, combining TAVO<sup>™</sup> with KEYTRUDA® in pretreated metastatic TNBC patients, is well underway with five patients now enrolled**

SAN DIEGO and PENNINGTON, N.J., Dec. 11, 2018 /PRNewswire/ -- OncoSec Medical Incorporated (OncoSec) (NASDAQ:ONCS), a company developing intratumoral cancer immunotherapies, announced today the presentation of new data that suggests treatment with TAVO<sup>™</sup> (tavokinogene telseplasmid) has the ability to improve immune responses in heavily pretreated, inoperable and locally advanced triple negative breast cancers by increasing tumor infiltrating lymphocyte (TIL) density, increasing effector cytokines, and upregulating immune-related gene expression, factors associated with long-term response to anti-PD1 antibodies.

The now completed Pilot TNBC study, OMS-140 (NCT02531425), was designed to determine whether a single cycle of TAVO<sup>™</sup> monotherapy could enhance anti-tumor immune responses in a TNBC salvage setting. Specifically, a comparative analysis of patient's pre-TAVO<sup>™</sup> tumor and blood samples to the post-TAVO<sup>™</sup> tumor and blood samples demonstrated that, with only a single cycle of TAVO<sup>™</sup>, a treatment-related increase of CD8<sup>+</sup> TIL was observed in four of 10 patients, while also demonstrating a relative decrease in immune suppressive cells.

Nanostring analysis (a novel platform for quantification of gene expression) of the tumor microenvironment revealed a meaningful increase of immune-related transcripts while on treatment. The investigator also evaluated the peripheral blood through a longitudinal analysis of PBMCs (peripheral blood mononuclear cells), and, in doing so, noted an increase of both effector and partially exhausted T cells, which complements the reduced frequency of immune-suppressive MDSC (myeloid-derived suppressor cells) reported earlier this year at AACR.

These data, along with increased effector cytokines noted in serum, demonstrate both local and systemic immune responses with only one cycle of TAVO<sup>™</sup> in this difficult to treat patient population. Additionally, as observed in other clinical trials with TAVO<sup>™</sup>, this study showed that TAVO<sup>™</sup> is safe and well tolerated in this patient population.

These data, as well as other clinical and immunological data, were presented at the 2018 San Antonio Breast Cancer Symposium (SABCS) taking place December 4-8 in San Antonio, Texas.

"The immunological signatures described here, including conversion of non-immunogenic tumors into immunologically active lesions, are very encouraging, especially when considering that patients with very advanced disease received only one cycle of TAVO™," said Dr. Christopher Twitty, Chief Scientific Officer of OncoSec. "Late-stage triple negative breast cancer patients have very few treatment options, and those that are available, come with serious toxicities and limited effectiveness. Recent data suggest that some patients with triple negative tumors will benefit from treatment with PD-1 checkpoint inhibitors, but only if the patient's tumor is immunologically active," continued Dr. Twitty. "This study represents the potential of a safe and effective immunotherapy to turn non-immunogenic tumors into an immunologically active tissue, expanding the benefits of PD-1 checkpoint inhibitors to a much broader subset of women with triple negative breast cancer, which would be an important advance for the treatment of these patients."

As previously reported, a subset of patients that completed a single cycle of TAVO in this study, were sequentially treated with an anti-PD-1 checkpoint therapy (nivolumab). Importantly, some of these patients, one with prior disease progression on anti-PD-L1 antibody monotherapy, experienced robust clinical responses beyond the TAVO treated lesions. One of these patients continues to be treated with TAVO under a compassionate use protocol.

Based on these findings, OncoSec and Merck initiated a second TAVO Phase 2 study in TNBC, KEYNOTE-890, to evaluate the combination of TAVO with Merck's anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in approximately 25 patients with treatment-refractory, inoperable or metastatic triple negative breast cancer (NCT03567720).

Since KEYNOTE-890 opened in October, investigators have already enrolled five patients into the trial. The KEYNOTE-890 study is testing the combination in patients with inoperable locally advanced or metastatic TNBC who have progressed on more than one line of prior therapy. Patients will be treated with the combination of TAVO with pembrolizumab. The primary endpoint is to assess efficacy as measured by objective response rate (ORR) based on Response Evaluation Criteria in Solid Tumors (RECIST) v1.1.

### **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).

### **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.

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