

# OncoSec Provides Encouraging Interim Data from Ongoing KEYNOTE-890 Study of TAVO in Combination with KEYTRUDA® for the Treatment of Heavily Pretreated Chemotherapy/Radiotherapy Refractory Metastatic Triple Negative Breast Cancer

# 50% of Evaluated Patients Experienced a 20% or Greater Tumor Reduction

SAN DIEGO and PENNINGTON, N.J., May 22, 2019 /PRNewswire/ -- OncoSec Medical Incorporated (OncoSec) (NASDAQ:ONCS), a late-stage cancer biotechnology company developing gene-based intratumoral immunotherapies, today announces interim data from KEYNOTE-890, an ongoing Phase 2 study of TAVO™ (intratumoral IL-12) in combination with KEYTRUDA® in patients with heavily pretreated, metastatic, chemotherapy refractory triple negative breast cancer (mTNBC). Patients who previously failed an average of 3.5 prior lines of chemotherapy were enrolled in KEYNOTE-890 to evaluate if the addition of TAVO (IL-12) could provide meaningful clinical activity when combined with KEYTRUDA, an anti-PD-1 checkpoint inhibitor.

Heavily pretreated patients with refractory mTNBC (average of 3.5 prior lines of chemotherapy) showed a rapid tumor reduction of 20% or greater at the initial 3-month evaluation in the first five of 10 patients. Two patients had a partial response, one with a 66% tumor reduction, including a significant reduction of liver lesions, and four patients had stable disease, three of which reported a 20% or greater tumor reduction. These preliminary findings, when compared to the results of KEYNOTE-086, which demonstrated a 5.3% response rate in mTNBC patients treated with KEYTRUDA monotherapy<sup>1</sup>, suggest TAVO's ability to unlock KEYTRUDA's potential anti-cancer efficacy in this very difficult to treat patient population. Four of the six patients who experienced tumor reductions have an ongoing response as of May 9, 2019.

"These interim data are impressive, especially when considering that all of the patients received numerous prior rounds of chemo/radiation with no success, and the safety profile associated with this platform continues to be unparalleled. Metastatic TNBC is a heterogeneous cancer with a poor prognosis where less than five percent of pre-treated patients achieve an objective response to PD-1/PD-L1 checkpoint treatments," explained Alain Algazi, M.D., Associate Professor of Clinical Medicine at UCSF and Clinical Strategic Advisor to OncoSec. "Therefore, the marked synergy shown in these patients adds even more support for our earlier findings demonstrating that TAVO primes the tumor microenvironment, dramatically improving the clinical results that would have been

anticipated with PD-1/PD-L1 checkpoint treatment alone. The combination of TAVO and KEYTRUDA represents a highly promising new therapeutic approach for TNBC and warrants expedited evaluation."

Of the four patients who progressed following treatment, two received only one cycle of combination treatment prior to rapid clinical deterioration. Importantly, treatment was very well-tolerated, with only three patients reporting Grade 1 TAVO-related adverse events (AE's). No TAVO-related Grade 2 or above AE's/SAE's were reported.

Patients demonstrated encouraging immunological responses in tumor and blood consistent with an IL-12-associated mechanism of action, including on-treatment reduction of the peripheral gMDSC suppressors, which aligns with observed clinical responses. Biomarker analysis of patient tumor and blood samples are ongoing.

The Company has enrolled over half of the targeted enrollment of 25 patients, and expects to complete enrollment and present the clinical data at the San Antonio Breast Cancer Symposium later this year.

Additional details can also be found atwww.clinicaltrials.gov here.

To learn more about the trial, visit <a href="www.oncosec.com">www.oncosec.com</a>.

## **About Triple Negative Breast Cancer (TNBC)**

TNBC is an aggressive type of breast cancer that characteristically has a high recurrence rate within the first five years after diagnosis. While some breast cancers may test positive for estrogen receptor, progesterone receptor or human epidermal growth factor receptor 2 (HER2), TNBC tests negative for all three. As a result, TNBC does not respond to therapies targeting these markers, making it more difficult to treat. Approximately 10-20% of patients with breast cancer are diagnosed with TNBC.

### **About KEYNOTE-890**

KEYNOTE-890 is designed as a multicenter Phase 2 open-label trial focusing on patients with a histologically confirmed diagnosis of inoperable locally advanced or metastatic TNBC and at least 1 prior line of approved systemic chemotherapy or immunotherapy. 25 patients are expected to be enrolled. Each patient will undergo 3-week treatment cycles with pembrolizumab administered as a 30-minute IV infusion day 1 of every cycle (flat dose of 200 mg) and treated with TAVO on days 1, 5 and 8 every six weeks.

### **OncoSec Medical Incorporated**

OncoSec is a clinical-stage biotechnology company focused on developing cytokine-based intratumoral immunotherapies to stimulate the body's immune system to target and attack cancer. OncoSec's lead immunotherapy platform − TAVO™ (tavokinogene telseplasmid) − enables the intratumoral delivery of DNA-based interleukin-12 (IL-12), a naturally occurring protein with immune-stimulating functions. The technology, which employs electroporation, is designed to produce a controlled, localized expression of IL-12 in the tumor microenvironment, enabling the immune system to target and attack tumors throughout the body. OncoSec has built a deep and diverse clinical pipeline utilizing TAVO™ as a potential treatment for multiple cancer indications either as a monotherapy or in combination with

leading checkpoint inhibitors; with the latter potentially enabling OncoSec to address a great unmet medical need in oncology: anti-PD-1 non-responders. Results from recently completed clinical studies of TAVO™ have demonstrated a local immune response, and subsequently, a systemic effect as either a monotherapy or combination treatment approach. In addition to TAVO™, OncoSec is identifying and developing new DNA-encoded therapeutic candidates and tumor indications for use with its new Visceral Lesion Applicator (VLA), to target deep visceral lesions, such as liver, lung or pancreatic lesions. For more information, please visit <a href="https://www.oncosec.com">www.oncosec.com</a>.

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

TAVO™ trademark of OncoSec Medical Incorporated.

1. Ann Oncol. 2019 Mar 1;30(3):397-404.

Pembrolizumab monotherapy for previously treated metastatic triple-negative breast cancer: cohort A of the phase II KEYNOTE-086 study.

Adams S1, Schmid P2, Rugo HS3, Winer EP4, Loirat D5, Awada A6, Cescon DW7, Iwata H8, Campone M9, Nanda R10, Hui R11, Curigliano G12,13, Toppmeyer D14, O'Shaughnessy J15,16,17, Loi S18, Paluch-Shimon S19, Tan AR20, Card D21, Zhao J21, Karantza V21, Cortés J22,23,24.

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