

# OncoSec Doses First Patient in KEYNOTE-890 Phase 2 Clinical Trial

KEYNOTE-890 is designed to evaluate TAVO™ in Combination with Merck's KEYTRUDA® (pembrolizumab) for the Treatment of Late-Stage Triple Negative Breast Cancer

SAN DIEGO and PENNINGTON, N.J., Nov. 7, 2018 /PRNewswire/ -- OncoSec Medical Incorporated (OncoSec) (NASDAQ:ONCS), a company developing intratumoral cancer immunotherapies, today announced that the first patient has been treated in KEYNOTE-890, a Phase 2 clinical trial for the treatment of late-stage triple negative breast cancer (TNBC) with TAVO™ (intratumoral plasma encoded IL-12, or tavokinogene telseplasmid, plus electroporation) in combination with Merck's KEYTRUDA® (pembrolizumab).

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.

"Treating the first patient in our KEYNOTE-890 clinical trial is an important milestone for OncoSec as we seek to rapidly advance this program," said Kellie Malloy Foerter, Chief Clinical Development Officer of OncoSec. "Additionally, this study is important for patients with metastatic triple negative breast cancer given the lack of treatment options currently available. Prior clinical observations suggest that TAVO™ in combination with pembrolizumab is a valid therapeutic approach for TNBC. Based on the outcome of the study and feedback from FDA, we may choose to expand the study and seek accelerated approval with the FDA for this patient population."

Breast cancer cells that test negative for estrogen receptors (ER-), progesterone receptors (PR-), and HER2 (HER2-) means the cancer is triple negative. Approximately 10-20 percent of U.S. breast cancer cases are triple negative breast cancer (TNBC), which disproportionately affects younger women, as well as African-American women, followed by Hispanic women.

TNBC remains a poor-prognosis breast cancer subtype, with limited treatment options for patients with advanced, recurrent disease. In the recurrent disease setting, chemotherapy remains the standard of care, and median survival is approximately 13 months from the time of disease recurrence. Emerging evidence shows immunotherapy options may play an important role in the treatment paradigm for TNBC. Preliminary data from early-phase studies demonstrated the anti-PD-1 antibody pembrolizumab led to an objective response in

18 to 19 percent of TNBC patients;<sup>5-7</sup> and median overall survival was 8.9 months in a pretreated cohort.<sup>6</sup> The anti-PD-L1 antibody atezolizumab (MPDL3280A) achieved an objective response in 25 percent of patients in the first-line and 11 percent of patients in the second-line setting.<sup>8</sup> There is increasing evidence that tumors need TILs for anti-PD-1/PD-L1 therapies to be most effective.<sup>9-12</sup> Data also show TILs promote better responses to chemotherapy and improve clinical outcomes in breast cancer, including TNBC.<sup>13-17</sup>

To learn more about the trial, visit<u>www.oncosec.com</u>. Additional details can also be found at <u>www.clinicaltrials.gov</u> via NCT03567720.

## **About 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 ImmunoPulse<sup>®</sup> platform. For more information, please visit www.oncosec.com.

 $\mathsf{KEYTRUDA}^{\texttt{®}}$  is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.

## **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.

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