

OncoSec Initiates KEYNOTE-890, a Phase 2 Clinical Trial of TAVO in Combination with Merck's KEYTRUDA® (pembrolizumab) for the Treatment of Late-Stage Triple Negative Breast Cancer

- KEYNOTE-890 is the second "KEYNOTE" study combining TAVO and KEYTRUDA®

SAN DIEGO and PENNINGTON, N.J., Oct. 15, 2018 /PRNewswire/ -- OncoSec Medical Incorporated (OncoSec) (NASDAQ:ONCS), a company developing intratumoral cancer immunotherapies, today announced that it has initiated 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). The initiation of KEYNOTE-890 marks the second Phase 2 trial for OncoSec involving a combination of TAVO and KEYTRUDA®. The first, PISCES/KEYNOTE-695, is a global, multicenter Phase 2 trial of TAVO in combination with KEYTRUDA® for metastatic melanoma.

"Metastatic triple negative breast cancer represents an extreme unmet medical need, where pre-treated patients rarely achieve objective responses with PD-1/PD-L1 checkpoint treatments," said Dr. Pamela Munster, Professor of Medicine and Program Leader of Experimental Therapeutics at University of California San Francisco (UCSF). "The marked synergy of TAVO and checkpoint inhibition shown in previous clinical observations strongly suggests that IL-12 may prime the tumor microenvironment for PD-1/PD-L1 checkpoint treatments. This represents a highly promising therapeutic approach for TNBC."

KEYNOTE-890 is a multicenter Phase 2 open-label trial of TAVO in combination with KEYTRUDA® in patients with histologically confirmed diagnosis of inoperable locally advanced or metastatic TNBC and at least one prior line of approved systemic chemotherapy or immunotherapy.

Breast cancer cells that test negative for estrogen receptors (ER-), progesterone receptors (PR-), and HER2 (HER2-) means the cancer is triple negative.¹ Approximately 10-20 percent of US breast cancer cases are triple negative breast cancer (TNBC),¹ which disproportionately affects younger women as well as African-American women,² followed by Hispanic women.³

"The initiation of KEYNOTE-890 is an important milestone for OncoSec as it marks a significant expansion of our clinical pipeline as well as our expanding relationship with Merck," said Daniel J. O'Connor, President and Chief Executive Officer of OncoSec. "Our

goal is to enroll this study as quickly as possible and provide preliminary topline data in 2019. Currently, overall survival for metastatic TNBC is one to two years from diagnosis, with therapies resulting in short-lived responses and/or significant toxicity. New approaches are desperately needed, and based on prior and ongoing clinical research, we believe that TAVO in combination with KEYTRUDA® has the potential to be effective in treating this disease. Given the severe unmet medical need, it is possible that TAVO for the treatment of TNBC could be granted Fast Track designation, Breakthrough Therapy designation, and be a candidate for accelerated approval."

TNBC remains a poor-prognosis breast cancer subtype,² 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.⁴ Emerging evidence shows immunotherapy options may play an important role in the treatment paradigm for TNBC.⁵⁻⁸ 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;⁵⁻⁷ and median overall survival was 8.9 months in a pretreated cohort.⁶ 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.⁸ There is increasing evidence that tumors need TILs for anti-PD-1/PD-L1 therapies to be most effective.⁹⁻¹² Data also show TILs promote better responses to chemotherapy and improve clinical outcomes in breast cancer, including TNBC.¹³⁻¹⁷

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

KEYTRUDA® is a registered trademark of Merck.

About OncoSec Immunotherapies

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® platform. For more information, please visit www.oncosec.com.

References

1. BreastCancer.org. Triple Negative Breast Cancer.

https://www.breastcancer.org/symptoms/diagnosis/trip_neg (Accessed October 10, 2018).

2. Foy KC, et al. "Disparities in breast cancer tumor characteristics, treatment, time to treatment, and survival probability among African American and white women." *npj Breast Cancer*. 2018; 4:7.
3. Nahleh Z, et al. "Disparities in breast cancer: a multi-institutional comparative analysis focusing on American Hispanics." *Cancer Medicine*. 2018; 7(6):2710–2717.
4. Andre F and Zielinski CC. "Optimal strategies for the treatment of metastatic triple-negative breast cancer with currently approved agents." *Annals of Oncology*. 2012;23(6): vi46-vi51.
5. Nanda R, et al., "A phase Ib multicohort study of MK-3475 in patients with advanced solid tumors." *Journal of Clinical Oncology*. 2014; 32:5s (suppl; abstr PS3119).
6. Adams S, et al. "Phase 2 Study of Pembrolizumab Monotherapy for Previously Treated Metastatic Triple-Negative Breast Cancer: KEYNOTE-086." *Journal of Clinical Oncology*. 2017; 35:15s (suppl abstr 1088).
7. Nanda R, et al. Pembrolizumab in Patients With Advanced Triple-Negative Breast Cancer: Phase Ib KEYNOTE-012 Study." *J Clin Oncol*. 2016;34(21): 2460-2467.
8. Schmid P, et al. "Atezolizumab in metastatic TNBC (mTNBC): Long-term clinical outcomes and biomarker analyses." Presented at the AACR Annual Meeting. 2017 (abstr 2986).
9. Gettinger SN, et al. "A dormant TIL phenotype defines non-small cell lung carcinomas sensitive to immune checkpoint blockers." *Nat Commun*. 2018;9(1): 3196.
10. Mattox AK, et al. "A dormant TIL phenotype defines non-small cell lung carcinomas sensitive to immune checkpoint blockers." *Cancer Res*. 2017;77(22): 6365-6374.
11. Hettich M, et al. "Checkpoint Antibodies but not T Cell-Recruiting Diabodies Effectively Synergize with TIL-Inducing γ -Irradiation." *Cancer Res*. 2016;76(16); 4673-4683.
12. Mahmoud SM, et al., "Tumor-infiltrating CD8+ lymphocytes predict clinical outcome in breast cancer." *Journal of Clinical Oncology*, 2011. 29(15): 1949-1955.
13. Adams S, et al., "Prognostic value of tumor-infiltrating lymphocytes in triple-negative breast cancers from two phase III randomized adjuvant breast cancer trials: ECOG 2197 and ECOG 1199." *Journal of Clinical Oncology*, 2014. 32(27): 2959-2966.
14. Loi S, et al., "Tumor infiltrating lymphocytes are prognostic in triple negative breast cancer and predictive for trastuzumab benefit in early breast cancer: results from the FinHER trial." *Annals of Oncology*, 2014. 25(8): 1544-1550.
15. Loi S, et al., "Prognostic and predictive value of tumor-infiltrating lymphocytes in a phase III randomized adjuvant breast cancer trial in node-positive breast cancer comparing the addition of docetaxel to doxorubicin with doxorubicin-based chemotherapy: BIG 02-98." *Journal of Clinical Oncology*, 2013. 31(7): 860-867.
16. Denkert C, et al., "Tumor-associated lymphocytes as an independent predictor of response to neoadjuvant chemotherapy in breast cancer." *Journal of Clinical Oncology*, 2010. 28(1): 105-313.
17. Denkert C, et al., "Tumor-infiltrating lymphocytes and response to neoadjuvant chemotherapy with or without carboplatin in human epidermal growth factor receptor 2-positive and triple-negative primary breast cancers." *Journal of Clinical Oncology*, 2014;58;1967.

CONTACT

Investor Relations:

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

Media Relations:
David Schemelia/ Jason Rando
Tiberend Strategic Advisors, Inc.
Phone: 212-827-0020
dschemelia@tiberend.com
jrando@tiberend.com



oncosec™
IMMUNOTHERAPIES

View original content to download multimedia <http://www.prnewswire.com/news-releases/oncosec-initiates-keynote-890-a-phase-2-clinical-trial-of-tavo-in-combination-with-mercks-keytruda-pembrolizumab-for-the-treatment-of-late-stage-triple-negative-breast-cancer-300730837.html>

SOURCE OncoSec Medical Incorporated