

OncoSec Enrolls First Patient in Biomarker-Focused Pilot Study in Triple Negative Breast Cancer

SAN DIEGO, Oct. 29, 2015 /PRNewswire/ -- OncoSec Medical Incorporated ("OncoSec") (NASDAQ: ONCS), a company developing DNA-based intratumoral cancer immunotherapies, announced today that the Company has enrolled the first patient into a pilot biomarker trial of ImmunoPulse™ IL-12 in patients with triple negative breast cancer (TNBC). ImmunoPulse™ IL-12, which employs intratumoral electroporation to enhance delivery of DNA-based interleukin-12 (IL-12), is designed to enhance tumor immunogenicity, leading to increased tumor infiltrating lymphocytes (TILs) and pro-inflammatory cytokines.

Previous studies have demonstrated that breast cancer patients whose tumors are associated with markers of inflammation, such as the presence of TILs, have better clinical outcomes. These data have initiated an effort by an international consortium to develop guidelines and recommendations for the routine evaluation of TILs for breast cancer. Further, preliminary data reported at the 2014 San Antonio Breast Cancer Symposium indicate that TNBC is responsive to cancer immunotherapies, such as anti-PD-1/PD-L1 checkpoint therapies. However, response rates in these TNBC patients, who were selected for study participation based upon TIL status, were only 18 to 33 percent.

"There is increasing evidence that breast cancer patients with tumors characterized by a 'pro-inflammatory phenotype,' including those with TNBC, have better responses to chemotherapy and experience longer disease-free and overall survival rates," said Mai H. Le, MD, Chief Medical Officer at OncoSec. "We anticipate that ImmunoPulse™ IL-12 will drive a tumor-specific inflammatory response in TNBC patients. The goal with ImmunoPulse™ IL-12 is to increase the number of patients who will benefit from anti-PD-1 therapy. We are very excited to be working closely with our colleagues at Stanford University to evaluate the role of ImmunoPulse™ IL-12 in promoting tumor immunogenicity."

Melinda L. Telli, MD, Assistant Professor of Medicine (Oncology) and Irene Wapnir, MD, Professor of Surgery (General Surgery), are leading this clinical trial at Stanford University Medical Center. Approximately 10 patients are planned for enrollment into this trial. The primary objective of the study is to evaluate the potential of ImmunoPulse™ IL-12 to promote a pro-inflammatory molecular and histological signature in tumor samples obtained from study participants. Secondary objectives include: evaluation of safety and tolerability; evaluation of local ablative effect (% necrosis); and description of other evidence of antitumor activity.

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

About Triple Negative Breast Cancer (TNBC)

Breast cancer cells that test negative for estrogen receptors (ER-), progesterone receptors

(PR-), and HER2 (HER2-) means the cancer is triple negative. Approximately 15-20 percent of US 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.⁴

Emerging evidence shows immunotherapy options may play an important role in the treatment paradigm for TNBC. Preliminary data demonstrated the anti-PD-1 antibody, pembrolizumab, led to an objective response in approximately 18 percent of TNBC patients;⁵ the anti-PD-L1 antibody, MPDL3280A, achieved an objective response in 33 percent of patients.⁶ There is increasing evidence that tumors need TILs for anti-PD-1/PD-L1 therapies to be most effective. Data also show TILs promote better responses to chemotherapy and improve clinical outcomes in breast cancer, including TNBC.⁷⁻¹²

About OncoSec Medical Incorporated

OncoSec is a biotechnology company developing DNA-based intratumoral immunotherapies for the treatment of cancer. The Company's investigational technology, ImmunoPulse™, is designed to enhance the local delivery and uptake of DNA-based immune-targeting agents, such as IL-12. In Phase I and II clinical trials, OncoSec's lead program, ImmunoPulse™ IL-12, demonstrated a favorable safety profile and evidence of anti-tumor activity in the treatment of various skin cancers as well as the potential to initiate a systemic immune response. ImmunoPulse™ IL-12 is currently in Phase II development for several indications, including metastatic melanoma, squamous cell carcinoma of the head and neck, and triple negative breast cancer. In addition to ImmunoPulse™ IL-12, the Company is also seeking to identify and develop new immune-targeting agents for use with the ImmunoPulse™ platform. For more information, please visit 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 "anticipate," "may," "will," "goal," "planned," 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. Onco Sec 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.

References

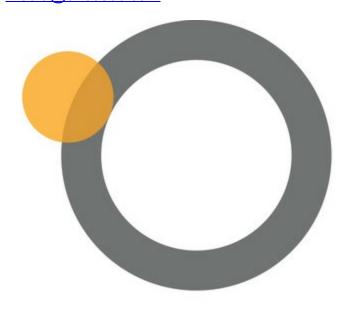
- BreastCancer.org. Triple Negative Breast Cancer.
- http://www.breastcancer.org/symptoms/diagnosis/trip_neg. Accessed September 7, 2015.
- 2. Bauer KR, et al., "Descriptive analysis of estrogen receptor (ER)-negative, progesterone receptor (PR)-negative, and HER2-negative invasive breast cancer, the so-called triple-negative phenotype: a population-based study from the California cancer Registry." *Cancer*. 2007 May 1; 109(9):1721-8.
- 3. BreastCancer.org. Who Gets Triple Negative Breast Cancer? http://www.breastcancer.org/symptoms/diagnosis/trip_neg/who_gets. Accessed September 7, 2015.
- 4. F Andre and CC Zielinski. "Optimal strategies for the treatment of metastatic triplenegative 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. Emens LA, et al., "Inhibition of PD-L1 by MPDL3280A leads to clinical activity in patients with metastatic triple-negative breast cancer." *San Antonio Breast Cancer Symposium*, 2014.
- 7. Mahmoud SM, et al., "Tumor-infiltrating CD8+ lymphocytes predict clinical outcome in breast cancer." *Journal of Clinical Oncology*, 2011. 29(15): p. 1949-55.
- 8. 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): p. 2959-66.
- 9. 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): p. 1544-50.
- 10. 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): p. 860-7.
- 11. 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): p. 105-13.
- 12. 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:
Jordyn Kopin
OncoSec Medical Inc.
855-662-6732
investors@oncosec.com

Media Relations:

Mary Marolla OncoSec Medical Inc. 855-662-6732 media@oncosec.com



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