September 27, 2015

OncoSec Announces Positive Results from Phase II Trial of ImmunoPulse™ IL-12 in Merkel Cell Carcinoma

SAN DIEGO, Sept. 27, 2015 /PRNewswire/ -- OncoSec Medical Incorporated ("OncoSec") (NASDAQ: ONCS), a company developing DNA-based intratumoral cancer immunotherapies, today announced results from a Phase II trial demonstrating that its investigational therapy, ImmunoPulse™ IL-12, promotes tumor-specific, systemic anti-tumor immune responses in patients with Merkel cell carcinoma (MCC). Shailender Bhatia, MD, Assistant Professor of Medicine, Division of Medical Oncology at the University of Washington School of Medicine and Principal Investigator of the trial, presented the findings today in an oral presentation at the 2015 European Cancer Congress in Vienna, Austria.

"The successful completion of the first prospective trial of immunotherapy in MCC marks an important milestone," said Dr. Bhatia. "Importantly, our findings support the hypothesis that intratumoral IL-12 DNA with electroporation promotes tumor immunogenicity. The results confirm the potential of this approach to make a clinically meaningful impact on patient outcomes for this virus-associated cancer."

In this Phase II study, 79% of patients (11/14) showed an increase in IL-12 protein levels in tumor biopsy samples obtained approximately 22 days after treatment compared to baseline, indicating that ImmunoPulse™ IL-12 leads to successful DNA transfection and sustained protein expression within the tumor microenvironment. ImmunoPulse™ IL-12 was well-tolerated, with no treatment-related adverse events above Grade 2 and no treatment-related serious adverse events. The most common adverse event was Grade 1 transient pain associated with the treatment procedure.

Analysis of individual lesions found that 30% of patients (3/10) who were evaluable for systemic anti-tumor immunity had regression of at least one distant, non-injected/non-electroporated lesion. In patients considered evaluable for objective response by modified RECIST criteria (i.e., Cohort B, N=12), 25% of patients (3/12) had an objective partial response (PR) and one patient had stable disease (SD) for a disease control rate (PR + SD) of 33%. In Cohort A (N=3), one patient had a pathologic complete response and continues to be recurrence-free at six months. Another patient has been recurrence-free for over three years. Immune correlative data suggest that ImmunoPulse™ IL-12 can increase tumor-infiltrating lymphocytes and may promote a tumor-specific CD8+ T-cell response.

"We are very excited to observe that ImmunoPulse™ IL-12 continues to demonstrate that intratumoral treatment with IL-12 DNA and electroporation can induce anti-tumor immune effects both locally and systemically," said Mai H. Le, MD, Chief Medical Officer at OncoSec. "These results are consistent with what we have previously observed in metastatic melanoma and underscore the broad-reaching potential of ImmunoPulse™ IL-12 in driving immunogenicity."

About the Phase II Study Design
OMS-I110 was a Phase II open-label study that enrolled 15 patients with MCC. The primary endpoint of the trial was IL-12 protein expression following treatment with ImmunoPulse™ IL-12. Secondary endpoints included: safety and tolerability; overall response rate evaluated by RECIST-modified criteria for MCC; distant lesion regression; and biological markers of pro-inflammatory changes in the tumor microenvironment. Modifications to the standard RECIST criteria included permitting more than two measurable lesions per organ (e.g., skin) to be considered evaluable as "target lesions" and the use of a combination of clinical and radiographic measurements for lesion assessment.

Patients enrolled into this study were separated into two cohorts. Cohort A (N=3) was comprised of patients whose disease status was amenable to definitive surgery or radiation following a single cycle of ImmunoPulse™ IL-12 treatment (i.e., neo-adjuvant). Patients with more advanced disease were enrolled into Cohort B (N=12) and permitted to receive up to four cycles of ImmunoPulse™ IL-12.

About Merkel Cell Carcinoma (MCC)
MCC is a rare, aggressive cancer with a disease-associated mortality estimated to be three times that of malignant melanoma and affects approximately 1,600 people per year in the US.[1-3] The reported incidence has more than tripled over the past 20 years and the health impact of MCC is growing rapidly with a proportional increase in the aging population.[2-4] The reported five year relative survival for patients with local, nodal and metastatic disease is 64%, 39% and 18% respectively.[1]

Treatment options in the metastatic setting are limited for patients. Responses to chemotherapy regimens are usually short-lived and the impact on survival is unclear.[5] Also, chemotherapy regimens are associated with toxicity and may not be suitable for MCC patients who tend to be older with multiple co-morbidities.[5] Therefore, there is a strong unmet need for biology-driven therapies in MCC.

The recent discovery of the Merkel cell polyomavirus has provided the missing link between MCC and its association with immune suppression.[5] MCC tumors are able to evade the immune system by establishing a local immunosuppressive microenvironment. Evidence shows the presence of intratumoral CD8+ T-cells are associated with better prognosis. As such, therapies aimed at promoting intratumoral inflammation may improve MCC patient outcomes.

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 IL-12. In Phase I and II clinical trials, ImmunoPulse™ IL-12 has 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. OncoSec's lead program, 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 identifying and developing 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," "intend," "estimate," "believe," "expect," "future," "may," "should," "will," 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.

References

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