

OncoSec Granted FDA Fast Track Designation for ImmunoPulse® IL-12 for the Treatment of Metastatic Melanoma Following Progression on Pembrolizumab or Nivolumab

Provides Opportunities for Upcoming Phase 2b PISCES Clinical Trial and Future Clinical Development

SAN DIEGO, Feb. 27, 2017 /PRNewswire/ -- OncoSec Medical Incorporated ("OncoSec") (NASDAQ: ONCS), a company developing DNA-based intratumoral cancer immunotherapies, received Fast Track designation from the U.S. Food and Drug Administration (FDA) for its ImmunoPulse® IL-12, a potentially first-in-class, Intratumoral anti-cancer gene therapy that expresses interleukin-12 (IL-12) for the treatment of metastatic melanoma, following progression on pembrolizumab or nivolumab.

"With the number of melanoma patients now being treated with either pembrolizumab or nivolumab in either the first- or second-line settings, there will be an increasing number of patients who will not respond to therapy. Thus, there is a clear need for treatments that can rescue these patients and help them benefit from these immunotherapies," said Punit Dhillon, OncoSec President and CEO. "With the recent presentation of our interim data from our ongoing combination study with pembrolizumab in patients predicted not to respond to single-agent anti-PD-1 therapy, we are increasingly confident in ImmunoPulse® IL-12 to potentially convert 'cold' tumors to 'hot' tumors to effectively and safely improve the response rates of these patients."

"This Fast Track designation by the FDA serves as an additional validation for OncoSec's clinical development program," said Sharron Gargosky, Ph.D., Chief Clinical and Regulatory Officer. "As we launch our upcoming Phase 2b PISCES clinical trial, we look forward to collaborating closely with the FDA at this important stage of our clinical program."

The PISCES (Anti-PD-1 IL-12 Stage III/IV Combination Electroporation Study) will be a Phase 2b, Simon 2-stage, non-comparative, open-label, single-arm, multicenter study of ImmunoPulse® IL-12 (intratumoral pIL-12 plus electroporation) in combination with an intravenous anti-PD-1 antibody in patients with histological diagnosis of melanoma with progressive locally advanced or metastatic disease defined as Stage III or Stage IV. Eligible patients will be those with Stage III/IV metastatic melanoma who are progressing or have progressed according to RECIST v1.1 guidelines on, or within, 24 weeks of receiving approved anti-PD-1 antibodies on either pembrolizumab or nivolumab treatment (either as monotherapy or in combination with another approved checkpoint inhibitor). The primary endpoint for this registration-directed trial will be overall response rate (ORR) at 24 weeks

with secondary endpoints of best overall response rate (BORR), duration of response (DOR), median progression-free survival (PFS) and overall survival (OS). This clinical trial is planned to initiate in the first half of 2017.

The FDA established the Fast Track program to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions, and demonstrate the potential to address unmet medical needs. Drugs that receive this designation benefit from more frequent communications and meetings with the FDA, to review the drug's development plan including the design of the proposed clinical trials, use of biomarkers, and the extent of data needed for approval. Fast Track designated drugs may qualify for expedited FDA review, and a rolling Biologics License Application (BLA), if certain criteria are met.

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 solid tumors as well as a systemic immune response. OncoSec's lead program, ImmunoPulse® IL-12, is currently in clinical development for several indications, including metastatic melanoma and triple-negative breast cancer. The program's current focus is on the significant unmet medical need in patients with melanoma who are refractory or non-responsive to anti-PD-1/PD-L1 therapies. 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 "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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