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OncoSec Granted Orphan Drug Designation from the U.S. FDA for the Treatment of Unresectable Metastatic Melanoma

SAN DIEGO, June 8, 2017 /PRNewswire/ -- OncoSec Medical Incorporated ("OncoSec") (NASDAQ: ONCS), a company developing DNA-based intratumoral cancer immunotherapies, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation for pIL-12, otherwise known as tavokinogene telsaplasmid, for the treatment of unresectable metastatic melanoma. Tavokinogene telsaplasmid is the active biologic agent in OncoSec's lead product candidate, ImmunoPulse® IL-12. The Orphan Drug status will provide OncoSec with eligibility for certain development incentives, including tax credits for clinical testing, exemption from a prescription drug user fee, and seven years of market exclusivity.

"This is an important regulatory milestone for OncoSec as we advance ImmunoPulse® IL-12 toward commercialization," said Punit Dhillon, CEO and President of OncoSec. "We are diligently working to address a significant unmet medical need in melanoma patients who are progressing or have progressed after treatment with anti-PD-1."

OncoSec is initiating the registration-directed PISCES trial, to evaluate the safety and efficacy of ImmunoPulse® IL-12 and the approved anti-PD-1 agent, pembrolizumab, in patients with metastatic melanoma following disease progression on previous treatment with an anti-PD-1 therapy.

The FDA grants Orphan Drug Designation status to products that treat rare diseases, providing incentives to sponsors developing drugs or biologics. The FDA defines rare diseases as those affecting fewer than 200,000 people in the U.S. at any given time. For a drug to qualify for orphan drug designation both the drug and the disease must meet certain criteria specified in Section 525 of the Federal Food, Drug, and Cosmetic Act (21 USC 360aa). The receipt of Orphan Drug Designation status does not change the regulatory requirements or process for obtaining marketing approval.

About PISCES

PISCES (Anti-**P**D-1 **I**L-12 **S**tage III/IV **C**ombination **E**lectroporation **S**tudy) will be a Phase II multicenter study of ImmunoPulse® IL-12 in combination with KEYTRUDA® 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 on an approved anti-PD-1 therapy. The primary endpoint for this registration-directed trial is best overall response rate (BORR).

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 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.

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