April 1, 2019

OncoSec Announces Advanced Therapy Medicinal Product Classification from the EMA for TAVO™ in Refractory Metastatic Melanoma

Classification as an ATMP Positions TAVO for Accelerated Review and Approval in Europe

SAN DIEGO and PENNINGTON, N.J., April 1, 2019 /PRNewswire/ -- OncoSec Medical Incorporated (OncoSec) (NASDAQ:ONCS), a company developing novel cancer immunotherapies, announced today that it has received Advanced Therapy Medicinal Product (ATMP) classification for the Company's lead investigational product candidate, TAVO™ (DNA plasmid vector expressing IL-12 gene), as a potential treatment for refractory metastatic melanoma from the European Medicines Agency (EMA).

Only innovative investigational product candidates that are based on gene, tissue or cell therapy are qualified for classification as advanced therapy medicinal products. The classification of TAVO as an ATMP is a significant step toward its potential accelerated approval in Europe. The ATMP classification qualifies TAVO to take advantage of a specific EMA regulatory framework designed to facilitate the accelerated review, approval, and access to innovative products in the European market. Further, OncoSec intends to avail itself of the numerous benefits and incentives for medicinal products undergoing clinical testing and marketing approval processes in Europe. Such incentives include fee reductions and exemptions in pre- and post-marketing authorization phases; administrative, procedural and scientific advice and eligibility for funding.

"The ATMP designation confirms TAVO as an innovative gene therapy potentially offering a groundbreaking new opportunity for the treatment of refractory metastatic melanoma," said Robert Ashworth, PhD, Senior Vice President of Regulatory and Quality at OncoSec.

"Similar to TAVO's existing FDA Fast Track Designation in the United States, the ATMP designation allows OncoSec to take advantage of a specific European regulatory framework designed to facilitate the accelerated review and approval of TAVO in the European market," said Daniel J. O'Connor, OncoSec's President and CEO. "Obtaining this important designation delivers on one of OncoSec's key objectives for 2019."

The Committee for Advanced Therapies (CAT) at the EMA is responsible for classifying and assessing the quality, safety and efficacy of products designated as ATMP. The CAT is a multidisciplinary committee of the best available experts in Europe. The main responsibility of the CAT is to prepare a draft opinion on each ATMP application submitted to the EMA before the Committee for Medicinal Products for Human Use (CHMP) adopts a final opinion on granting a marketing authorization for the product. During drug development, CAT also

reviews and certifies the acceptability of quality and non-clinical data.

In February 2017, the U.S. Food and Drug Administration (FDA) designated the investigation of OncoSec's TAVO in combination with KEYTRUDA® (pembrolizumab) to stop or cause the regression of the tumor of patients with Stage III/IV melanoma who are progressing on either KEYTRUDA® (pembrolizumab) or OPDIVO® (nivolumab) treatment as a Fast Track Development Program. Fast Track designation is a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need. A drug that receives Fast Track designation is eligible for Accelerated Approval if relevant criteria are met.

About OncoSec Medical Incorporated and TAVO™

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.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.

OPDIVO® is a registered trademark of Bristol-Myers Squibb.

ImmunoPulse® is a registered trademark of OncoSec Medical Incorporated.

CONTACT

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

Media Relations:
Katie Dodge
JPA Health Communications
(617) 657-1304
kdodge@jpa.com

View original content to download multimedia: http://www.prnewswire.com/news-releases/oncosec-announces-advanced-therapy-medicinal-product-classification-from-the-ema-for-tavo-in-refractory-metastatic-melanoma-300821598.html

SOURCE OncoSec Medical Incorporated