

# OncoSec Provides KEYNOTE-695 Clinical Update And Outlines 2019 Milestones

**-- Tumor responses observed in 5 of first 21 patients, approximately 24% ORR in ongoing KEYNOTE-695 study**

**-- Primary endpoint of KEYNOTE-695 is 20% ORR**

**-- Durable responses observed at 10 months; all responding patients still on study; responses demonstrate regression of distant visceral lesions**

**-- Company to host conference call and live audio webcast today at 9:00 am E.T.**

SAN DIEGO and PENNINGTON, N.J., Feb. 1, 2019 /PRNewswire/ -- OncoSec Medical Incorporated (OncoSec) (NASDAQ:ONCS), a company developing intratumoral cancer immunotherapies, provided a clinical data update today regarding KEYNOTE-695, as well as progress of its ongoing clinical development efforts and its outlook for 2019.

**KEYNOTE-695** (TAVO<sup>™</sup> + KEYTRUDA® (pembrolizumab) for metastatic/recurrent melanoma)

- With one fifth of patients in the study now evaluated, the observed preliminary response rate is approximately 24% (5/21) with enrollment ongoing
- The observed preliminary ORR of approximately 24% is encouraging given the primary endpoint of KEYNOTE-695 is a 20% ORR
- As of December 15, 2018, 21 patients have been treated and evaluated for tumor response by RECIST v1.1
- Five of these 21 patients have experienced objective tumor responses, of which four were partial responses and one was a complete response
- Responses have been determined at approximately three months and subsequently confirmed at approximately six months by either the investigator or by blinded independent review at the first assessment timepoint
- Currently, all five responding patients continue to be treated with KEYTRUDA®; two patients are no longer being treated with TAVO<sup>™</sup> due to regression of all TAVO<sup>™</sup> accessible lesions
- Durable responses have been observed, with all responding patients still on study from 6 to 10 months
- Responding patients demonstrate regression of both distant internal (or visceral) lesions and lesions not treated with TAVO<sup>™</sup>
- All patients entered KEYNOTE-695 with late-stage, progressive metastatic melanoma and had large, bulky established tumors

- All patients unequivocally failed prior treatment with either KEYTRUDA® or OPDIVO® according to their approved labels
- 33 patients have been enrolled in the study and approximately 100 patients are planned to be enrolled
- Safety profile mirrors earlier TAVO™ studies; nearly exclusively Grade 1 or 2 adverse events; safety profile is a key strength
- Enrollment is ongoing at sites in the U.S, Canada and Australia
- Filing for E.U. Advanced Therapy Classification will occur later this year
- Study enrollment completion is anticipated in 2019, with a potential filing for accelerated approval in the U.S. in 2020 and a potential application for conditional approval in Europe shortly thereafter

#### **OMS-150 Cervical Cancer Study** (TAVO™ and commercially available KEYTRUDA® for recurrent/persistent cervical cancer)

- Registration-enabled study of TAVO™ in recurrent/persistent cervical cancer to be conducted in collaboration with the Gynecologic Oncology Group (GOG), a world-renowned non-profit organization conducting clinical research for the prevention and treatment of all gynecologic cancers, including cervical cancer
- Single-arm study of TAVO™ and KEYTRUDA® by prescription, expected to enroll 80 or more patients, powered to detect a response meaningfully higher than seen with KEYTRUDA® monotherapy of 14% ORR
- Along with GOG, study preparations are underway with first site initiation and patient enrollment expected to begin in the U.S. in the first half of 2019, with potential expansion into other countries
- Anticipated U.S. regulatory filing in 2021
- With only two drugs approved in the past 30 years, there is a significant need for better treatment options for advanced cervical cancer
- A press release announcing this collaboration can be found [here](#)

#### **KEYNOTE-890** (TAVO™ + KEYTRUDA® for triple negative breast cancer (TNBC))

- Study enrolling as expected with eight of 25 patients currently enrolled in the study
- Anticipated study enrollment completion in 2019
- Plan to report preliminary data later this year

#### **New Product Candidate**

- Based upon immunological findings made from previously treated TAVO™ patients, OncoSec's research laboratory has designed a new, second product candidate targeting not only IL-12, but also other important, immunologically relevant targets
- IND filing for this new product candidate expected in 2H 2019
- Details regarding this new product candidate, including pre-clinical data, will be presented at a major medical meeting this year

#### **Expanding TAVO™ to Interior Lesions with new Visceral Lesions Applicator (VLA)**

- Significant opportunities exist with OncoSec's current technology, which allows physicians to treat accessible lesions up to a depth of 15 millimeters
- TAVO's mechanism of action is likely to be relevant in nearly all solid tumors

- Considering the therapeutic benefit and associated market impact, expansion is planned beyond accessible lesions, with the development of a new applicator able to access internal, or visceral, lesions
- OncoSec's engineering and research groups have successfully miniaturized the new visceral applicator or VLA, achieving the requisite energy parameters and therapeutic effect in multiple tumor models
- VLA can be used with both the current clinical generator and planned next generation generator, allowing for a minimally invasive, safe and effective delivery of local IL-12 and other important, immunologically relevant targets into visceral tumors

"2018 was a busy and productive year for OncoSec, and as we enter 2019, we are well-positioned to continue advancing our lead program, TAVO™, towards registration in multiple tumor settings in the United States beginning as early as 2020," said Daniel O'Connor, OncoSec's Chief Executive Officer. "Our focus in 2019 will be moving TAVO™ towards registration in our current indication of PD-1 refractory, late-stage melanoma, progressing our recently announced registration-enabled clinical study in cervical cancer, expanding our ability to target tumors affecting internal organs, advancing a new, second pipeline candidate for which we expect to file an IND in 2019, and completing KEYNOTE-890, our combination study with TAVO + KEYTRUDA® in TNBC. We believe that executing on this plan will extend the long-term valuation of our company and, most importantly, bring meaningful new treatments to patients and clinicians who very much need them."

### **Anticipated 2019 Milestones**

- Receive Advanced Therapy Medicinal Product (ATMP) Classification in Europe by EMA's committee for Advanced Therapies for melanoma in 1H 2019
- Initiate European trial sites in KEYNOTE-695 this year
- Complete enrollment in KEYNOTE-695 2H 2019
- Dose first patient in OMS-150 cervical cancer study in 1H 2019
- Provide preliminary data update for the KEYNOTE-890 TNBC study in 2H 2019
- Present New Product Candidate at a major medical meeting this year
- File IND for New Product Candidate in 2H 2019

### **Conference Call and Webcast Information**

OncoSec will host a conference call and live audio webcast today at 9:00 a.m. ET. To access the live conference call, please dial (844) 562-3893 (domestic) or (409) 220-9946 (international) at least five minutes prior to the start time, and refer to conference ID 4067388.

An accompanying presentation will be referenced during the conference call and can be accessed under "Events and Presentations" in the Investors section of OncoSec's website at [ir.oncosec.com](http://ir.oncosec.com). A replay will be available shortly after the conference call and can be accessed for 30 days following the call.

### **About OncoSec Medical Incorporated**

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](http://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 Company.

ImmunoPulse® is a registered trademark of OncoSec Medical Incorporated.

### **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," "anticipate," "believe," "estimate," "may," "expect" 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; the success and timing of our clinical trials; the success and timing of our IND submission to the FDA; our ability to obtain and maintain marketing approval from regulatory agencies for our products in the U.S. and foreign countries; our ability to successfully implement our strategy; 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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