

January 3, 2018



# OncoSec Provides 2018 Business Outlook

**Complete stage 1 enrollment of PISCES/KEYNOTE-695 clinical trial of ImmunoPulse® IL-12 in combination with KEYTRUDA® (pembrolizumab)**

**Present preliminary data from PISCES/KEYNOTE-695 at a medical meeting**

**Seek preliminary FDA feedback on accelerated approval pathway**

**Apply for advanced-therapy medicinal product (ATMP) classification in EU**

SAN DIEGO, Jan. 3, 2018 /PRNewswire/ -- OncoSec Medical Incorporated ("OncoSec" or the "Company") (NASDAQ:ONCS), a company developing intratumoral cancer immunotherapies, announced its anticipated operational milestones for 2018 and a review of business highlights for year-end 2017.

"The momentum we achieved in late 2017 provides the foundation for a transformational year in 2018," said Daniel J. O'Connor, Chief Executive Officer of OncoSec. "The year ahead is critical for OncoSec with preliminary data expected in key clinical programs; preliminary feedback from regulators on an accelerated approval pathway for ImmunoPulse® IL-12 in unresectable metastatic melanoma patients who have progressed or are progressing on an anti-PD-1 therapy; and advances in our intratumoral delivery platform."

He continued, "Operational execution will dominate 2018, with a focus on laying the groundwork for future BLA and IND filings. We plan to conduct a second clinical trial in triple negative breast cancer (TNBC), as well as two investigator sponsored trials in squamous cell carcinoma of the head and neck (SCCHN) and in the melanoma neoadjuvant setting. These trials will be in combination with anti-PD-1 therapy. We look forward to sharing progress toward our vision throughout the year: to have multiple products that will make a dramatic patient impact and an innovative pipeline driven by a sustainable product engine."

## **2018 OPERATIONAL MILESTONES**

OncoSec anticipates the following operational milestones in 2018:

### **Clinical Operations**

#### **ImmunoPulse IL-12 Melanoma**

- Complete stage 1 enrollment of PISCES/KEYNOTE-695; a Phase 2b registration-directed clinical trial of ImmunoPulse IL-12 (intratumoral pIL-12 [tavokinogene

telseplasmid or "tavo"] with electroporation), in combination with KEYTRUDA® (pembrolizumab) for patients with unresectable metastatic melanoma who have progressed or are progressing on an anti-PD-1 therapy

- Present preliminary data from PISCES/KEYNOTE-695 at a medical meeting
- Seek preliminary FDA feedback on an accelerated approval pathway for ImmunoPulse IL-12 Biologics License Application (BLA) in patients with unresectable metastatic melanoma who have progressed or are progressing on an approved anti-PD-1 therapy
- Apply for classification as an Advanced-Therapy Medicinal Product (ATMP) for the treatment of unresectable metastatic melanoma who have progressed or are progressing on an approved anti-PD-1 therapy by the European Medicines Agency's Committee for Advanced Therapies (CAT)
- Prepare to commercially launch ImmuoPulse IL-12 in the U.S.
- Initiate a Phase 2 investigator-sponsored clinical trial in combination with an anti-PD-1 therapy in the neoadjuvant setting

#### ImmunoPulse IL-12 Triple Negative Breast Cancer (TNBC)

- Provide update of preliminary clinical observations for OMS-I140 TNBC pilot study conducted in collaboration with the Stanford University Medical Center
- Present preliminary data for OMS-I140 TNBC study at a medical meeting
- Initiate a Phase 2 clinical trial in combination with an anti-PD-1 therapy in the recurrent and/or metastatic setting

#### ImmunoPulse IL-12 Squamous Cell Carcinoma of the Head and Neck (SCCHN)

- Initiate a Phase 2 investigator-sponsored clinical study in combination with two other immunotherapies in the recurrent and/or metastatic setting

### **Business Development**

- Seek partner for the development, registration and commercialization of ImmunoPulse IL-12 in metastatic melanoma in the U.S. and EU, as well as in other important regions
- Pursue multiple partnerships and collaborations for cancer immunotherapy platform to enable additional research in combination with other cancer therapies and novel immunotherapies

### **Expanding Clinical Pipeline**

- Prepare an IND for a second product candidate utilizing our proprietary, multi-gene expression Polycistronic Interleukin-12 Immune Modulator (PIIM) platform technology

### **Enhanced Platform Engineering and Manufacturing**

- Advance second-generation proprietary GENESIS™ generator to be ready for introduction into the clinic
- Advance proprietary applicators in cancer indications beyond cutaneous and subcutaneous tumors
- Undertake technology transfers with partners and install new innovative technologies to improve the overall supply chain

## **2017 OPERATIONAL MILESTONE REVIEW**

OncoSec achieved several important clinical, regulatory, business and operational milestones during 2017.

### **Clinical Operations**

#### **ImmunoPulse IL-12 Metastatic Melanoma**

- Presented updated positive long-term follow-up data from our Phase 2 trial of ImmunoPulse IL-12 in combination with KEYTRUDA (pembrolizumab) at the 2017 Society for Immunotherapy of Cancer Annual Meeting
  - Selected as a Late Breaking Abstract and Oral Poster Presentation, OncoSec presented updated clinical and correlative immune-focused biomarker data demonstrating a 57% progression free survival (PFS) rate at 15 months with 100% (11/11) duration of response, median PFS not yet reached, and a best overall response rate (BORR) of 50% (41% complete response [CR] rate) in patients selected to not respond to anti-PD-1 monotherapy
  - Data indicate that ImmunoPulse IL-12 coordinates innate and adaptive anti-tumor immune responses, converting "cold" tumors to "hot," which drives adaptive resistance and strongly suggests a synergistic relationship between ImmunoPulse IL-12 and anti-PD-1 combination.
- Presented preclinical data demonstrating multigene platform for delivery of multiple cancer immunotherapies at the 2017 Society for Immunotherapy of Cancer Annual Meeting
  - Emerging data was presented from our novel, multi-gene (PIIM) expression platform, demonstrating enhanced therapeutic potential
- Announced the initiation of global, multi-center, registration-directed open-label PISCES/KEYNOTE-695 Phase 2b clinical trial, evaluating the combination of ImmunoPulse IL-12 and pembrolizumab in patients with unresectable metastatic melanoma who have progressed or are progressing on an approved anti-PD-1 therapy
  - First patient dosed and multiple sites opened in the U.S. and Australia
- Granted Orphan Drug Designation for ImmunoPulse IL-12 for the treatment of unresectable metastatic melanoma from U.S. Food and Drug Administration (FDA)
- Granted Fast Track designation from the FDA for ImmunoPulse IL-12 in combination with pembrolizumab for stage III/IV melanoma patients who are progressing or who have progressed on either pembrolizumab or nivolumab treatment

### **Technology Access Program**

- Established the OncoSec Technology Access Program (TAP) using OncoSec's proprietary GENESIS™ research generator, which was developed specifically for gene electro-transfer and features customizable electroporation parameters for construct-specific optimization of expression. It is the only *in vivo* electroporation device enabled with TRACE™ Technology (Tissue-Based, Real-Time Adaptive Control Electroporation)
  - Entered into a preclinical agreement through TAP with Jounce Therapeutics, Inc., InhibRx, LP, and others

### **Corporate**

- Appointed Daniel J. O'Connor, JD, as Chief Executive Officer and Director
- Expanded intellectual property estate for ImmunoPulse Platform
- Completed two successful public offerings of common stock and warrant exercise, raising net proceeds of \$17.5 million
- Promoted Christopher G. Twitty, Ph.D. to Chief Scientific Officer

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

ImmunoPulse® is a registered trademark of OncoSec Medical Incorporated, San Diego, CA, USA.

## **About Metastatic Melanoma**

Melanoma is a type of skin cancer that begins in skin cells called melanocytes. As the cancer progresses and begins to spread beyond the skin, such as to the lymphatic system (metastatic disease), melanoma becomes more difficult to treat. Given its occurrence in young individuals, the potential years of life lost to melanoma can be higher when compared with other cancers. Although melanoma is a rare form of skin cancer, it accounts for over 75% of skin cancer deaths. The American Cancer Society estimates that approximately 87,000 new melanoma cases and 10,000 deaths from the disease will have occurred in the United States in 2017. Additionally, the World Health Organization estimates that approximately 132,000 new cases of melanoma are diagnosed around the world every year.

## **About PISCES (Anti-PD-1 IL-12 Stage III/IV Combination Electroporation Study)/KEYNOTE-695**

PISCES/KEYNOTE-695 is a global, multicenter phase 2b, open-label trial of intratumoral plasmid-encoded IL-12 (tavokinogene telseplasmid or "tavo") delivered by electroporation in combination with intravenous pembrolizumab in patients with stage III/IV melanoma who have progressed or are progressing on either pembrolizumab or nivolumab treatment. The Simon 2-stage study of intratumoral tavo plus electroporation in combination with pembrolizumab will enroll approximately 48 patients with histological diagnosis of melanoma with progressive locally advanced or metastatic disease defined as Stage III or Stage IV. The primary endpoint will be the Best Overall Response Rate (BORR).

To learn more about the trial, visit <http://www.piscescalclinicaltrial.com>. Additional details can also be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) via NCT03132675.

## **About OncoSec Technology Access Program**

The OncoSec GENESIS™ research generator was developed specifically for gene electro-transfer. It features customizable electroporation parameters for construct-specific optimization of expression, and it is the only *in vivo* electroporation device enabled with TRACE™ Technology (Tissue-Based, Real-Time Adaptive Control Electroporation.) TRACE™ technology incorporates an electrochemical tissue-sensing control system to automatically adjust pulse width and treatment duration in real time during the electroporation procedure. This feature enables tissue- and therapeutic-specific delivery optimization, maximizing uptake of the therapeutic while reducing unnecessary cell ablation or damage. In research models, GENESIS™ with TRACE™ has yielded higher and more

consistent *in vivo* protein expression versus fixed-parameter electroporation, even in heterogeneous tissues.

Potential advantages of using GENESIS™ with TRACE™ for the objectives of animal immunization include cost savings versus recombinant protein administration, a shortened pre-immunization timeline relative to recombinant protein production, and display of the immunizing antigen in its native conformation. The latter benefit may be particularly relevant for certain therapeutic indications, including immuno-oncology, in which many key targets require functional agonism and/or structurally-complex therapeutic modalities such as multimeric forms. To date, OncoSec has generated multiple high-titer antibody libraries against immuno-therapeutic targets.

The OncoSec Technology Access Program makes OncoSec's electroporation technologies available to collaborators for preclinical research. Devices are available for intratumoral, intradermal, and intramuscular delivery. For more information, please contact [bd@oncosec.com](mailto:bd@oncosec.com).

### **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 plasmid encoded IL-12 (tavokinogene telseplasmid or "tavo"). In Phase 1 and 2 clinical trials, ImmunoPulse® IL-12 has demonstrated a favorable safety profile, evidence of anti-tumor activity in the treatment of various solid tumors, and the potential to reach beyond the site of local treatment to initiate 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 have relapsed on anti-PD-1 therapies. In addition to tavo, 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](http://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, including statements about OncoSec's business strategies, including advancement of its lead melanoma program and its broader clinical portfolio and plans to pursue collaborations with industry partners, as well as the potential contributions and impact of new directors on these strategies. In some cases, you can identify forward-looking statements by terminology such as "may", "should", "expects", "plans", "anticipates", "believes", "estimates", "predicts", "potential" or "continue" or the negative of these terms or other comparable terminology.

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 OncoSec's 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: the status, progress and results of clinical programs; ability to obtain regulatory approvals for, and the level of market opportunity for, OncoSec's product candidates; OncoSec's business plans, strategies and objectives, including plans to pursue collaboration, licensing or other similar arrangements or transactions; expectations regarding OncoSec's liquidity and performance, including expense levels, sources of capital and ability to maintain operations as a going concern; the competitive landscape of OncoSec's industry; and general market, economic and political conditions; and the other factors discussed in OncoSec's filings with the Securities and Exchange Commission, including its annual report on Form 10-K for the year ended July 31, 2017.

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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