

## OncoSec Collaborates with Providence Cancer Institute to Conduct First-in-Human Trial of OncoSec's CORVax12, an Investigational Vaccine to Prevent COVID-19, Combining an Enhanced "Spike" DNA Sequence and TAVO™

# Providence Submits Investigator Initiated IND with CORVax12 for a Phase 1 Clinical Trial

SAN DIEGO and PENNINGTON, N.J., April 6, 2020 /PRNewswire/ -- OncoSec Medical Incorporated (NASDAQ:ONCS) (the "Company" or "OncoSec"), a company developing late-stage intratumoral DNA-based cancer immunotherapies, today announced that Providence Cancer Institute, a part of Providence St. Joseph Health ("Providence"), is pursuing a first-in-human Phase 1 clinical trial of OncoSec's novel DNA-encodable, investigational vaccine, CORVax12, which is designed to act as a prophylactic vaccine to prevent COVID-19. CORVax12 consists of OncoSec's existing product candidate, TAVO™ (interleukin-12 or "IL-12" plasmid), in combination with an immunogenic component of the SARS-CoV-2 virus recently developed by researchers at NIH's National Institute of Allergy and Infectious Diseases ("NIAID") and licensed to OncoSec on a non-exclusive basis.

Specifically, OncoSec's CORVax12 vaccine approach combines the co-administration of TAVO<sup>TM</sup> (plasmid IL-12) with a DNA-encodable version of the SARS-CoV-2 spike or "S" glycoprotein to enhance immunogenicity of the component developed by scientists at the NIAID Vaccine Research Center. CORVax12 is designed to drive a coordinated vaccine response, capable of drawing upon the innate, adaptive humoral, and adaptive cellular arms. We believe this multi-pronged innate, adaptive and cellular immune response is likely to be important in generating a robust anti-viral response.

"Previous vaccine efforts against coronaviruses, including the SARS coronavirus, have focused on the S glycoprotein, which facilitates interaction with the host cell through binding to the ACE2 receptor," said Rom Leidner, MD, Co-Medical Director, Head and Neck Cancer Program at Providence Cancer Institute, and Assistant Member, Earle A. Chiles Research Institute and the Principle Investigator on the planned study. "Given the structural similarities between ACE2-receptor binding domain of the SARS-CoV-2 and SARS-CoV viruses, we would like to explore whether a similar strategy with OncoSec's CORVax12 may hold potential as an effective vaccine. Importantly, we believe the delivery of CORVax12 using OncoSec's electroporation system may allow for highly effective DNA transfer to drive this investigational vaccine."

Dr. Leidner continued, "Providence is among the U.S.'s largest, not-for-profit network of hospitals and includes 51 hospitals in Alaska, Washington, Oregon, Montana and California. We are positioned to rapidly initiate studies following FDA clearance of our IND and are hopeful that CORVax12, driven by OncoSec's IL-12 and NIH's spike DNA sequence, could have a meaningful impact on COVID-19 prevention and guide the development of a new generation of vaccines."

Providence investigators have filed an Investigator-Initiated Investigational New Drug (IND) Application with the United States Food and Drug Administration (FDA) and have designed a clinical trial protocol that will evaluate the vaccination of healthy adult volunteers utilizing OncoSec's next-generation, investigational APOLLO generator technology for the first time clinically if FDA clears the APOLLO to enter the clinic. The trial will also include extensive immune monitoring.

"Teams of scientists at the Earle A. Chiles Research Institute, a division of Providence Cancer Institute, have moved quickly, using philanthropic support and experience from cancer vaccine manufacture to construct and manufacture the viral component of the CORVax12 vaccine that is licensed to OncoSec," said Bernard A. Fox, PhD, Harder Family Chair and Member of the Earle A. Chiles Research Institute.

OncoSec will supply CORVax12 and its investigational APOLLO electroporation device to Providence as part of this effort and does not anticipate any additional capital commitment at this time. Additionally, OncoSec will contribute manufacturing, preclinical, and prior clinical information and data for TAVO, along with manufacturing data for its APOLLO technology, to support FDA's allowance of the Providence IND. Providence will hold the IND, if cleared by FDA, and perform the preclinical and clinical development work.

"During a pandemic such as COVID-19, any opportunity to find a medical solution should be fully investigated," said Christopher Twitty, Chief Scientific Officer of OncoSec. "We are excited to extend our deep expertise in IL-12 based immunotherapies along with an innovative vaccine candidate in support of the clinicians at Providence and their exploration of our CORVax12 vaccine to address this crisis. We hope to make a meaningful impact on COVID-19 as well as gaining a deeper understanding of its associated immunobiology."

"While it is incumbent on OncoSec to assist Providence in the face of this pandemic, I want to take this opportunity to reiterate our primary focus is on advancing our ongoing pivotal KEYNOTE-695 study of TAVO and KEYTRUDA® (pembrolizumab) combination therapy in late-stage checkpoint refractory metastatic melanoma, which remains open and actively recruiting patients at participating clinical sites," said Daniel J. O'Connor, President and Chief Executive Officer of OncoSec, "However, when word of COVID-19 was emerging from China, we realized that our experience with IL-12 and electroporation and knowledge of cancer immunotherapy could be important in addressing this health issue. We are pleased to support the research and medical teams at Providence in their desire to investigate CORVax12 with our Apollo generator and to understand its potential for COVID-19."

The anticipated work and clinical trials outlined above are subject to FDA allowance of the Investigator-Initiated IND filed by Providence.

Fox 12 Oregon recently highlighted the efforts of Drs. Fox and Leidner from Providence regarding their work with CORVax12. Watch the video <a href="here">here</a>.

## **About OncoSec Medical Incorporated**

OncoSec Medical Incorporated (the "Company," "OncoSec," "we" or "our") is a late-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 investigational product candidate – 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<sup>TM</sup> 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<sup>TM</sup> have demonstrated a local immune response, and subsequently, a systemic effect as either a monotherapy or combination treatment approach along with an acceptable safety profile, warranting further development. In addition to TAVO<sup>TM</sup>, OncoSec is identifying and developing new DNAencoded therapeutic candidates and tumor indications for use with its new Visceral Lesion Applicator (VLA), to target deep visceral lesions, such as liver, lung or pancreatic lesions. For more information, please visit <u>www.oncosec.com</u>.

TAVO™ is a trademark of OncoSec Medical Incorporated.

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

#### **About Providence Cancer Institute**

Providence Cancer Institute, a part of Providence St. Joseph Health, offers the latest in cancer services, including diagnostic, treatment, prevention, education, support and internationally-renowned research. Providence Cancer Institute is home to the Earle A. Chiles Research Institute, a world-class research facility located within the Robert W. Franz Cancer Center in Portland, Oregon, and is a recognized leader in the field of cancer immunotherapy since 1993. Visit providenceoregon.org/cancer to learn more.

#### **Risk Factors and Forward-Looking Statements**

This release, as well as other information provided from time to time by the Company or its employees, may contain forward-looking statements that involve a number of risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Forward-looking statements provide the Company's current beliefs, expectations and intentions regarding future events and involve risks, uncertainties (some of which are beyond the Company's control) and assumptions. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. You can identify forward-looking statements by the fact that they do not relate strictly to historical or current facts. These statements may include words such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "should," "will" and "would" and similar expressions (including the negative of these terms). Although we believe that expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. The Company intends these forward-looking statements to

speak only at the time they are published on or as otherwise specified, and does not undertake to update or revise these statements as more information becomes available, except as required under federal securities laws and the rules and regulations of the Securities Exchange Commission ("SEC"). In particular, you should be aware that the success and timing of our clinical trials, including safety and efficacy of our product candidates, patient accrual, unexpected or expected safety events, the impact of COVID-19 on the supply of our candidates or the initiation or completion of clinical trials, the allowance by FDA of the clinical use of CORVax12 and our next-generation APOLLO generator in this or any future clinical trials, and the usability of data generated from our trials may differ and may not meet our estimated timelines. Please refer to the risk factors and other cautionary statements provided in the Company's Annual Report on Form 10-K for the fiscal year ended July 31, 2019 and subsequent periodic and current reports filed with the SEC (each of which can be found at the SEC's website <a href="https://www.sec.gov">www.sec.gov</a>), as well as other factors described from time to time in the Company's filings with the SEC.

### **Company Contact:**

Gem Hopkins Head of Corporate Communications 858-210-7334 ghopkins@oncosec.com



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