



IMUNON and Break Through Cancer Commence Enrollment in a Phase 1/2 Clinical Study of IMNN-001 in Combination with Avastin in Advanced Ovarian Cancer

February 27, 2023

The study will be partially funded by Break Through Cancer through the Ovarian Minimal Residual Disease Team Lab

LAWRENCEVILLE, NJ and CAMBRIDGE, MA (February 27, 2023) – [IMUNON, Inc.](#) (NASDAQ: IMNN), a clinical-stage biotechnology company, and *Break Through Cancer*, a public foundation dedicated to empowering outstanding researchers and clinicians to both intercept and find cures for some of the most difficult-to-treat cancers, announces the commencement of patient enrollment in a collaboration to evaluate IMUNON's IMNN-001 (formerly GEN-1) in combination with bevacizumab in patients with advanced ovarian cancer. The trial is now active at the University of Texas MD Anderson Cancer Center. IMNN-001 is a DNA-based interleukin-12 (IL-12) immunotherapy currently in Phase 2 clinical development for the localized treatment of advanced ovarian cancer (the OVATION 2 Study).

This new Phase 1/2 study, titled "A Phase I/II Study Evaluating the Effect of IMNN-001 (IL-12 Plasmid Formulated with PEG-PEI-Cholesterol Lipopolymer) on Minimal Residual Disease (MRD) as determined by Second Look Laparoscopy when Administered in Combination with Bevacizumab and Neoadjuvant Chemotherapy in Subjects Newly Diagnosed with Advanced Ovarian, Fallopian Tube or Primary Peritoneal Cancer" is expected to enroll 50 patients with Stage III/IV advanced ovarian cancer and is being led by principal investigator Amir Jazaeri, M.D., Professor of Gynecologic Oncology and Reproductive Medicine at MD Anderson.

Patients undergoing frontline neoadjuvant therapy will be randomized 1:1 to receive standard chemotherapy vs. chemotherapy plus IMNN-001. The primary endpoint is detection of minimal residual disease (MRD) by second look laparoscopy (SLL) and the secondary endpoint is progression-free survival (PFS). Initial SLL data are expected within one year from the completion of enrollment and final PFS data are expected approximately three years from the completion of enrollment. This trial will also include a wealth of translational endpoints aimed at understanding the clonal evolution and immunogenomic features of the MRD phase of ovarian cancer that is currently undetectable by imaging or tumor markers.

Tyler Jacks, Ph.D., President of *Break Through Cancer*, Founding Director of MIT's Koch Institute for Integrative Cancer Research, and the David H. Koch Professor of Biology said, "Break *Through Cancer* is excited to support this important study. Our foundation has brought together some of the nation's top cancer research centers to collaborate, accelerate research and clinical trials, and ultimately intercept and find cures for the deadliest cancers."

Commenting on the study, Dr. Corinne Le Goff, President and Chief Executive Officer of IMUNON, said, "The medical need for new innovative therapeutic approaches in ovarian cancer is major. The majority of patients with ovarian cancer are diagnosed with Stage III/IV disease and face low cure rates of 15% or less. The amount of data this study will generate will be a huge contribution to the treatment of ovarian cancer and we believe the combination of IMNN-001 and bevacizumab has important potential. In our animal studies, the combination clearly showed strong synergies. We are hoping that with this study we can potentially transform the current treatment landscape and provide new hope to women suffering from this deadly cancer."

"We have been very thoughtful about funding our clinical programs and are delighted that *Break Through Cancer* will cover approximately two-thirds of the costs of this clinical trial. IMUNON is committing to providing approximately \$2.0 million to \$2.5 million in IMNN-001 product costs, data and safety monitoring and project management services," Dr. Le Goff concluded.

About Epithelial Ovarian Cancer

Epithelial ovarian cancer (EOC) is the fifth deadliest malignancy among women in the United States. There are approximately 22,000 new cases of ovarian cancer every year and the majority (approximately 70%) are diagnosed in advanced Stages III and IV. EOC is characterized by dissemination of tumor in the peritoneal cavity with a high risk of recurrence (75%, Stages III and IV) after surgery and chemotherapy. Since the five-year survival rates of patients with Stages III and IV disease at diagnosis are poor (41% and 20%, respectively), there remains a need for a therapy that not only reduces the recurrence rate but also improves overall survival. The peritoneal cavity of advanced ovarian cancer patients contains the primary tumor environment and is an attractive target for a regional approach to immune modulation.

About IMNN-001 Immunotherapy

Designed using IMUNON's proprietary TheraPlas platform technology, IMNN-001 is an IL-12 DNA plasmid vector encased in a nanoparticle delivery system that enables cell transfection followed by persistent, local secretion of the IL-12 protein. IL-12 is one of the most active cytokines for the induction of potent anticancer immunity acting through the induction of T-lymphocyte and natural killer cell proliferation. The Company previously reported positive safety and encouraging Phase 1 results with IMNN-001 administered as monotherapy or as combination therapy in patients with advanced peritoneally metastasized primary or recurrent ovarian cancer and completed a Phase 1b dose-escalation trial (the OVATION 1 Study) of IMNN-001 in combination with carboplatin and paclitaxel in patients with newly diagnosed ovarian cancer. It announced full enrollment in the OVATION 2 Study in September 2022 and expects to report topline data in the second half of 2023.

About Break Through Cancer

Launched in February 2021, *Break Through Cancer* is a public foundation designed to find new solutions to the most intractable challenges in cancer.

The foundation was launched with an extraordinary challenge pledge of \$250 million from Mr. and Mrs. William H. Goodwin, Jr. and their family, and the estate of William Hunter Goodwin III. This represents one of the largest gifts ever in support of cancer research. Led by Dr. Tyler Jacks, the David H. Koch Professor of Biology and Director of the Koch Institute for Integrative Cancer Research at MIT, *Break Through Cancer* funds and supports collaborative research teams drawn from several of the country's top cancer centers.

Multidisciplinary research teams are selected from across five participating institutions: Dana-Farber Cancer Institute, the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, MD Anderson, Memorial Sloan Kettering Cancer Center, and MIT's Koch Institute for Integrative Cancer Research.

Break Through Cancer is focused on historically highly challenging cancer types, including pancreatic cancer, ovarian cancer, glioblastoma and acute myelogenous leukemia for its initial programs, aided by the guidance of a scientific advisory board of cancer experts from outside the participating institutions. Teams will receive substantial funding to bring new approaches and new thinking as rapidly as possible to the clinical challenges of cancer.

About IMUNON

IMUNON is a fully integrated, clinical-stage biotechnology company focused on advancing a portfolio of innovative treatments that harness the body's natural mechanisms to generate safe, effective and durable responses across a broad array of human diseases, constituting a differentiating approach from conventional therapies.

IMUNON has two platform technologies: the TheraPlas modality for the development of immunotherapies and other anti-cancer nucleic acid-based therapies, and the PLACCINE modality for the development of nucleic acid vaccines for infectious diseases and cancer. The company's lead clinical program, IMNN-001, is a DNA-based immunotherapy for the localized treatment of advanced ovarian cancer currently in Phase 2 development. IMNN-001 works by instructing the body to produce safe and durable levels of powerful cancer-fighting molecules, such as interleukin-12 and interferon gamma, at the tumor site. Additionally, the company is conducting preclinical proof-of-concept studies on a nucleic acid vaccine candidate targeting the SARS-CoV-2 virus to validate its PLACCINE platform. IMUNON's platform technologies are based on the delivery of nucleic acids with novel synthetic delivery systems that are independent of viral vectors or devices. IMUNON will continue to leverage these platforms and to advance the technological frontier of nucleic acid-based products to better serve patients with difficult-to-treat conditions. For more information on IMUNON, visit www.imunon.com.

Forward-Looking Statements

IMUNON wishes to inform readers that forward-looking statements in this news release are made pursuant to the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Readers are cautioned that such forward-looking statements involve risks and uncertainties including, without limitation, unforeseen changes in the course of research and development activities and in clinical trials; the uncertainties of and difficulties in analyzing interim clinical data; the significant expense, time and risk of failure of conducting clinical trials; the need for IMUNON to evaluate its future development plans; possible acquisitions or licenses of other technologies, assets or businesses; possible actions by customers, suppliers, competitors or regulatory authorities; and other risks detailed from time to time in IMUNON's periodic reports and prospectuses filed with the Securities and Exchange Commission. IMUNON assumes no obligation to update or supplement forward-looking statements that become untrue because of subsequent events, new information or otherwise.

CONTACTS:

IMUNON Corporation

Jeffrey W. Church
Executive Vice President and CFO
609-482-2455
jchurch@IMUNON.com

LHA Investor Relations

Kim Sutton Golodetz
212-838-3777
kgolodetz@lhai.com

Break Through Cancer

Kari McHugh
781-964-6557
km@breakthroughcancer.org

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