# Genelux Corporation Initiates a Pivotal Phase 3 Trial, Evaluating Olvi-Vec for the treatment of Platinum-Resistant/Refractory Ovarian Cancer

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- ***The Company's first Phase 3 trial, OnPrime (GOG-3076), will evaluate Olvi-Vec, a modified vaccinia virus, as immunochemotherapy***
- ***Trial will be conducted as a collaboration between Genelux and The Gynecological Oncological Group (GOG)***

WESTLAKE VILLAGE, Calif., Sept. 21, 2022 (GLOBE NEWSWIRE) -- Genelux Corporation, a clinical-stage immunotherapy company, announced today that it has initiated OnPrime, a multi-center, randomized, open-label Phase 3 registrational trial evaluating the efficacy and safety of Olvi-Vec in combination with platinum-doublet + bevacizumab compared to platinum-doublet + bevacizumab in patients with platinum-resistant/refractory ovarian cancer (PRROC).

OnPrime is a US-based trial that will be conducted at approximately 30 sites across the country and has a planned enrollment of 186 women with PRROC, randomized 2:1 into an Experimental Arm of Olvi-Vec and platinum-doublet + bevacizumab and an Active Comparator Arm of platinum-doublet + bevacizumab.

"Initiating the OnPrime trial represents a major milestone for Genelux," said Thomas D. Zindrick, President and CEO, Genelux. "Based on the positive results of our VIRO-15 Phase 2 trial, we believe that Olvi-Vec-primed immunochemotherapy has the potential to address the high unmet need of patients living with PRROC. Our goal in Phase 3 is to replicate these positive results and transform the treatment paradigm for this particularly difficult-to-treat cancer. We look forward to progressing our study and sharing updates on the Olvi-Vec clinical development program."

To date, Olvi-Vec has been studied in multiple early- and mid-phase clinical trials via regional, local and systemic deliveries, as a monotherapy and in combination with other therapies, in approximately 150 patients with a variety of cancer types. In the VIRO-15 Phase 2 trial, twenty-seven PRROC patients with a median of four prior lines and disease progressed after the last prior line, were enrolled. Olvi-Vec met the pre-established efficacy and safety endpoints as shown in data presented in an Oral Plenary Session at the International Gynecologic Cancer Society 2020 Annual Global Meeting. Median progression-free survival by Response Evaluation Criteria in Solid Tumors (RECIST) 1.1 was 11.0 months (95% CI, 6.7-13.0 months), overall response rate (ORR) by RECIST1.1 was 54%, and ORR by GCIG CA-125 was 85%. The most frequent grade 3 treatment-related adverse event was abdominal pain (7.4%), with no observed treatment-related discontinuations or patient deaths. Our clinical trials have yielded data that has informed future clinical strategy and trial design involving multiple indications and methods of delivery.

OnPrime Study eligibility: Eligible patients will have a minimum of 3 prior lines of therapy, but there is no limitation on the maximal number of prior therapies. The primary endpoint is progression-free survival based on RECIST 1.1 as assessed by a blinded independent central review, with overall response rate, overall survival and safety as key secondary endpoints.

Additional information about OnPrime can be found at www.clinicaltrials.gov (NCT05281471, GOG-3076) and about VIRO-15 Phase 2 trial results can be found at the publications tab of www.genelux.com.

**About Platinum-Resistant/Refractory Ovarian Cancer**
Ovarian cancer is the fifth most common cause of cancer death in women. In 2019, there were an estimated 233,565 women living with ovarian cancer in the United States (including those who had been cured of the disease) [1]. A majority who respond to treatment will relapse, with few treatment options. Median overall survival following recurrence of disease is 12 months or less with single-agent chemotherapy.[2] No approved therapy has been shown to significantly extend overall survival in patients with platinum-resistant/refractory ovarian cancer compared to standard chemotherapy.[3]

[1]Surveillance, Epidemiology, and End Results Program (SEER) database, 2019

[2]Therapeutic Advances in Medical Oncology (*Luvero et al.*, Ther Adv Med Oncol. 2014 Sep;6(5):229-39)

[3]Journal of Clinical Oncology *(Pujade-Lauraine et al.*, J Clin Oncol. 2014 May 1;32(13):1302-8*)*

**About Olvimulogene Nanivacirepvec (Olvi-Vec)**
Olvi-Vec is a proprietary, non-pathogenic oncolytic vaccinia virus, modified to increase its safety, tumor selectivity and therapeutic potential. Virus-mediated oncolysis results in immunogenic cell death and triggers immune activation and memory for long-term immunotherapy against cancer. Olvi-Vec has been administered to more than 150 patients in clinical studies. In these studies, Olvi-Vec was generally well tolerated, and demonstrated evidence of clinical benefit.

**About Genelux Corporation**
Genelux is a clinical-stage biopharmaceutical company focused on developing a pipeline of next-generation oncolytic immunotherapies for patients suffering from difficult-to-treat solid tumor types. The Company's most advanced product candidate, Olvi-Vec (olvimulogene nanivacirepvec), is a proprietary, modified strain of the vaccinia virus, a stable DNA virus with a large engineering capacity. The core of Genelux' discovery and

development efforts revolves around the company's proprietary CHOICE™ platform from which the Company has developed an extensive library of isolated and engineered oncolytic vaccinia virus immunotherapeutic product candidates, including Olvi-Vec.

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**About The GOG Foundation, Inc. (www.gog.org)**
The GOG Foundation, Inc. (GOG) is a not-for profit organization with the purpose of promoting excellence in the quality and integrity of clinical and basic scientific research in the field of gynecologic malignancies. The GOG Foundation is committed to maintaining the highest standards in clinical trials, development, execution, analysis and distribution of results. The GOG Foundation is the only clinical trialist group in the United States that focuses its research on patients with pelvic malignancies, such as cancers of the ovaries, uterus, cervix, vagina, and vulva.

The GOG Partners, a GOG Foundation program, is structured to work directly with pharmaceutical organizations and operate clinical trials outside the National Cancer Institute (NCI) framework. The GOG Partners shares the same mission of the GOG Foundation dedicated to transforming the care in Gynecologic Oncology. By providing an alternative venue for patient accrual and site infrastructure support, GOG Partners has helped provide additional trials and opportunities for patients outside the national gynecologic clinical trials network.