



PRESS RELEASE

## **Genelux Initiates Phase 2 Clinical Trial of GL-ONC1 in Recurrent Ovarian Cancer**

*First patient dosed in Phase 2 Trial (VIRO-15) in Ovarian Cancer at Florida Hospital Cancer Institute (FHCI)*

**SAN DIEGO, CA, September 27, 2017** – Genelux Corporation, a privately-held biopharmaceutical company focused on the development of its proprietary oncolytic immunotherapy platform, today announced that it has treated the first patient in a Phase 2 clinical trial in recurrent ovarian cancer, with its lead clinical-stage candidate, GL-ONC1.

The Phase 2 trial, VIRO-15 (Oncolytic **V**accinia Immunotherapy in **R**ecurrent **O**varian Cancer), is being conducted at Florida Hospital Cancer Institute (FHCI) in Orlando, FL and is being led by Dr. Robert Holloway, a world-renowned gynecologic oncologist with extensive clinical trial experience in gynecologic malignancies. Additional site(s) in the US are planned as the trial progresses.

VIRO-15 is based on positive data of GL-ONC1 from a Phase 1b clinical study conducted at FHCI in heavily pretreated, platinum-resistant/refractory ovarian cancer patients. Administration of GL-ONC1 as a monotherapy was shown to have clinically-significant results, including:

- (i) Documented objective response and tumor-specific T-cell response;
- (ii) A favorable trend of durable response; and
- (iii) A quality of life benefit.

The data exceeded the futility boundary of an equivalent interim analysis for a 2-stage Simon design at the current Phase 2 dose level, supporting the continued development of GL-ONC in this patient population.

Thomas Zindrick, President and CEO of Genelux Corporation, commented, “These exciting data provided Genelux with insights on optimizing parameters to launch our Phase 2 trial, which is an important milestone in the clinical advancement of GL-ONC1.”

Ovarian cancer remains the most lethal gynecologic malignancy owing to late detection, remarkable heterogeneity, intrinsic and acquired chemo-resistance, and recurrence in a majority of patients. Patients who are considered platinum-resistant/refractory following front-line treatment and multiple rounds of chemotherapy have the poorest prognosis. Accordingly, there is an urgent need to develop new therapeutic modalities.

Robert Holloway, MD, FACOG, FACS, Medical Director of Gynecologic Oncology at the Florida Hospital Cancer Institute and Principal Investigator of the current GL-ONC1 trial in ovarian cancer, commented, “The early response and clinical benefit data achieved with GL-ONC1 are particularly impressive in this heavily pre-treated, late-stage patient population who have failed prior therapies and enrolled into our trial with documented progressive disease.”

### **About the Study**

The open label, Phase 2 study ([NCT02759588](https://clinicaltrials.gov/ct2/show/study/NCT02759588)) is currently recruiting participants, is expected to enroll up to a total of 40 patients, in two cohorts, with recurrent ovarian, fallopian tube, or primary peritoneal cancer. The monotherapy treatment regimen consists of a single cycle, with GL-ONC1 being intraperitoneally administered to patients in bolus infusions on 2 consecutive days. The study’s primary

endpoint is progression-free survival, and secondary endpoints include incidence of adverse events, anti-tumor response, objective response, disease control rate, and overall survival.

#### **About GL-ONC1**

GL-ONC1, the company's lead product candidate, is an attenuated therapeutic vaccinia virus, a non-pathogenic virus, modified by Genelux to increase its safety, tumor selectivity and anti-tumor activity. Clinical results in over 100 subjects treated in Genelux studies have shown GL-ONC1 is well tolerated with documented clinical benefits.

#### **About Genelux Corporation**

Headquartered in San Diego, California, Genelux Corporation is a leader in oncolytic immunotherapy, utilizing its potent CHOICE™ discovery platform to develop a library of proprietary, oncolytic vaccinia virus-based diagnostic and therapeutic candidates. For more information please visit [www.genelux.com](http://www.genelux.com).

#### **Contact**

Investor Relations  
[info@genelux.com](mailto:info@genelux.com)  
(909) 307-9300