



PRESS RELEASE

Genelux Initiates Two Clinical Trials of GL-ONC1 in Ovarian Cancer and Solid Organ Cancers with Leading Oncology Institutions

First two patients dosed in Phase 1b Trial in Ovarian Cancer at Florida Hospital Cancer Institute (FHCI)

First three patients dosed in Phase 1b Trial in Solid Organ Cancers at Moores Cancer Center at UC San Diego Health

Results of both trials represent significant near-term milestones

SAN DIEGO, CA, July 28, 2016 – Genelux Corporation, a clinical-stage biopharmaceutical company focused on the development of proprietary oncolytic vaccinia virus for immunotherapy of cancers, today announced that it has initiated two new Phase 1b clinical trials of its lead oncolytic virotherapy GL-ONC1 with leading oncology institutions, Florida Hospital Cancer Institute (FHCI) in Orlando and Moores Cancer Center at UC San Diego Health.

Thomas Zindrick, President and CEO of Genelux Corporation, commented, “The initiation of these two trials with leading U.S. medical institutions is a significant milestone in the clinical advancement of GL-ONC1 and will provide Genelux with significant near-term data milestones. Following positive results in four completed clinical trials including the two Phase 1 trials in head and neck cancer and mesothelioma presented at the 2015 ASCO Annual Meeting, which confirmed the safety and favorable trend of clinical benefits of GL-ONC1 administered either intravenously (IV) or intrapleurally, we are excited to have commenced further evaluation of our lead oncolytic virotherapy. While the focus of the Phase I trials was safety, we are pleased to see a consistent efficacy trend across our studies conducted at different sites, with different premier investigators, under different protocols and in different cancer types. These data provide us with insights on optimizing treatment schedule, dosing, routes of delivery, and help us to improve the design of future trials.”

Mr. Zindrick continued, “Our next primary goal is to establish the optimized parameters of a strategic Phase 2 clinical trial design in ovarian cancer. In addition, results from the solid organ cancer trial will inform dosing parameters for improving the anti-tumor activity of GL-ONC1 via systemic delivery, particularly in targeting dispersed and difficult-to-treat metastatic diseases, which will provide an important clinical advantage over other virotherapies. We look forward to continuing enrollment and providing first clinical results of both studies by the first half of 2017.”

Clinical Trial for Ovarian Cancer at Florida Hospital

A Genelux-sponsored dose-escalation clinical trial of GL-ONC1 ([NCT02759588](https://clinicaltrials.gov/ct2/show/study/NCT02759588)) is being conducted at Florida Hospital Cancer Institute and is being led by Dr. Robert Holloway, a world-renowned gynecologic oncologist, to evaluate the safety, tolerability and antitumor effect of GL-ONC1 in female patients with

recurrent ovarian cancer. The first two patients have been dosed, with the second patient dosed this week and, to date, both show the treatment was well-tolerated.

GL-ONC1 is administered intraperitoneally at high doses over a condensed schedule. Additionally, a Phase 2a expansion portion of the study is anticipated following interim data analysis. In subsequent stages of the trial, GL-ONC1 will be administered as combination therapy to further augment the clinical effect. Furthermore, Genelux expects that the results of this trial will establish the optimal parameters to propose a Phase 2 clinical trial design focusing on the registration pathway in ovarian cancer.

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, "Ovarian cancer remains a challenging cancer to treat effectively. Despite improvements in median survival over the past few decades through new drug development and improved surgery, there has been only modest improvements in overall survival, or cure rates. Unfortunately, approximately three-fourths of patients who achieve a full remission following first-line therapy develop recurrent disease that requires ongoing treatment, but most often results in death.¹ In clinical trials to date, GL-ONC1 has demonstrated safety and promising broad-spectrum anti-cancer activity across a number of tumor types including ovarian cancer, and we are very enthusiastic about evaluating this oncolytic immunotherapy as a potentially vital treatment option for women with recurrent ovarian cancer."

Clinical Trial for Solid Organ Cancers at Moores Cancer Center

An investigator-initiated dose-escalation clinical trial ([NCT02714374](https://clinicaltrials.gov/ct2/show/study/NCT02714374)) is being conducted at Moores Cancer Center and led by Dr. Kaitlyn Kelly, a surgical oncologist trained at the prestigious Memorial Sloan-Kettering Cancer Center (MSKCC), to evaluate the safety and efficacy of GL-ONC1 alone or in combination with eculizumab (marketed as Soliris®) prior to surgery in patients with advanced solid organ cancers.

The study is designed to answer fundamental questions regarding the optimal systemic administration of GL-ONC1. GL-ONC1 is administered intravenously in the form of an aggressive dosing regimen. The first three patients have been dosed and have shown the treatment to be well-tolerated.

Genelux anticipates the results of this trial will inform dosing parameters to further augment the anti-tumor activity of GL-ONC1 virotherapy, particularly in targeting dispersed and difficult-to-treat metastatic diseases, which would provide an important clinical advantage over other virotherapies. A Phase 2a expansion portion of the study is anticipated following interim data analysis.

Dr. Kaitlyn Kelly, Assistant Professor of Surgery at Moores Cancer Center and Principal Investigator of this trial, commented, "In previous trials across various tumor types and via multiple different administrations, GL-ONC1 has successfully demonstrated an enhanced ability to select, infiltrate and destroy tumors while leaving healthy tissue unharmed. We are excited to collaborate with Genelux to initiate this clinical trial in solid organ cancers to expand our evaluation of systemic administration and identify tumor types to focus on for further development of this unique oncolytic vaccinia virus for immunotherapy of cancers."

References

1. Cancer Network. <http://www.cancernetwork.com/oncology-journal/recurrent-epithelial-ovarian-cancer-update-treatment>

About GL-ONC1

GL-ONC1, the company's oncology product candidate, is an attenuated therapeutic vaccinia virus for immunotherapy of cancers. Vaccinia virus, a non-pathogenic virus, was used safely in millions of people as the vaccine against smallpox. Scientists at Genelux have modified this virus to increase its safety, tumor selectivity and anti-tumor activity. Virus-mediated oncolysis results in immunogenic cell death and triggers immune activation and memory for long-term immunotherapy against cancer. GL-ONC1 has been and is currently under evaluation in multiple Phase 1/1b/2a clinical trials in the U.S. and Europe. Clinical results have shown GL-ONC1 is well tolerated with minimal toxicity and exhibits evidence of anti-tumor activities.

About Genelux Corporation

Headquartered in San Diego, California, Genelux Corporation is a privately-held, clinical-stage biopharmaceutical company dedicated to fundamentally changing the way in which cancer is diagnosed and treated. The company has developed a proprietary, oncolytic vaccinia virus-based immunotherapy platform. Such a platform can also be engineered to carry additional foreign genes with powerful therapeutic and diagnostic capabilities. For more information please visit www.genelux.com.

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