PRESS RELEASE

Genelux Announces Promising Data from Two Phase I Trials of GL-ONC1 in Head & Neck Cancer and Mesothelioma

Data Demonstrate Favorable Safety Profile and Anti-Tumor Activity

Results to be presented at ASCO Annual Meeting 2015 during Two Poster Presentations

SAN DIEGO, May 27, 2015 – Genelux Corporation, a clinical-stage biopharmaceutical company focused on the development of vaccinia virus for oncolytic immunotherapy, today announced that data from two Phase I trials evaluating its lead oncolytic virotherapy GL-ONC1 in head and neck cancer and malignant pleural mesothelioma demonstrate a favorable safety profile and support further investigation of the therapy in both indications.

The results will be presented by lead investigators from **Memorial Sloan Kettering Cancer Center** and **UC San Diego Moores Cancer Center** at the upcoming 2015 American Society of Clinical Oncology (ASCO) Annual Meeting, being held May 29-June 2 in Chicago, IL.

Thomas Zindrick, President & CEO of Genelux Corporation, commented, "Data from our two Phase I trials evaluating GL-ONC1 in head and neck cancer and in mesothelioma further validate the proof of concept and add to the growing body of evidence underpinning the safety and efficacy of our lead oncolytic virotherapy. Together, these findings confirm the safety of GL-ONC1 administered either intravenously or intrapleurally, which is important for designing future studies and optimally tailoring the therapy for specific cancers in patients as we continue to advance our clinical development programs. The head and neck trial is the first to establish the safety of intravenously-delivered GL-ONC1 in combination with radiation and chemotherapy for patients with locoregionally advanced head and neck carcinoma. In addition, the Phase I trial in patients with malignant pleural effusion demonstrates a favorable safety profile for single, escalating doses of GL-ONC1 and indicates the potential of GL-ONC1 as an efficacious treatment for mesothelioma patients, meriting the ongoing evaluation at multiple doses."

Data from the two Phase I trials are outlined below.

Abstract 6026 (Poster 349) – Phase I trial of intravenous administration of attenuated vaccinia virus (GL-ONC1) with concurrent chemoradiotherapy (CRT) for locoregionally advanced head and neck carcinoma.[1]

Lead Investigator:	Loren K. Mell, M.D., UC San Diego Moores Cancer Center
Poster Session:	Head and Neck Cancer
Date, Time, Location:	Saturday, May 30; 1:15 - 4:45 p.m. CDT; S Hall A, McCormick Place

Data from 19 enrolled patients who completed the Phase I trial demonstrate and establish the safety of intravenously-delivered GL-ONC1 in combination with radiation and chemotherapy for patients with locoregionally advanced head and neck carcinoma and support further evaluation in this patient population.

The open-label, single-arm, dose-escalation study (NCT01584284) evaluated increasing doses of GL-ONC1 plus radiation and cisplatin in five cohorts of patients with late-stage disease (IVA or IVB), without reaching the maximum tolerated dose, indicating increased doses of GL-ONC1 may be feasible within the well-tolerated safety profile. Enrollment focused mostly on patients who have HPV-negative head and neck cancer, who are known to have poorer responses to standard of care than those with HPV-positive cancer.

Loren K. Mell, MD, Chief of the Head and Neck Radiation Oncology Service and Director of the Clinical and Translational Research Division for the Department of Radiation Medicine and Applied Sciences at UC San Diego Moores Cancer Center and lead investigator of the Phase I GL-ONC1 study in head and neck cancer, said, "These findings are very encouraging as they establish the safety of GL-ONC1 when intravenously administered to patients with advanced head and neck cancer and indicate its potential efficacy based on overall response rate and survival benefit analyses, such as progression free survival, in this patient population. GL-ONC1 warrants further evaluation in a Phase II trial."

Grade 1 or 2 adverse events included rigors (47%), thrombocytopenia, or low blood platelet count (32%), fever (26%) and rash (21%), with the transient and self-limiting rash confirmed to be viral in origin in two patients.

The study also assessed tumor susceptibility to viral infection in baseline specimens and for tumor infection on mid-treatment biopsies. Viral infection of tumor tissue was confirmed through quantitative PCR of viral DNA in four patients. No shedding of virus was found in saliva and urine samples.

The study found 1-year and 2-year progression-free survival (PFS) rates at 66% and 57%, respectively, and overall survival (OS) rates for the same durations at 86% and 76% respectively in HPV-negative stage IV patients, which is significantly more favorable than the well-documented historical data of 1-and 2-year PFS at 60% and 45%, and OS at 70% and 60% as reported by Ang *et al*. that included both stage III & IV patients (NEJM 2010; 363(1): 24–35).

Abstract 7559 (Poster 307) – Phase I study of intra-pleural administration of GL-ONC1, an oncolytic vaccinia virus, in patients with malignant pleural effusion (MPE).[2]

Lead Investigator:	Lee M. Krug, MD, Memorial Sloan Kettering Cancer Center
Poster Session:	Lung Cancer—Non-Small Cell Local-Regional/Small Cell/Other Thoracic Cancers
Date, Time, Location:	Monday, June 1; 8:00 - 11:30 a.m. CDT; S Hall A, McCormick Place

Data from 13 evaluable patients with pleural effusion, a buildup of fluid in the chest cavity caused by cancer, from malignant pleural mesothelioma (MPM), non-small cell lung cancer (NSCLC), or breast cancer, demonstrate that a single dose of GL-ONC1 administered intrapleurally is safe and feasible.

Lee M. Krug, MD, Deputy Chief of Thoracic Oncology Service at Memorial Sloan Kettering Cancer Center and one of the lead investigators of the Phase I study of GL-ONC1 in pleural effusion patients, commented, "Results from this study are encouraging, and confirm the safety profile of intrapleurally-administered GL-ONC1, with no dose limiting toxicities observed. In addition, the study signals GL-ONC1's potential as a viable treatment for patients with mesothelioma. The lab results confirmed viral infection of mesothelioma tumors at a high rate. Based on these findings of single dose GL-ONC1, we are

now exploring multi-day treatment, and treatment in conjunction with pleurectomy for patients with MPM. ”

The open-label, single-arm, dose-escalation study (NCT01766739) evaluated increasing single doses of GL-ONC1 and found no dose limiting toxicities. The most common toxicities were all Grade 1 or 2 occurring mostly in the 24 hours following infusion, and were fever (n=7), chills (n=6), and flu-like symptoms (n=5). One patient at dose level 4 had transient Grade 3 elevation of liver enzymes (AST/ALT).

In addition, blood, sputum, and urine samples taken post-treatment for viral shedding analysis by viral plaque assays (VPA) were all negative aside from one of 28 urine samples showing positive. GL-ONC1 infection of tumor specimens was confirmed in six of eight patients with MPM and overall nine of 13 evaluable patients. Furthermore, the study demonstrated five of the nine patients with epithelioid MPM had time to progression at 9 months, with one patient experiencing time to progression at 18 months. Patients continue to be followed in this ongoing trial.

About GL-ONC1

GL-ONC1, the company’s lead oncology product candidate, is an attenuated vaccinia virus (Lister strain). 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 is currently under evaluation in multiple Phase 1 and 1/2 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 activity.

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, vaccinia virus-based technology platform. Such a platform can also be engineered to insert specific genes for delivery of therapeutic and diagnostic proteins. For more information please visit www.genelux.com.

References

1. Mell, L. *et al*. J Clin Oncol 33, 2015 (suppl; abstract 6026)
2. Krug, L. *et al*. J Clin Oncol 33, 2015 (suppl; abstract 7559)

Contact

The Ruth Group
Lee Roth (investors)
lroth@theruthgroup.com
(646) 536-7012

Kirsten Thomas (media)
kthomas@theruthgroup.com
(646) 536-7014