Genelux to Present Data from Phase 2 Trial of Olvi-Vec in Heavily Pre-treated Platinum-Resistant/Refractory Ovarian Cancer at ESMO Virtual Congress 2020

September 16, 2020

- Treatment with olvimulogene nanivacirepvec (Olvi-Vec)-primed immunochemotherapy shows promising overall survival benefit in this heavily pretreated late-stage patient population

- The majority of patients benefited from apparent reversal of platinum resistance with preserved or improved performance status

- Olvi-Vec treatment was tolerated with safety results consistent with previous Phase 1b study

SAN DIEGO, Sept. 16, 2020 /PRNewswire/ -- Genelux Corporation, a privately-held biopharmaceutical company, today announced that data from the Phase 2 VIRO-15 study evaluating its lead oncolytic virus, Olvi-Vec-primed immunochemotherapy in platinum-resistant/refractory ovarian cancer (PRROC) (NCT02759588), will be presented at the upcoming European Society for Medical Oncology (ESMO) Virtual Congress 2020, being held September 19-21.

"The Phase 2 data in PRROC patients demonstrated remarkable overall survival in combination with a platinum-based regimen, especially in the difficult-to-treat platinum-refractory disease population, considering these patients were heavily pretreated and largely at pre-hospice stage," said Robert Holloway, MD, principal investigator for VIRO-15 and Chair of Genelux's Clinical Advisory Board on gynecologic cancers.

"Genelux is pleased with the promising data out of the Phase 2 VIRO-15 study, and we are optimistic about the potential of Olvi-Vec-primed immunochemotherapy to extend the life expectancy and improve the quality of life of patients who currently lack effective treatment options," said Thomas Zindrick, J.D., President and CEO of Genelux. "A registration trial of Olvi-Vec-primed immunochemotherapy is being planned."

Data from the Phase 2 VIRO-15 trial are outlined below.

Abstract Number: 2982

Abstract Title: *Phase 2 Trial of Oncolytic Vaccinia Virus Olvi-Vec-Primed Immunochemotherapy in Heavily Treated Platinum-Resistant/Refractory Ovarian Cancer (PRROC)*

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Session Title/Date: ESMO Virtual Congress 2020, Science Weekend, September 19-21, 2020

Abstract Highlights:

Background: Intraperitoneal infusion of Olvi-Vec virus followed by IV carboplatin-doublet (CD) ± bevacizumab (Bev) in heavily pretreated patients with PRROC was evaluated. Primary objectives were RECIST overall response rate (ORR) and progression-free survival (PFS). Secondary objectives included overall survival (OS), CA-125 response, safety and translational studies.

Methods: Patients who progressed on most recent therapies received 2 consecutive days of Olvi-Vec followed by CD ± Bev, and then maintenance single agent ± Bev. Pre- & post-virotherapy tumor biopsies and blood were obtained for analyses.

Key results: 27 patients (median 4 prior lines, 52% platinum-refractory, 48% platinum-resistant) enrolled. Median OS was 15.7 mos (95% CI: 12.3 – 23.5) for all patients. 9/27 (33.3%) patients have survival > 18 months, with 4 of these patients still alive beyond 3-4 years. In patients with platinum-refractory disease, median OS was 15.2 months (95% CI: 10.8 – 33.6).

Conclusions: Despite having PRROC and documented disease progression at enrollment, most patients responded to CD therapies after oncolytic virotherapy, with OS exceeding historical comparisons in heavily pretreated PRROC patients. Virus-induced changes in the tumor microenvironment may explain the apparent reversal of platinum resistance.

About Olvimulogene Nanivacirepvec (Olvi-Vec)
Olvi-Vec is a proprietary, non-pathogenic oncolytic vaccinia virus, modified 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. Clinical results in more than 150 subjects have shown Olvi-Vec 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.

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