REDEFINING IMMUNO-ONCOLOGY

Genelux Announces Oral Plenary Presentation of VIRO-15 Phase 2 Trial Data at the 2020 xDigital Annual Global Meeting of the International Gynecologic Cancer Society

September 10, 2020

-- Treatment with olvimulogene nanivacirepvec (Olvi-Vec)-primed immunochemotherapy shows objective response and progression-free survival clinical benefits well exceed historical comparisons and patients' own last prior therapy

-- 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. 10, 2020 /PRNewswire/ -- Genelux Corporation, a privately-held biopharmaceutical company, today announced that the abstract covering data from the VIRO-15 Phase 2 trial (NCT02759588) has been accepted for an Oral Plenary Session at the 2020 xDigital Global Annual Meeting of the International Gynecologic Cancer Society (IGCS). VIRO-15 assessed Olvi-Vec in combination with a platinum-based regimen in platinum-resistant/refractory ovarian cancer (PRROC) patients. These data are being presented on Friday, September 11, 2020.

"We are encouraged by the Phase 2 data in PRROC patients, which show Olvi-Vec is well tolerated and demonstrated remarkable anti-tumor activity with durable responses in combination with a platinum-based regimen, especially in patients with difficult-to-treat platinum-refractory disease," said Robert Holloway, MD, principal investigator for VIRO-15 and Chair of Genelux's Clinical Advisory Board on gynecologic cancers. "Translational analyses results point to Olvi-Vec-mediated immune modulation of the tumor microenvironment and long-term therapeutic effect with cytotoxic platinum-based chemotherapy."

Key findings in 27 heavily pre-treated PRROC patients (median 4 prior lines; 48% platinum-resistant, 52% platinum-refractory) who had documented disease progression from their last line of therapy prior to enrollment are as follows (data of patients eligible for evaluation after initiation of chemotherapy):

- Median Progression-free Survival (PFS) is 11.0 months (95% CI: 6.7 – 13.0) and PFS-6-month is 77%.
- Objective Response Rate (ORR) by RECIST1.1 criteria is 54% [95% CI: 33-74%; 2 (8%) complete response (CR), 11 (46%) partial response (PR)]; median Duration of Response is 7.6 months; and 86% of patients achieved tumor shrinkage.
- ORR by CA-125 tumor biomarker is 85% [95% CI: 65-96%; 10 (38%) CR, 12 (46%) PR]; and 96% of patients achieved decrease of CA-125.
- There are no differences in PFS & ORR between platinum-resistant & -refractory patients.
- Most common adverse events: Grades 1&2 (≥ 20% patients) were pyrexia 59%, nausea 48%, abdominal distension 44%, abdominal pain 44%, chills 37%, fatigue 33% and vomiting 26%; Grade 3 (≥ 2 patients) were abdominal pain 7% and hypophosphatemia 7%; Grade 4 (none).
- Performance status was preserved or improved in 93% of patients while on subsequent platinum-based regimen.
- Translational analyses data indicate Olvi-Vec engages the immune system and induces favorable immune response (such as large intraepithelial infiltration of CD4+ & CD8+ T cells into tumors) and gene expression changes to the tumor microenvironment to aid clinical reversal of platinum resistance.

"Genelux is excited about the potential of Olvi-Vec-primed immunochemotherapy to generate meaningful clinical responses and improve the quality of life of PRROC 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."

Oral Presentation Session Details
Title: Oncolytic Vaccinia (Olvi-Vec) Primed Immunochemotherapy in Heavily Treated Platinum-Resistant/Refractory Ovarian Cancer
Session Information: Plenary III
Date/Time: Friday, September 11, 2020/ 7:25 a.m. Eastern Time/11:25 a.m. Coordinated Universal Time
Presenter: Robert W. Holloway, MD, Medical Director, Gynecologic Oncology, AdventHealth Cancer Institute, Orlando, FL, USA
Additional information can be found at www.igcs.org

About Olvimulogene Nanivacirepvec
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 over 150 subjects treated in Genelux studies 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.

Contacts

Investor Relations
Kim Duffy
info@genelux.com
(909) 307-9300

Tiberend Strategic Advisors, Inc.
Miriam Miller (Investors)
mmiller@tiberend.com
212-375-2694

Ingrid Mezo (Media)
imezo@tiberend.com
646-604-5150

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