

Genelux Corporation Announces Productive Type C Meeting with FDA

Continues Preparation of Registrational Trial of Olvi-Vec in the Treatment of Platinum-Refractory/Resistant Ovarian Cancer Patients



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SAN DIEGO, May 7, 2020 /PRNewswire/ -- Genelux Corporation, a privately-held, clinical-stage immunotherapy company, today announced the outcome of a Type C meeting with the U.S. Food and Drug Administration (FDA) held on May 6, 2020. The discussion focused on elements of the Company's proposed Phase 3 registrational clinical trial design for oncolytic virus Olvi-Vec in the treatment of platinum-refractory/resistant ovarian cancer, a patient population with grave prognosis and a significant unmet medical need.

"We are pleased with the guidance received from the FDA and appreciate their continued collaborative approach in our clinical advancement of Olvi-Vec," said Thomas Zindrick, President and CEO of Genelux. "Genelux looks forward to incorporating their guidance as we prepare for our End-of-Phase 2 meeting to advance Olvi-Vec into a registrational trial."

This was the Company's second meeting with the FDA in the past 12 months, with plans for the next FDA meeting later this year following data lock of the Phase 2 VIRO-15 trial in 4Q 2020. The Company plans to initiate its Phase 3 Registrational trial and to extend clinical development of VIRO-15 to other indications, including platinum-resistant cervical cancer, in 2021.

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. The Company planned to present the VIRO-15 data as a Featured Poster presentation discussion session at the Society of Gynecologic Oncology (SGO) 2020 Annual Meeting (March 28-31 in Toronto, Canada), which was canceled due to the COVID-19 pandemic and is planning to present its data at a future oncology conference.

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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