Genelux Corporation Announces Publication of Positive Topline Data from Phase 2 VIRO-15 Trial Evaluating Olvimulogene Nanivacirepvec (Olvi-Vec) in Platinum-Resistant or Refractory Ovarian Cancer in the Journal of the American Medical Association (JAMA) Oncology

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- *Phase 2 Trial of Olvi-Vec-primed immunochemotherapy in heavily pre-treated patients*
  - *Met primary endpoint of objective response rate with deep and durable responses*
  - *Generated promising progression-free survival*
  - *Demonstrated clinical reversal of platinum resistance and refractoriness*
- *Phase 3 OnPrime/GOG-3076 randomized active-controlled registrational trial in collaboration with GOG Foundation/Partners is currently enrolling*
- *The Article was featured on JAMA Oncology's podcast with lead investigator, Robert W. Holloway, MD*

WESTLAKE VILLAGE, Calif., May 25, 2023 (GLOBE NEWSWIRE) -- Genelux Corporation (NASDAQ: GNLX), a late clinical-stage immuno-oncology company, today announced the publication of positive topline results from its Phase 2 VIRO-15 trial of Olvi-Vec-primed immunochemotherapy in heavily pretreated patients with platinum-resistant or -refractory ovarian cancer (PRROC) in JAMA Oncology. The article by Holloway *et al*. was published in print and online and is available here.

"We are incredibly pleased to have the Phase 2 trial data featured as an Original Investigation in such a prominent peer-reviewed journal. The results published in JAMA Oncology add to the body of evidence supporting the clinically-meaningful efficacy and safety of Olvi-Vec," said Thomas Zindrick, President, Chairman and CEO of Genelux. "Furthermore, we were privileged to have a companion Editorial of our Phase 2 data which we believe further validates the use of our proprietary oncolytic virus in the treatment paradigm of ovarian cancer."

Patients with PRROC have limited therapeutic options, representing a considerable unmet medical need. In this Phase 2 clinical trial of 27 patients [platinum-resistant (n=14) or platinum-refractory (n=13)] and median 4 prior lines of therapy, Olvi-Vec followed by platinum-based chemotherapy ± bevacizumab as immunochemotherapy demonstrated objective response rate (ORR) of 54% and a median progression-free survival (PFS) of 11.0 months with a manageable safety profile.

Key Findings

- All patients completed both Olvi-Vec infusions and chemotherapy. Median follow-up duration was 47.0 months (95% CI, 35.9 months to NA, upper limit not reached).
- ORR by RECIST1.1 was 54% (95% CI, 33%-74%), with Duration of Response of 7.6 months (95% CI, 3.7-9.6 months). Disease Control Rate was 88% (21/24). Overall, 19 of 22 evaluable patients (86%) showed tumor shrinkage. ORR by tumor biomarker CA-125 was 85% (95% CI, 65%-96%), and 25 of 26 evaluable patients (96%) exhibited decreased CA-125 levels.
- Median PFS by RECIST1.1 was 11.0 months (95% CI, 6.7-13.0 months), and 6-month PFS rate was 77% in all patients. Median PFS was 10.0 months (95% CI, 6.4-NA months) in the platinum-resistant group and 11.4 months (95% CI, 4.3-13.2 months) in the platinum-refractory group.
- Median overall survival (OS) was 15.7 months (95% CI, 12.3-23.8 months) in all patients, with median OS of 18.5 months (95% CI, 11.3-23.8 months) in platinum-resistant group and 14.7 months (95% CI, 10.8-33.6 months) in platinum-refractory group.
- Most frequent treatment-related adverse events (TRAEs) (any grade, grade 3) were pyrexia (63.0%, 3.7%) and abdominal pain (51.9%, 7.4%). There were no grade 4 treatment-related adverse events and no treatment-related discontinuations or deaths.

Robert W. Holloway, MD, the lead investigator and the Medical Director of the Gynecologic Oncology Program at AdventHealth Cancer Institute, Orlando said, "The results from the Phase 2 trial suggest potential survival benefits of this novel immunochemotherapy approach for women with recurrent platinum-resistant or -refractory disease. This patient population represents a considerable unmet medical need in gynecologic oncology. The data also demonstrated modification of the tumor immune microenvironment with oncolytic virus Olvi-Vec in ways that reverse platinum resistance, and in addition induce tumor specific T-cell response. We believe the currently enrolling Phase 3 OnPrime/GOG-3076 clinical trial will hopefully provide more evidence that we can produce a life changing therapy."

Dr. Holloway further discussed the article "*Clinical Activity of Olvimulogene Nanivacirepvec–Primed Immunochemotherapy in Heavily Pretreated Patients With Platinum-Resistant or Platinum-Refractory Ovarian Cancer - The Nonrandomized Phase 2 VIRO-15 Clinical Trial*" on the JAMA Oncology podcast series interviewed by Dr. Jack West, Clinical Executive Director for AccessHope and an Associate Professor in Medical Oncology at City of Hope. The podcast is available on iTunes , Spotify and other streaming platforms.

About Olvimulogene Nanivacirepvec (Olvi-Vec)
Olvi-Vec is a proprietary, oncolytic vaccinia virus, modified to increase its safety, tumor selectivity and therapeutic potential. Vaccinia virus is a non-human pathogen utilized as a vaccine to eradicate smallpox. Virus-mediated oncolysis results in immunogenic cell death and triggers immune activation and memory for long-term immunotherapy against cancer. Olvi-Vec has been administered to more than 150 patients in clinical studies. In these studies, Olvi-Vec was generally well tolerated and the data provided evidence of clinical benefit.

About Genelux Corporation
Genelux is a late clinical-stage biopharmaceutical company focused on developing a pipeline of next-generation oncolytic immunotherapies for patients suffering from aggressive and/or difficult-to-treat solid tumor types. The Company's most advanced product candidate, Olvi-Vec (olvimulogene nanivacirepvec), is a proprietary, modified strain of the vaccinia virus (VACV), a stable DNA virus with a large engineering capacity. Olvi-Vec currently is being evaluated in Phase 3 OnPrime/GOG-3076, a multi-center, randomized, open-label registrational trial, evaluating the efficacy and safety of Olvi-Vec in patients with platinum-resistant/refractory ovarian cancer. The core of Genelux' discovery and development efforts revolves around the company's proprietary CHOICE™ platform from which the Company has developed an extensive library of isolated and engineered oncolytic vaccinia virus immunotherapeutic product candidates, including Olvi-Vec. For more information please visit www.genelux.com.

Forward-Looking Statements
This release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and such forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. "Forward-looking statements" describe future expectations, plans, results, or strategies and are generally preceded by words such as "believes," "anticipates," "expect," "may," "plan" or "will". Forward-looking statements in this release include, but are not limited to, statements related to Olvi-Vec being a life-changing therapy for patients with PRROC. Such statements are subject to a multitude of risks and uncertainties that could cause future circumstances, events, or results to differ materially from those projected in the forward-looking statements. These and other risks are identified under the caption "Risk Factors" in Genelux' filings with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date. Genelux does not undertake any obligation to publicly update any forward-looking statements, whether as a result of the receipt of new information, the occurrence of future events or otherwise.

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