Genelux Corporation Reports Encouraging Interim Data of Systemic Administration of Olvi-Vec in Ongoing Lung Cancer Trials

January 5, 2026

-- Interim data from 14 patients with progressive lung cancers in dose-escalation cohorts of systemically administered Olvi-Vec-primed immunochemotherapy across ongoing SCLC and NSCLC trials; enrollment ongoing –

-- In platinum-relapsed or platinum-refractory advanced SCLC, two of three partial responses (PRs) occurred in the highest dose cohort tested as of the data review cutoff date (tumor shrinkage of ~55% and ~85%), with three PRs out of nine subjects (33%) across all dose cohorts; observed durable response signals and treatment tolerability (Phase 1b/2 SCLC) --

-- In advanced or metastatic recurrent NSCLC, observed anti-tumor activity in initial dose cohort and Olvi-Vec generally well tolerated (Phase 2 VIRO-25) --

-- Additional systemic lung cancer data expected throughout 2026, alongside topline data from Phase 3 ovarian cancer trial (OnPrime/GOG-3076) in second half of 2026 --

WESTLAKE VILLAGE, Calif., Jan. 05, 2026 (GLOBE NEWSWIRE) -- Genelux Corporation (NASDAQ: GNLX), a late clinical-stage immuno-oncology company, today announced interim results from two ongoing trials – Phase 1b/2 SCLC and Phase 2 VIRO-25 - evaluating systemic (intravenous) administration of Olvi-Vec in patients with progressive small cell lung cancer (SCLC) and progressive non-small cell lung cancer (NSCLC), respectively, after failure of prior platinum-based regimens.

Together, the open-label studies are designed to demonstrate that the Olvi-Vec-primed immunochemotherapy mechanism of resensitizing tumors to platinum-based chemotherapy can extend beyond intraperitoneal delivery into a systemic delivery setting across multiple solid tumor types.

“We are encouraged by the emerging data from our lung cancer programs, where systemically delivered Olvi-Vec continues to demonstrate promising anti-tumor activity and tolerability in patients with relapsed or refractory lung cancers,” said Thomas Zindrick, President, CEO, and Chairman of Genelux. “While these data remain preliminary, they reinforce our commitment to advancing two registration-path trials in progressive lung cancers, addressing a significant unmet medical need and building on our success in platinum-resistant/refractory ovarian cancer. We remain focused on establishing Olvi-Vec as a differentiated immunotherapeutic agent designed to modify the tumor microenvironment and resensitize tumors to platinum-based chemotherapy across multiple types of cancer. Looking ahead, 2026 will be a pivotal year with topline data from the Phase 3 registration trial in ovarian cancer expected in the second half and additional lung cancer trial readouts anticipated throughout the year.”

Platinum-relapsed or platinum-refractory advanced SCLC (OLVI-VEC-SCLC-202 Ph1b/2 Clinical Trial)

The open-label Phase 1b/2 SCLC trial (NCT07136285) is evaluating a single intravenous cycle with multiple doses of Olvi-Vec administered in combination with platinum and etoposide chemotherapy in SCLC patients with platinum-relapsed or platinum-refractory disease after failing previous treatment with platinum and etoposide chemotherapy. The trial is being conducted by the Company’s licensing partner, Newsoara HYK Biopharmaceuticals Co., Ltd. (Newsoara), in China.

As of the data review cutoff date of December 23, 2025, systemic administration of Olvi-Vec in the initial dose escalation cohorts achieved the following preliminary results:

- 9 evaluable patients
- Overall response rate (ORR) of 33% (3/9 patients), including three PRs
  - Two of the three PRs occurred in Cohort 4, the highest dose cohort tested as of the data review cutoff date, with tumor shrinkage of approximately 55% and 85% from baseline, representing an ORR of 67% (2/3) in Cohort 4 and potentially suggesting a dose-response trend
- Disease control rate (DCR) of 67% (6/9 patients)
  - Tumor shrinkage of 24–85% among the six DCR patients, all of whom experienced a reduction in all target lesions from baseline
- Olvi-Vec generally well tolerated
- Exploratory durability signals: Two PR patients across different cohorts have been evaluated in long-term follow-up:
  - A patient with 1 prior line, at last scan, achieved a PR with an ongoing progression-free survival (PFS) of 12.1 months
  - A patient with 4 prior lines had a PFS of 7.7 months, which exceeds the PFS in the immediately preceding line in the same patient (1.9 months) by 5.8 months

Notably, this SCLC trial is primarily evaluating safety and tolerability and, as such, patients who achieved objective responses from Olvi-Vec immunochemotherapy in this trial do not receive any subsequent standard maintenance immunotherapy to extend durability of response.

Advanced or metastatic recurrent NSCLC (Phase 2 VIRO-25 Clinical Trial)

The open-label Phase 2 VIRO-25 trial (NCT06463665) is evaluating a single intravenous cycle with multiple doses of Olvi-Vec in combination with platinum chemotherapy and an immune checkpoint inhibitor (ICI) in patients with advanced or metastatic recurrent NSCLC who failed standard frontline treatment of platinum chemotherapy and an ICI. The trial is being conducted in the United States.

As of the data review cutoff date of December 31, 2025, systemic administration of Olvi-Vec in the initial dose escalation cohorts achieved the following preliminary results:

- 5 evaluable patients
- DCR of 60% (3/5 patients)
- Tumor size changes among the three DCR patients were 8.9%, -18.9%, and -22.7%, respectively, as compared to baseline
- Olvi-Vec generally well tolerated

Upcoming Milestones

The Phase 1b/2 SCLC trial and Phase 2 VIRO-25 trial are actively enrolling in dose escalation cohorts with an aim to optimize efficacy, safety, and tolerability of Olvi-Vec. The trials are being conducted to align a systemic dosing regimen to support future multi-regional registrational clinical trials.

- Additional interim (updated dose-finding) data readouts expected throughout 2026 in Phase 1b/2 SCLC trial and Phase 2 VIRO-25 trial
- Topline data from the Phase 3 platinum-resistant/refractory ovarian cancer trial (OnPrime/GOG-3076) expected in second half of 2026

About Olvi-Vec

Olvi-Vec (olvimulogene nanivacirepvec), Genelux's lead investigational asset, is a proprietary, modified vaccinia virus being evaluated as an oncolytic immunotherapy. Olvi-Vec's differentiated mechanism of action (MoA) is designed to directly kill cancer cells, stimulate a tumor-specific immune response, remodel the tumor microenvironment, and resensitize tumors to platinum-based chemotherapy with or without ICIs. Genelux is developing Olvi-Vec immunotherapy for multiple cancer types in a strategically integrated program based on robust preclinical data and clinical evidence of its differentiated MoA, feasibility of repeat dosing and a dose-dependent overall survival benefit in cancer patients with primary or metastatic lung diseases. To date, Olvi-Vec has been administered to more than 150 patients across seven completed clinical trials, where Olvi-Vec has been generally well tolerated and demonstrated clinically meaningful benefits. Genelux has granted Newsoara an exclusive license to develop and commercialize Olvi-Vec in greater China (i.e., Mainland China, Hong Kong, Macau and Taiwan).

About Genelux Corporation

Genelux is a late clinical-stage biopharmaceutical company focused on developing next-generation oncolytic immunotherapies for patients suffering from aggressive and/or difficult-to-treat solid tumor types. Olvi-Vec is currently being evaluated in two U.S.-based clinical trials: OnPrime/GOG-3076, a multi-center, randomized, open-label Phase 3 registrational trial evaluating the efficacy and safety of Olvi-Vec in combination platinum-doublet + bevacizumab compared with physician's choice of chemotherapy and bevacizumab in patients with platinum-resistant/refractory ovarian cancer; and VIRO-25, a multi-center, randomized, open-label Phase 2 trial evaluating the efficacy and safety of Olvi-Vec & platinum-doublet + physician's choice of immune checkpoint inhibitor compared to docetaxel in NSCLC. Additionally, Olvi-Vec is currently being evaluated for dose selection in Olvi-Vec-SCLC-202, a China-based, multi-center, open-label Phase 1b/2 trial evaluating the efficacy and safety of Olvi-Vec & platinum-doublet in progressive SCLC. The core of Genelux's discovery and development efforts revolves around its 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.

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 "potential," "expected," "anticipated," "look forward," or "aim." Forward-looking statements in this release include, but are not limited to, statements related to Genelux's future plans and prospects, the potential capabilities advantages, safety, tolerability, activity and efficacy of Olvi-Vec, including the potential of Olvi-Vec to resensitize tumors to frontline platinum therapy; the potential for the ongoing Phase 1b/2 SCLC and Phase 2 VIRO-25 trials to support the systemic route of delivery program of Olvi-Vec; the potential for positive data, including the interim data reported to date from systemic administration lung cancer trials to further validate Genelux's oncolytic immunotherapy platform; the potential regulatory requirements and approval pathway of Olvi-Vec; and the planned timing of Genelux's data results in its ongoing clinical trials and continued development of Olvi-Vec. 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's 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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