Genelux and Newsoara Announce Positive Preliminary Phase 1b/2 Data of Olvi-Vec in Advanced Small-Cell Lung Cancer

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– Systemic administration of Olvi-Vec in the initial dose escalation cohorts achieved a 71% disease control rate (5/7) with two partial responders. All participants with disease control experienced a reduction in all target lesions, with one participant achieving a tumor reduction of approximately 79%.

– Additionally, three participants, including one individual with three prior lines of treatment, achieved stable disease at lower dose cohorts, with tumor size reductions ranging between 24% to 29.2%.

– Data are supportive of Olvi-Vec being a platinum resensitizing agent beyond ovarian cancer and, consistent with earlier studies, being systemically administered in multiple solid tumor types which underscore the current clinical development strategy.

– Olvi-Vec was generally well-tolerated with a favorable safety profile. Participant enrollment into dose escalation cohorts continues to investigate safety and the recommended intravenous dose of Olvi-Vec for the Phase 2 trial.

WESTLAKE VILLAGE, Calif., March 25, 2025 (GLOBE NEWSWIRE) -- Genelux Corporation (NASDAQ: GNLX), a late clinical-stage immuno-oncology company, and Newsoara BioPharma Co., Ltd., a pre-commercial-stage biopharmaceutical company, today announced preliminary safety and anti-tumor activity data from the dose escalation Phase 1b portion of the companies' co-sponsored ongoing Phase 1b/2 clinical trial (OLVI-VEC-SCLC-202) of Olvi-Vec immunochemotherapy in patients with platinum-relapsed or platinum-refractory extensive small cell lung cancer.

"We are encouraged by the Phase 1b trial data which suggests preliminary anti-tumor activity. Consistent reductions in all individual target lesions in participants experiencing disease control (5/7), combined with encouraging anti-tumor activity of the first evaluable participant in the most recent dose-escalation cohort, highlights the potential of systemically administered Olvi-Vec to provide meaningful clinical benefit for patients with relapsed or refractory extensive small cell lung cancer," said Thomas Zindrick, President, CEO, and Chairman of Genelux. "These results are consistent with our previous Phase 2 results in platinum-resistant/refractory ovarian cancer and, with further investigation in our ongoing trials in relapsed/refractory lung cancer, we anticipate demonstrating the potential of Olvi-Vec as a platinum resensitizing immunotherapeutic agent across multiple types of recurrent cancers with significant unmet medical needs."

Preliminary Dose Escalation Results Update
The primary objectives of this trial are to assess the safety, tolerability, pharmacokinetics, and preliminary efficacy of systemically administered Olvi-Vec in the target population. The data cutoff for this announcement was February 19, 2025, with enrollment currently ongoing. Genelux anticipates providing updates on the trial's progress as it continues to advance, whether through future publications or conference presentations.

Key findings from the ongoing Phase 1b trial include:

Favorable Safety and Tolerability Profile:

- Systemic administration of Olvi-Vec via intravenous delivery demonstrated a manageable safety and tolerability profile, consistent with previous findings in other clinical studies of the investigational immunochemotherapy. Treatment-related adverse events were mostly mild to moderate, including fever, anemia, reduced lymphocyte counts, and nausea. No maximum tolerated dose has been reached to date.

Antitumor Activity:

- Preliminary evidence indicates anti-tumor effect from Olvi-Vec immunochemotherapy. Five of the seven (71%) evaluable participants for anti-tumor response achieved disease control as the best response. The five participants with disease control showed reductions in all of their individual target lesions. All seven evaluable participants had documented disease progression at baseline before joining this study.
- Of the five participants with disease control, two participants exhibited a partial response according to RECIST 1.1. Notably, the first participant in our current dose escalation cohort, who remains on treatment, experienced a tumor reduction of approximately 79%. Additionally, the three remaining participants with disease control, including one individual with three prior lines of treatment, achieved stable disease at lower dose cohorts, with tumor size reductions ranging from 24% to 29.2%.

"The initial results are promising, especially considering the challenging and fragile nature of this patient population with extensive-stage disease and poor prognosis. What stands out is the anti-tumor responses in these participants, some who have been heavily pre-treated and have failed prior platinum-based therapy, which offers significant potential for Olvi-Vec to provide meaningful clinical benefits in small cell lung cancer, even in a patient

population with complex and late-stage disease," said Dr. Benny Li, CEO of Newsoara. "Ongoing evaluation of the Phase 1b results is consequentially informing the design elements of the Phase 2 portion of the clinical trial."

About the Olvi-Vec-SCLC-202 Trial
Olvi-Vec-SCLC-202 is a Phase 1b/2, open-label, multicenter clinical trial evaluating the safety, tolerability, pharmacokinetics and efficacy of intravenously delivered Olvi-Vec combined with platinum and etoposide in the treatment of platinum-relapsed or platinum-refractory extensive small cell lung cancer patients. The Phase 1b trial is currently enrolling patients in China at Shanghai Chest Hospital, the lead clinical site, and Zhejiang Provincial People's Hospital.

Patients receive a single cycle of Olvi-Vec treatment for three consecutive days and, 21 days after the last dose of Olvi-Vec, receive platinum chemotherapy plus etoposide until disease progression or intolerable toxicity occurs.

The dose escalation part of the trial is assessing the safety and tolerability of increasing doses of Olvi-Vec to determine the recommended dose and dosing regimen for Phase 2 expansion. Additionally, safety data may be evaluated to support the potential for Olvi-Vec to be safely combined with other agents, such as an immune checkpoint inhibitor, to further drive deep and durable responses in the Phase 2 portion of the trial.

The Phase 2 portion of the trial is planned to follow and further evaluate the safety and tolerability as well as efficacy of Olvi-Vec at the recommended dose.

About Olvi-Vec
Olvi-Vec (olvimulogene nanivacirepvec), Genelux's most advanced product candidate is a proprietary, modified oncolytic vaccinia virus, a stable DNA virus with a large engineering capacity. Genelux is developing Olvi-Vec for the treatment of multiple types of cancer based on the results of preclinical studies that suggest Olvi-Vec has the potential to infect and directly kill a wide range of tumor cell types *in vitro* and *in vivo* and produce an anti-tumor immune response. Genelux granted Newsoara an exclusive license to develop and commercialize Olvi-Vec in greater China (i.e., Mainland China, Hong Kong, Macau and Taiwan). To date, Olvi-Vec has been administered to more than 150 patients in seven completed clinical trials. In these trials, Olvi-Vec was observed to be generally well tolerated with data demonstrating 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. In addition to Olvi-Vec-SCLC-202, Olvi-Vec currently is 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 non-small-cell lung cancer. 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. For more information, please visit www.genelux.com and follow us on Twitter @Genelux_Corp and on LinkedIn.

About Newsoara
Newsoara is a pre-commercial-stage biopharmaceutical company with a mission to develop and commercialize life changing medicines for cancer, autoimmune, metabolic and other major diseases to patients in China and around the world. Since its founding, Newsoara has developed a fully integrated platform which includes R&D, CMC and clinical development capabilities and built a robust and broad pipeline in major therapeutics areas. Newsoara has assembled a world-class management team with extensive experience in innovative drug development that is motivated to improve and impact human health worldwide.

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, the potential capabilities, advantages, safety and efficacy of Olvi-Vec to treat small cell lung cancer and other indications and the trial design of the Phase 2 portion of the Phase 1b/2 clinical trial. 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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