Genelux Corporation Announces First Patient Dosed in Phase 2 Trial Evaluating Systemic Therapy with Olvi-Vec in Non-Small Cell Lung Cancer

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– VIRO-25 trial to assess efficacy & safety of olvimulogene nanivacirepvec (Olvi-Vec) & platinum-doublet + physician's choice of immune checkpoint inhibitor compared to docetaxel in recurrent non-small cell lung cancer –

– Trial represents second indication in the clinic for Olvi-Vec via systemic administration –

– Interim readout expected mid-2025 –

WESTLAKE VILLAGE, Calif., Oct. 22, 2024 (GLOBE NEWSWIRE) -- Genelux Corporation (NASDAQ: GNLX), a late-stage clinical immuno-oncology company, today announced that the first patient has been dosed in the U.S.-based Phase 2 (VIRO-25) trial evaluating systemically delivered Olvi-Vec in patients with recurrent non-small cell lung cancer (NSCLC) who have failed frontline platinum and immune checkpoint inhibitor (ICI) therapies.

"Today's milestone holds profound significance for patients with recurrent non-small cell lung cancer who face limited therapeutic options," said Thomas Zindrick, President, CEO and Chairman of Genelux. "This Phase 2 trial, in addition to our ongoing Phase 1b/2 trial evaluating intravenous delivered Olvi-Vec in patients with recurrent small cell lung cancer, co-sponsored with Newsoara Biopharma Co. Ltd., signifies the key advancement of Olvi-Vec to potentially be an important systemically administered oncolytic virus treatment option, setting the stage for the future of this promising field."

The VIRO-25 clinical trial (NCT06463665), is an open-label, randomized study in NSCLC designed to evaluate the efficacy and safety of an intravenously delivered oncolytic vaccinia virus, Olvi-Vec, followed by platinum-doublet chemotherapy + Physician's Choice of ICI compared with docetaxel in patients with advanced or metastatic NSCLC who have shown first disease progression while on front-line treatment or maintenance ICI therapy after front-line treatment with platinum-doublet chemotherapy + ICI as standard of care. Olvi-Vec's previous data suggests a manageable safety profile, and this trial looks to further confirm the hypothesis that Olvi-Vec may resensitize to platinum in multiple tumor types. Genelux expects interim data readout in mid-2025.

About Olvi-Vec
Olvi-Vec 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 cancers 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. To date, Olvi-Vec has been administered to more than 150 patients in seven clinical trials. In these studies, Olvi-Vec was observed to be generally well tolerated and the data provided evidence of clinical benefit.

About Genelux Corporation
Genelux is a late-stage clinical 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. Olvi-Vec currently is being evaluated in 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. 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.

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 Genelux’s future plans and prospects, the planned timing of Genelux’s data results in its ongoing clinical trials and continued development of Olvi-Vec, and the potential capabilities and advantages 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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