



REDEFINING IMMUNO-ONCOLOGY

## Genelux Announces Alignment with FDA on Key Elements of the Approval Pathway for Olvi-Vec in Platinum Resistant/Refractory Disease

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- U.S. Food and Drug Administration states that data from the ongoing OnPrime/GOG-3076 Phase 3 registrational trial could potentially support traditional approval -

WESTLAKE VILLAGE, Calif., March 25, 2025 (GLOBE NEWSWIRE) -- [Genelux Corporation](#) (NASDAQ: GNLX), a late clinical-stage immuno-oncology company, today announced that Genelux has concluded a productive Type D meeting with the U.S. Food and Drug Administration (FDA) for Olvi-Vec in the treatment of platinum resistant/refractory ovarian cancer (PRROC).

Currently, Olvi-Vec is being evaluated in the OnPrime/GOG-3076 Phase 3 registrational trial in the United States, with the primary endpoint of progression free survival ([Clinicaltrials.gov](#) identifier [NCT05281471](#)). The purpose of the FDA meeting was to discuss the FDA's expectations with respect to the requirements necessary for the granting of traditional approval of Olvi-Vec.

In response to a question seeking the FDA's guidance on their expectations regarding a confirmatory trial using the ongoing OnPrime/GOG-3076 trial, the FDA responded that "As stated previously, an interim analysis of overall survival (OS) should be planned at the time of the primary PFS analysis. If a clinically meaningful PFS advantage is demonstrated in the absence of a decrement in OS, this could potentially support traditional approval." The FDA further recommended Genelux request a pre-BLA meeting with FDA with topline safety and efficacy data following completion of the study to discuss next steps.

"We appreciate the feedback from the FDA regarding our clinical strategy for OnPrime/GOG-3076 and the plan for submission of an eventual marketing application, which could avoid the need for conducting a separate confirmatory study if the clinically meaningful PFS advantage is demonstrated," stated Thomas Zindrick, President and CEO. "The FDA's guidance regarding their expectations for the ongoing trial represents a significant milestone as we look forward to reporting topline safety and efficacy data in the first half of 2026. We remain committed to advancing a therapeutic option with the potential to provide a significant benefit for individuals living with PRROC, whose critical unmet need for innovative treatments is urgent."

### About the OnPrime/GOG-3076 Trial

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 PRROC. The trial is enrolling patients who are platinum resistant/refractory by standard definitions and received a minimum of 3 prior lines of therapy. The experimental arm patients receive a single cycle (two doses) of Olvi-Vec administered intraperitoneally and, approximately four weeks later, a regimen of a platinum-based doublet plus bevacizumab followed by maintenance therapy. The active comparator arm patients receive a regimen of single agent chemotherapy with optional platinum, plus bevacizumab followed by maintenance therapy. The trial will enroll a sufficient number of patients to achieve 127 events, with the primary endpoint of progression free survival and with secondary endpoints including overall survival.

The trial is designed to address a broad and underserved pool of ovarian cancer patients with no approved standard of care therapies. The inclusion criteria allows patients to enroll regardless of (i) tumor biomarkers, (ii) platinum refractory tumors or (iii) the maximum number of prior lines of treatments (i.e., no cap on previous treatments).

### 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. Olvi-Vec has been granted Fast Track designation by the US FDA for the treatment of platinum resistant/refractory ovarian cancer.

### 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. In addition to OnPrime/GOG-3076, Olvi-Vec currently is being evaluated in two clinical studies designed to demonstrate the ability to induce platinum re-sensitization via systemic administration: VIRO-25, a U.S.-based 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 and in Olvi-Vec-SCLC-202, a Phase 1b/2, open-label, China-based 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 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 "believes," "anticipates," "expect," "may," "plan" or "will". Forward-looking statements in this release include, but are not limited to, the potential regulatory approval pathway; the submission of a marketing application; capabilities, advantages, safety and efficacy of Olvi-Vec to treat platinum resistant/refractory ovarian cancer; and the Company's expectations regarding the timing and availability of data. 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.

**Investor and Media Contacts**

Ankit Bhargava, MD  
Allele Communications, LLC  
[genelux@allelecomms.com](mailto:genelux@allelecomms.com)

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