Genelux Corporation Receives FDA Fast Track Designation for Olvi-Vec in Platinum Resistant/Refractory Ovarian Cancer

November 27, 2023

- Pivotal Phase 3 Study of Olvi-Vec in Platinum Resistant/Refractory Ovarian Cancer Initiated in September 2022 -

- Phase 2 Trial of Olvi-Vec- Demonstrated Clinical Reversal of Platinum Resistance and Refractoriness and Met Primary Endpoint of Objective Response Rate with Durable Responses -

WESTLAKE VILLAGE, Calif., Nov. 27, 2023 (GLOBE NEWSWIRE) -- Genelux Corporation (NASDAQ: GNLX), a late clinical-stage immuno-oncology company, today announced that the United States Food and Drug Administration (FDA) has granted Fast Track designation for the development program of Olvi-Vec (olvimulogene nanivacirepvec) for the treatment of patients with platinum resistant/refractory ovarian cancer.

“The Fast Track designation granted for Olvi-Vec underscores its potential to address unmet medical needs in ovarian cancer, a significant recognition as we continue to enroll our Phase 3 OnPrime study,” said Thomas Zindrick, President, Chairman and CEO of Genelux. “We eagerly anticipate ongoing engagement with the FDA as we progress in the development of this promising treatment.”

Genelux is currently conducting OnPrime/GOG-3076, a Phase 3 multi-center, randomized, open-label registrational trial evaluating the efficacy and safety of Olvi-Vec in combination with platinum-based chemotherapy in patients with platinum-resistant/refractory ovarian cancer. More information about the trial is accessible at www.ClinicalTrials.gov, identifier NCT05281471.

The purpose of Fast Track designation is to facilitate the development and hasten the review process of drugs aimed at treating serious and life-threatening conditions, ensuring that an approved product can swiftly enter the market. Notable aspects of Fast Track designation encompass regular engagements with the FDA review team, and, if specific criteria are satisfied, potential eligibility for Priority Review and Rolling Review.

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. 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 with platinum-doublet + bevacizumab compared to platinum-doublet + bevacizumab 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 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, the execution of its corporate strategy and operating plan, clinical trials for Olvi-Vec and their potential success, and Olvi-Vec’s potential to address unmet medical needs in ovarian cancer. 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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