Genelux Corporation Reports Fourth Quarter and Full Year 2024 Financial Results and Provides Business Update

March 28, 2025

– Alignment reached with U.S. Food and Drug Administration on key elements of the approval pathway for Olvi-Vec in Platinum Resistant/Refractory Ovarian Cancer –

– Positive Preliminary Phase 1b/2 Data of Olvi-Vec in Advanced Small-Cell Lung Cancer –

– Matt Pulisic joined the company as its new Chief Financial Officer –

– Closing of $10.5 Million Underwritten Offering of Common Stock –

– $30.9 million in cash, cash equivalents and short-term investments –

WESTLAKE VILLAGE, Calif., March 28, 2025 (GLOBE NEWSWIRE) -- Genelux Corporation (NASDAQ: GNLX), a late clinical-stage immuno-oncology company, reported fourth quarter and full year 2024 financial results and business updates.

"Our progress in the fourth quarter of 2024 and into 2025 marks a pivotal period for patients, our company, and our investors," said Thomas Zindrick, President, CEO and Chairman of Genelux. "We are pleased with the continued progress and promise of our clinical development program. The strengthening of our management team, with the addition of Matt, and of our balance sheet, with our recent financing, further positions the Company to execute on our mission to transform the lives of patients who need it most."

Pipeline Highlights

OnPrime/GOG-3076 Phase 3 Registrational Trial Update

The Company continues to enroll patients in the ongoing pivotal Phase 3 OnPrime/GOG-3076 registration trial (Phase 3 trial) in platinum resistant/refractory ovarian cancer (PRROC), with the primary endpoint of progression free survival (PFS) (Clinicaltrials.gov identifier NCT05281471), and continues to have productive discussions with the U.S. Food and Drug Administration (FDA).

The Company recently concluded a productive Type D meeting with the FDA for Olvi-Vec in the treatment of PRROC. In response to a question seeking the FDA's guidance on their expectations regarding a confirmatory trial using the ongoing Phase 3 trial results, 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. This could potentially avoid the need for conducting a separate confirmatory study.

The trial will enroll a sufficient number of patients to achieve 127 events, with the primary endpoint of PFS and with secondary endpoints including OS. The Company anticipates reporting topline data in the first half of 2026.

Recurrent Lung Cancer Trials: Systemic Administration of Olvi-Vec Update

Phase 1b/2 Olvi-Vec-SCLC-202 has generated preliminary safety and anti-tumor activity data from the dose escalation Phase 1b portion of the ongoing Phase 1b/2 clinical trial of Olvi-Vec immunochemotherapy in patients with platinum-relapsed or platinum-refractory extensive small cell lung cancer. The trial is co-sponsored by the Company and its licensing partner, Newsoara BioPharma Co., Ltd. (Newsoara).

- 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%.
- 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 Phase 2 portion of the trial, with updated interim results anticipated in the second half of 2025.

Phase 2 VIRO-25 is actively enrolling recurrent non-small cell lung cancer (NSCLC) patients (NCT06463665), with interim data anticipated in second half of 2025.

Business Updates

Chief Financial Officer

Matt Pulisic has joined the Company as its new Chief Financial Officer, effective January 30, 2025. Mr. Pulisic is an accomplished, senior executive with over 19 years of finance and commercial experience in the biopharmaceutical industry, having worked across the United States, Europe, and Asia. He is recognized for his expertise in financial leadership, corporate strategy and operational execution.

Underwritten Offering of Common Stock

On March 26, 2025, the Company closed an underwritten offering of 3,000,000 shares of its common stock at an offering price of $3.50 per share. The gross proceeds from the offering are expected to be $10.5 million, before deducting underwriting discounts and commissions and estimated offering expenses payable by the Company. The net proceeds from the offering are to be used for working capital and for general corporate purposes, including the continued clinical development of Olvi-Vec.

Fourth Quarter and 2024 Financial Results

Cash, cash equivalents and short-term investments were $30.9 million as of December 31, 2024. The Company expects its cash, cash equivalents and short-term investments as of December 31, 2024 will provide runway into the first quarter of 2026.

Research and development expenses were $19.0 million and $12.8 million for the years ended December 31, 2024 and 2023, respectively, an increase of approximately $6.2 million. Significant variations between periods are primarily a result of a $4.5 million increase in clinical and regulatory expenses relating to increased clinical trial costs associated with the Company's Phase 3 On Prime Registration trial in 2024 and Phase 2 clinical trial for NSCLC, which the Company's partner, Newsoara, is obligated to fully reimburse per the terms of their agreement; and a $1.2 million increase in employee compensation in 2024, primarily related to new employee hires in 2024.

General and administrative expenses were $12.7 million and $11.6 million for the years ended December 31, 2024 and 2023, respectively, an increase of approximately $1.1 million. Significant variations between periods are primarily a result of a $0.2 million increase in employee compensation in 2024, a $0.8 million increase in stock compensation expense in 2024, due to the increase in the cost of stock options and restricted stock units in 2024, and a $0.4 million increase in consulting and contract labor expenses in 2024, primarily resulting from increased accounting and finance costs in 2024, partially offset by a $0.5 million decrease in professional services, primarily resulting from the decrease in legal expenses in 2024.

Net loss was $29.9 million or $0.95 per share for the year ending December 31, 2024, as compared to $28.3 million or $1.16 for the year ending December 31, 2023.

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. 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. Additionally, Olvi-Vec currently is being evaluated for dose selection in Olvi-Vec-SCLC-202, a China-based, multi-center, open label Ph1b evaluating the efficacy and safety of Olvi-Vec & Platinum-doublet in recurrent 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.

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, the potential capabilities advantages, safety and efficacy of Olvi-Vec and the potential regulatory approval pathway 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.

Investor and Media Contacts

Ankit Bhargava, MD
Allele Communications, LLC
genelux@allelecomms.com

Source: Genelux Corporation

Genelux Corporation
Balance Sheets

(In thousands, except for share amounts and par value data)

	December 31,	
	2024	2023
ASSETS		
Current Assets		
Cash and cash equivalents	$ 8,565	$ 9,418
Short-term investments	22,330	13,773
Prepaid expenses and other current assets	653	1,012
Total Current Assets	31,548	24,203
Property and equipment, net	1,316	1,170
Right of use assets	1,760	2,428
Other assets	92	92
Total Other Assets	3,168	3,690
TOTAL ASSETS	$ 34,716	$ 27,893
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current Liabilities		
Accounts payable and accrued expenses	$ 5,570	$ 3,784
Accrued payroll and payroll taxes	1,004	2,117
Lease liabilities, current portion	329	653
Total Current Liabilities	6,903	6,554
Lease liabilities, long-term portion	1,539	1,866
Total Liabilities	8,442	8,420
Commitments and Contingencies		
Shareholders' Equity		
Preferred stock, par value $0.001, 10,000,000 shares authorized; no shares issued and outstanding, respectively;	-	-
Common stock, par value $0.001, 200,000,000 shares authorized; 34,728,140 and 26,788,986 shares issued and outstanding	35	27
Treasury stock, 433,333 shares, at cost	(433)	(433)
Additional paid-in capital	278,001	241,389
Accumulated other comprehensive income	64	14
Accumulated deficit	(251,393)	(221,524)
Total Shareholders' Equity	26,274	19,473
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 34,716	$ 27,893

The accompanying notes are an integral part of these financial statements.

Genelux Corporation
Statements of Operations
(in thousands, except for share amounts and per share data)

	Years Ended December 31,	
	2024	2023

Revenues	$ 8	$ 170
Operating expenses:		
Research and development	18,998	12,767
General and administrative	12,706	11,568
Total operating expenses	31,704	24,335
Loss from operations	(31,696)	(24,165)
Other income (expenses):		
Interest income	1,457	244
Gain on extinguishment of accounts payable	370	-
Interest expense	-	(173)
Debt discount amortization	-	(649)
Financing costs	-	(3,152)
Debt extinguishment costs		(402)
Total other income (expenses), net	1,827	(4,132)
NET LOSS	$ (29,869)	$ (28,297)
LOSS PER COMMON SHARE - BASIC AND DILUTED	$ (0.95)	$ (1.16)
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING - BASIC AND DILUTED	31,450,727	24,429,278

The accompanying notes are an integral part of these financial statements.

Genelux Corporation
Statements of Comprehensive Loss
(in thousands)

	Years Ended December 31 ,	
	2024	**2023**
Net loss	$ (29,869)	$ (28,297)
Other comprehensive loss:		
Net unrealized gain on short and long-term investments	50	12
Comprehensive loss	$ (29,819)	$ (28,285)

The accompanying notes are an integral part of these financial statements.

Source: Genelux Corporation