

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 8, 2024

Genelux Corporation
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-41599
(Commission
File Number)

77-0583529
(I.R.S. Employer
Identification No.)

2625 Townsgate Road, Suite 230
Westlake Village, California
(Address of principal executive offices)

91361
(Zip Code)

Registrant's telephone number, including area code: (805) 267-9889

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|-------------------|---|
| Common stock, par value \$0.001 per share | GNLX | The Nasdaq Stock Market LLC |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01 Regulation FD Disclosure.

On November 8, 2024, Genelux Corporation (the “Company”) made available the corporate presentation attached hereto as Exhibit 99.1 (the “Corporate Presentation”). Information from the Corporate Presentation may also be used by the management of the Company in future meetings regarding the Company. For important information about forward-looking statements in the Corporate Presentation, see the slide titled “Forward-Looking Statements” in Exhibit 99.1 attached hereto.

The information contained or incorporated in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933, as amended (the “Securities Act”), except as expressly set forth by specific reference in such filing to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

| Exhibit No. | Description |
|--------------------|--|
| 99.1 | Corporate Presentation, dated November 8, 2024. |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document). |

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Genelux Corporation

Date: November 8, 2024

By: /s/ Thomas Zindrick, J.D.
Thomas Zindrick, J.D.
President and Chief Executive Officer

The logo for GENELUX features the word "GENELUX" in a bold, black, sans-serif font. The letter "G" is stylized with a green dot and a green swoosh that extends to the right, underlining the letters "E", "N", "E", "L", "U", and "X".

GENELUX

Redefining Immuno-Oncology

Corporate Presentation November 2024

Forward Looking Statements

This presentation 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, which are subject to the "safe harbor" created by those sections, about Genelux Corporation ("Genelux," the "Company," "we," "us" or "our") that are based on the beliefs and assumptions of our management team, and on information currently available to such management team. These forward-looking statements include, but are not limited to, statements concerning: the expansion and advancement of our platform and pipeline and our approach and strategy related to the platform and pipeline; Olvi-Vec's potential utility and our plans and expectations for Olvi-Vec across various designs and indications; our expectations regarding the field of oncolytic viral immunotherapy; Olvi-Vec's potential to provide utility across multiple tumor types, and our expectations regarding our Phase 3 trial; the potential of our current and future pipeline to produce best-in-class drugs; our clinical trial strategy and design; our expectations regarding (i) the timing of our Phase 2 and Phase 3 clinical trials and (ii) our intellectual property rights under the Newsoara license agreement; our planned investments to meet worldwide clinical trial demand and facilitate our U.S. commercial launch; the commercial market opportunity for Olvi-Vec in the United States; our various commercial strategies for self-launching Olvi-Vec for ovarian cancer in the United States, including expected milestones related to clinical trials and commercial partnerships and collaborations; and our expectations regarding our cash operating runway, including funding from Newsoara. These forward-looking statements are subject to numerous risks and uncertainties, many of which are beyond our control. All statements, other than statements of historical fact, contained in this presentation, including statements regarding future events, future financial performance, business strategy and plans, and objectives of ours for future operations, are forward-looking statements.

Although we do not make forward-looking statements unless we believe we have a reasonable basis for doing so, we cannot guarantee their accuracy. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks set forth under the heading "Risk Factors" in Quarterly Report on Form 10-Q for the quarter ended June 30, 2024 and in our other filings with the Securities Exchange Commission ("SEC"), which may cause our actual results, levels of activity, performance or achievements of and those of our industry to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. You should not place undue reliance on any forward-looking statement. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. In some cases, you can identify forward-looking statements by terminology such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will" or "would," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these identifying words. You should not put undue reliance on any forward-looking statements. Forward-looking statements should not be read as a guarantee of future performance or results, and will not necessarily be accurate indications of the times at, or by, which such performance or results will be achieved, if at all. Except as required by law, Genelux does not undertake any obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future developments or otherwise.

Trade names, trademarks and service marks of other companies appearing in this presentation are the property of their respective owners. Solely for convenience, the trademarks and tradenames referred to in this presentation appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor to these trademarks and tradenames.

This presentation discusses a product candidate that is under clinical study and which has not yet been approved for marketing by the U.S. Food and Drug Administration. No representation is made as to the safety or effectiveness of this product candidate for the use for which it is being studied.

Highlights



Olvi-Vec: *late-stage Clinical Program focused on Platinum Resensitization in Multiple Indications*

Ongoing pivotal Phase 3 trial in late-stage platinum resistant/refractory ovarian cancer (PRROC)
Ongoing Phase 2 trial via systemic administration in recurrent non-small cell lung cancer (NSCLC)
Ongoing Phase 1b/2 trial via systemic administration in recurrent small cell lung cancer (SCLC)



CHOICE™ Platform; Broad and Diverse Discovery Engine

Library with over 500 novel vaccinia strains and 110+ transgenes



Validating Strategic Partnership

Newsoara Biopharma (Greater China rights) has paid \$11M to date and Genelux is eligible for additional development, regulatory and sales milestone payments and up to mid-double-digit percentages royalties on net sales



Focused Commercial Strategy

US launch in Ovarian Cancer initially; strategic partnerships for ex-US rights



Estimated Billion Dollar Plus Annual Market Opportunity

Potential well beyond ovarian and lung cancers in numerous settings via systemic administration

The Most Advanced Non-local Delivery Oncolytic Immunotherapy

Olvi-Vec: 7 Completed Clinical Trials (>150 Patients)



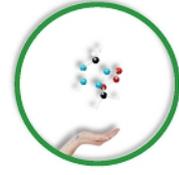
Physician-preferred routes of delivery

- **Regional and Systemic Administration** to preferentially locate, colonize and destroy tumor cells, including metastatic disease
- IV therapy currently being used in small cell lung cancer Phase 1b/2 trial and in non-small cell lung cancer Phase 2 trial
- Potential utility in multiple cancers (demonstrated in 20 pre-clinical solid & liquid tumor models, e.g., ovarian, lung, breast, colon, kidney, prostate, lymphoma)



Antitumor Effect and Well Tolerated

- Strong ORR, mPFS & mOS* data in Phase 1b/2 trial in platinum-resistant/refractory ovarian cancer
- **No Maximum Tolerated Dose (MTD) observed**
- In Ovarian Cancer trial, catheter placement is prior to chemotherapy, with removal 2 days after initial placement



Ideal Backbone of Combination Therapy

- Turns tumors “hot” by localized inflammation and induction of the influx of tumor infiltrating lymphocytes (TILs)
- Positively modulates anti-tumor pathways in tumor microenvironment
- Potential to use with various modalities including in patients who failed platinum-based chemotherapy in multiple tumor types

Program Builds on Completed Trials to Exploit Competitive Advantages

- 3 Upcoming Trial Readouts have Potential to Redefine:**
- Therapy (platinum resensitization in multiple indications)
 - Modality (systemic administration of an oncolytic virus)

| Olvi-Vec | Indication | Design | Preclinical | Phase 1 | Phase 2 | Phase 3 | Anticipated Milestones | Collaborators | |
|----------------|---|--|---|---------|---------|-------------------------------------|------------------------|--------------------------------------|---|
| Regional Route | Ovarian Cancer (platinum-resistant/refractory) | Olvi-Vec (i.pe) +Platinum-based regimen | Ph3 OnPrime/GOG-3076 Study Actively Enrolling | | | Received FDA Fast Track Designation | | Topline results expected in 2H, 2025 | GOG FOUNDATION (Cooperative Group) |
| Systemic Route | Non-Small Cell Lung Cancer (recurrent/platinum-ICI failure) | Olvi-Vec (IV) +Platinum/Checkpoint inhibitor-based regimen | Ph2 Actively Enrolling | | | | | Interim readout expected mid 2025 | |
| | Small Cell Lung Cancer (recurrent/platinum failure) | Olvi-Vec (IV) +Platinum-based regimen | Ph1b/2 Actively Enrolling | | | | | Interim readout expected in 2H, 2024 | NEWSQARA (Greater China) |
| | Ovarian Cancer (recurrent/platinum failure) | Olvi-Vec (IV) +Platinum-based regimen | Ph1b/2 Regulatory Submission | | | | | | |
| | Non-Small Cell Lung Cancer (recurrent/platinum-ICI failure) | Olvi-Vec (IV) +Platinum/Checkpoint inhibitor-based regimen | Planned | | | | | | |
| | Pancreatic Cancer (recurrent) | Olvi-Vec (IV) +Adoptive Cell Therapy | Regulatory Submission | | | | | | VACT THERAPEUTICS (Worldwide Rights Ex-Greater China) |

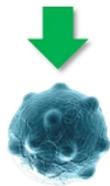
Olvi-Vec Seeks to Unleash Immune System Against Cancer

Key Takeaways

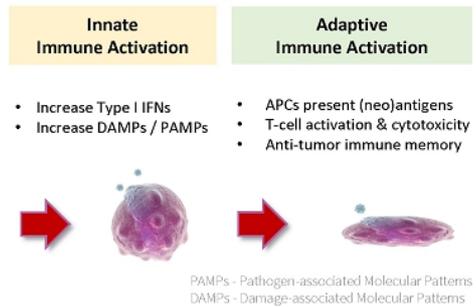
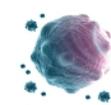
Olvi-Vec is being developed as a robust immune modulator that utilizes a triple mode of action to mount a personalized attack against cancer cells throughout the body and aims to:

- Selectively replicate in tumors to kill cancer cells directly, including cancer stem cells
- Enhance (neo)antigen presentation and stimulates a tumor-specific immune response
- Convert tumor microenvironment from immunosuppressive (cold state) to immunoreactive (hot state)

Olvi-Vec
viral infection



Oncolysis and release of tumor (neo)antigens



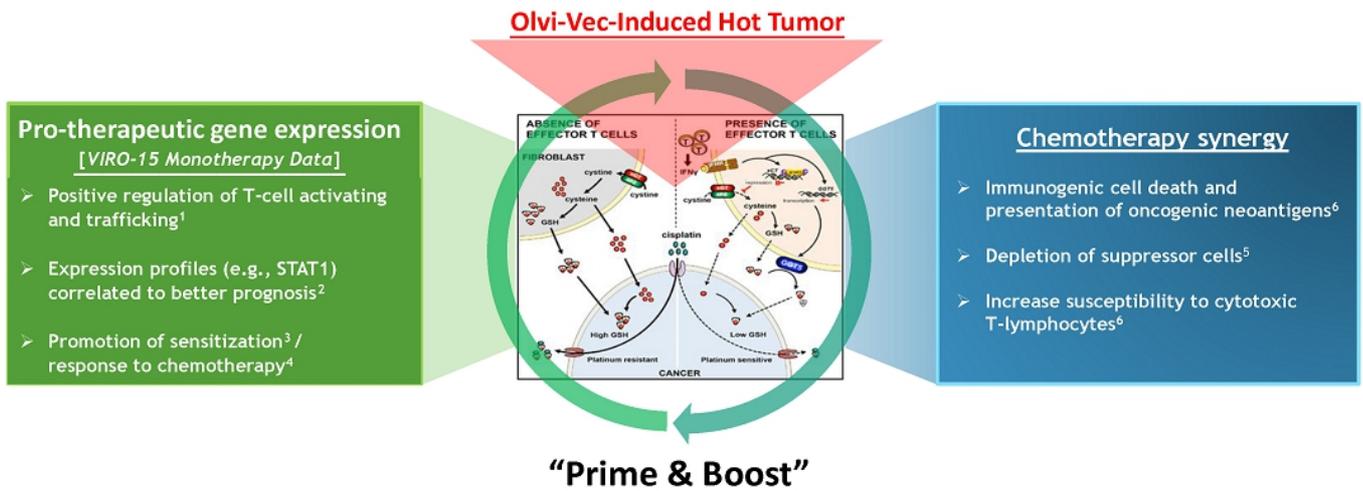
'Cold' tumor before Olvi-Vec

- No or relatively low number of immune effector cells
- Relatively high number of immune suppressor cells

'Hot' tumor following Olvi-Vec immunotherapy

- Increase of proinflammatory cytokines/chemokines
- Influx of CD8+ effector T cells
- M2 to M1 transition of tumor-associated macrophages
- Decrease of immune suppression
- Changes of tumor gene expression profile
- Immunogenic tumor cell death
- Vascular collapse

Olvi-Vec-Primed Immunotherapy: Reversing Platinum Resistance



¹Sang et al. *Mol Ther* (2007) 15(8):1558–1563

²Wang et al. *Cell* 2016; 165(6): 1092–1105

³Mantovani et al. *J Exp Med* 2015; 212(4):435–445

⁴Ahmed et al. *Mol Aspects Med* 2014; 26:113–26

⁵Weir et al. *Cancers (Basel)* (2011) 3(3):214–314; Ermsen et al. *Cancer Immunol Res* (2015) 3(5):436–443

⁶Ermsen et al. *Cancer Immunol Res* (2016) 3(5): 436–443.

A Maturing Modality with Phase 3 Companies Validating OV Potential



Next Generation
Regional & Systemic
Administration

Systemic Delivery
Potential to be
First-in-Class
Across multiple tumor types

Phase 2 Ovarian Cancer

Apparent tumor re-sensitization to
platinum-based therapy

Phase 1b Solid Tumors

Dose-dependent mOS in metastatic lung-diseased
solid tumor patients after multiple IV doses

Potential Clinical Advantages of Olvi-Vec

- ✓ Systemic Dosing and Redosing
- ✓ Target & Treat Metastatic Diseases
- ✓ Robust Immune Activation Profile
- ✓ Broad spectrum of accessible tumor types
- ✓ Multiple Routes of Delivery
- ✓ Tumor Selectivity
- ✓ Strong immune activator
- ✓ Nonhuman Pathogen

Limitations of 1st Gen Viruses

- Limited to local delivery and scope of addressable cancers

AMGEN

FDA/EMA Approval
in Melanoma



PMDA Approval in
malignant glioma

BCG
ONCOLOGY

Phase 3 monotherapy
trial [interim data] in
bladder cancer



mOS: median overall survival



Regional
Administration
Program

Ovarian Cancer

Ovarian Cancer Program: Regional (Intraperitoneal) Delivery

Key Takeaways

- Phase 1 tested condensed dosing schedule and demonstrated tolerability with evidence of anti-tumor activity
- Phase 2 demonstrated promising Overall Response Rate (ORR) and Progression Free Survival (PFS), and clinical reversal of platinum resistance and refractoriness

Expected Milestones

- Phase 3 registrational trial: ongoing with topline results expected in 2H, 2025

Completed and ongoing clinical trials in heavily pre-treated platinum resistant/refractory patients

| Trial Sites Location / (#) | Clinical Stage | Design | Patients | Randomization | Status |
|----------------------------|----------------|--------------------------------------|----------|---------------|------------------------|
| US / (~30) | Phase 3 | Combination (platinum-based regimen) | 186 | 2:1 | Enrolling ³ |

| | | | | | |
|----------|---------|--------------------------------------|----|------------|------------------------|
| US / (1) | Phase 1 | Monotherapy (Dose Escalation) | 11 | Single Arm | Completed ¹ |
| US / (2) | Phase 2 | Combination (platinum-based regimen) | 27 | Single Arm | Completed ² |

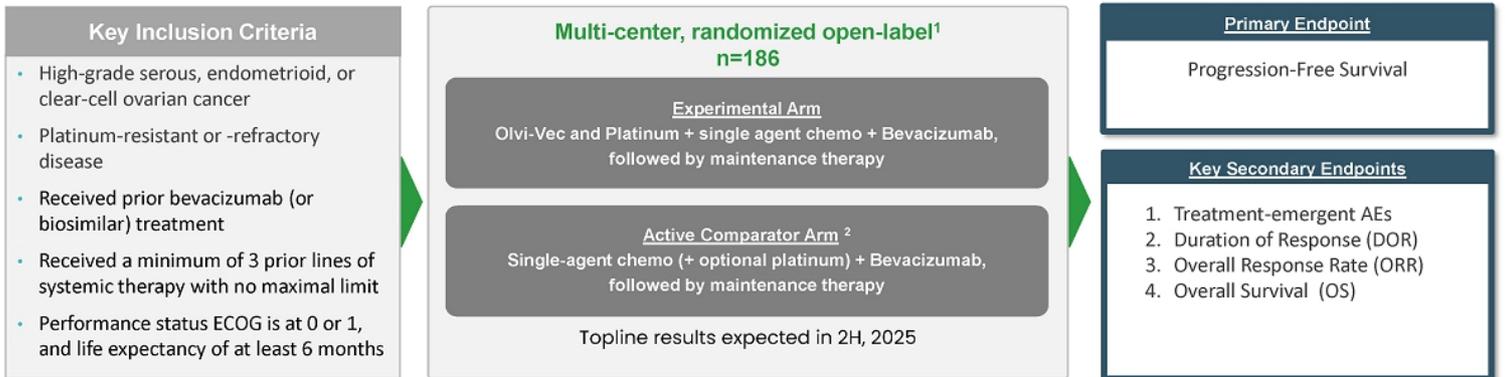
¹ Manyam et al., Gynecol Oncol. 2021;163(3):481-489.

² Holloway et al., JAMA Oncol. 2023 Jul 1;9(7):903-908.

³ Holloway et al., Int J Gynecol Cancer. 2023 Sep 4;33(9):1458-1463.

Phase 3 Pivotal Trial Design Founded on Phase 2 Trial Design & Results

Trial design intends to replicate previous data showing anti-tumor activity of Olvi-Vec and reversal of platinum resistance.



A platinum resensitizing agent is a long-standing desirable and highly demanded mechanism of action of Gyn-Oncs, their so-called "Holy Grail".³

¹ International Journal of Gynecological Cancer, Holloway RW, et al. 2023;33:1458–1463.
² Protocol amended to make platinum optional in the Active Comparator Arm with intent to implement upon receipt of IRB approvals.
³ Journal of Investigative Medicine High Impact Case Reports, Volume 6: 1–3, 2018
DOI: 10.1177/2324709618760080 | journals.sagepub.com/home/hic

Completed Phase 1b Anti-tumor Activity as Monotherapy Leading into Combination

Key Clinical Takeaways

- Median progression free survival (mPFS) of 6.1 months (median 4 prior lines; 95%CI: 2.2-NA) for the six patients in Cohort 1 virus monotherapy – the dose used in Phase 2.
 1. SOC-AURELIA regimen (1-2 prior lines)
 - mPFS: 6.7 mos
 2. ELAHERE (1-3 prior lines)
 - mPFS: 5.62 mos
- Cohort 2/3 dosing done exponentially higher with no MTD reached.

Olvi-Vec Monotherapy¹



Patient Background & Study Treatment

- Heavily pre-treated PRROC patients with documented progressive disease
- Cohort 1 received a single cycle of intraperitoneal delivery on 2 consecutive days; total dose: 6×10^9 pfu, same dose as Phase 1/2



Tolerability:

- No Dose Limiting Toxicity (DLT)
- No Maximum Tolerated Dose (MTD)
- No Grade 4 Adverse Events (AE)



Antitumor activity:

- Clinical Benefit Rate: 73% (8/11)
- 4/11 patients over three dose cohorts had >2x PFS relative to immediate prior chemotherapy



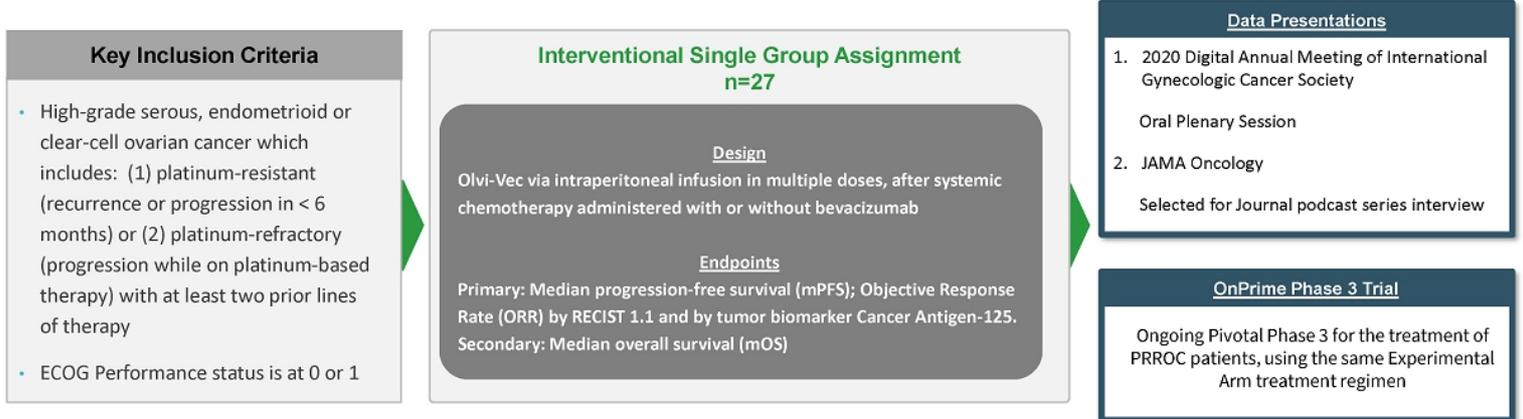
Translational Evidence:

- Activation of tumor-specific T cell response detected in blood
- Documented immune activation in tumor microenvironment with significant influx of TILs
- Favorable immune-related genetic signatures

¹Manyam et al., Gynecologic Oncology 163 (2021) 481 - 489

Completed Phase 2 Tested Olvi-Vec-primed Immunochemotherapy

Heavily Pretreated Patients with Platinum-Resistant or Platinum-Refractory Ovarian Cancer



Results of the VIRO-15 Phase 2 Trial were
published in JAMA Oncology¹

¹ Holloway et al., JAMA Oncol. 2023 Jul 1;9(7):903-908.

Phase 2: Clinically-Meaningful Responses in Heavily Pretreated Patients

Overall Response Rate (ORR), including Complete Responses (CR) & Partial Responses (PR), and Progression-Free Survival (PFS)*

Key Clinical Takeaways

Promising ORR and PFS, and clinical reversal of platinum resistance and refractoriness among patients with PRROC

- All patients had documented progressive disease at enrollment
- The mPFS of the patients' immediately preceding line of therapy was ~4.5 months
- Based on historical data, the mPFS would be expected to decrease in the subsequent line of therapy
- No Grade 4 adverse events. Typical adverse events were transient, mild-to-moderate flu-like symptoms

| | ORR by RECIST1.1** | Duration of Response | ORR by CA-125 | Median PFS | Median Overall Survival (OS) |
|---|--|-------------------------------|---|---------------------------------|----------------------------------|
| All patients (n= 27) (95% CI) | 54% (13 [§] /24 ^{¶¶}) CR=8% PR=46% | 7.6 mos (3.7 - 9.6) | 85% (22/26 ^{¶¶¶}) (65 - 96) | 11.0 mos (6.7 - 13.0) | 15.7 mos (12.3 - 23.8) |
| Platinum-resistant (n=14) (95% CI) | 55% (6/11) (26 - 84) CR=18% PR=36% | 7.6 mos (3.7 - NA) | 85% (11/13) (55 - 98) | 10.0 mos (6.4 - NA) | 18.5 mos (11.3 - 23.8) |
| Platinum-refractory (n=13) (95% CI) | 54% (7/13) (27 - 81) CR=0% PR=54% | 8.0 mos (3.7 - NA) | 85% (11/13) (55 - 98) | 11.4 mos (4.3 -13.2) | 14.7 mos (10.8 - 33.6) |

*Baseline for ORR & PFS evaluation is the timepoint immediately prior to starting post-Olvi-Vec carboplatin doublet +/- bevacizumab to allow direct comparison to historical data or patients' own previous line of chemotherapy

**Eligible for evaluation: with at least 1 measurable target lesion at baseline, including 2 patients without post-chemo scan after virotherapy, and therefore are assigned to the 'inevaluable for response' category per RECIST1.1

†Including 3 unconfirmed; 2 in resistant and 1 in refractory groups

¶Three of 27 patients were not evaluable as defined by RECIST 1.1 criteria due to no measurable disease.

¶¶However, these 3 patients were evaluable by the Gynecological Cancer InterGroup (GCIG) CA-125 criteria, showing 2 partial responses and 1 complete response as best response.

¶¶¶One of 27 patients was not evaluable by GCIG CA-125 criteria. However, this patient was evaluable by RECIST 1.1, showing stable disease as best response.

Demonstrated Deep and Durable Tumor Shrinkage

Key Clinical Takeaways

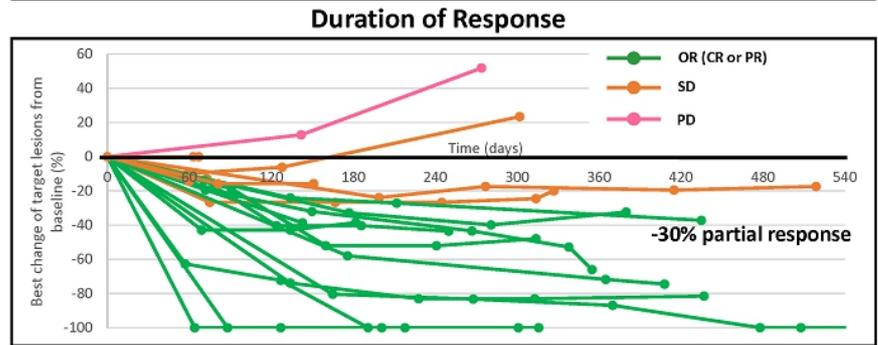
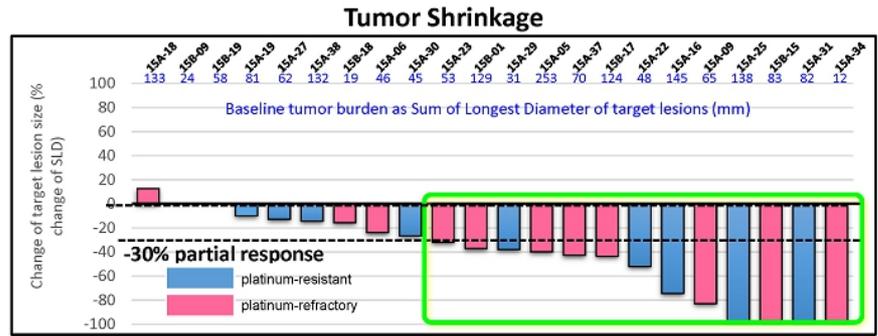
Refractory patients performed as well as resistant patients

Tumor Shrinkage

- Overall, 86% of PRROC patients showed tumor reduction, with 91% of platinum-refractory patients showing tumor reduction
- Four patients had 100% reduction of target lesions (two with confirmed CR), including two platinum-refractory patients

Duration of Response (DOR)

- DOR of 7.6 Months in all platinum-Resistant patients
- DOR of 8.0 Months in platinum-refractory patients



Olvi-Vec-Primed Immunotherapy Overcomes "Refractoriness"

Exemplary platinum-refractory patients, after platinum re-challenge, achieved PFS exceeding any prior lines

15B-01:

- Stage IIIB papillary serous
- ECOG: 0
- BRCA negative
- PD-L1 negative

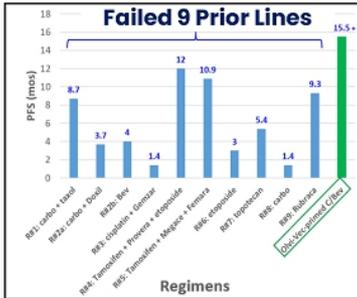
15B-15:

- Stage IIIB high-grade serous
- ECOG: 0
- BRCA negative
- PD-L1 negative

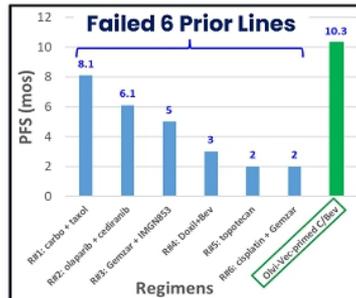
15B-17:

- Stage IIIC high-grade serous
- ECOG: 1
- BRCA negative

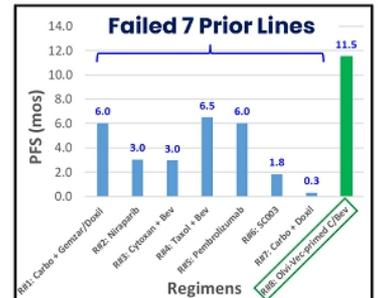
Overall Survival: 23.2 Months



Overall Survival: 12.3 Months



Overall Survival: 15.7 Months



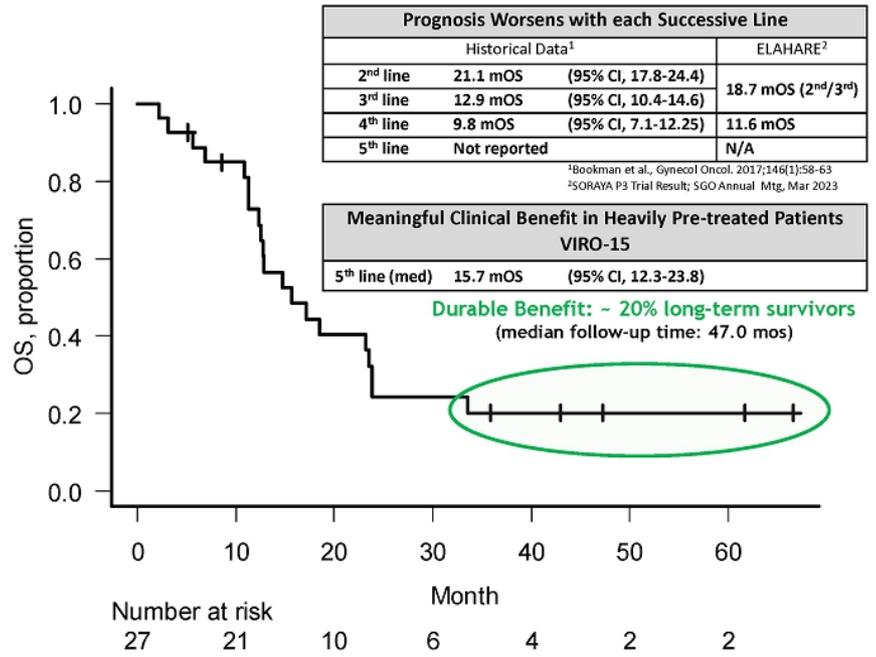
Durable Survival Benefit

Key Clinical Takeaways

Encouraging mOS and Long-term survival data

20% long-term survivors consistent with clinically beneficial immunotherapies

- On a median 5th line of treatment, VIRO-15 Phase 2 patients achieved a mOS of 15.7 mos
- 4 of 6 long-term survivors were platinum-refractory at enrollment



Phase 2 Compared to Approved Standard of Care in Earlier Lines

Key Clinical Takeaways

Olvi-Vec addresses a broad and underserved pool of patients

- Olvi-Vec trial inclusion criteria allows patients regardless of
 - tumor biomarkers,
 - platinum refractory tumors, or
 - number of prior lines of treatment (i.e., no cap)
- Olvi-Vec Phase 2 results approach results in less pre-treated platinum-sensitive patients

| | Bevacizumab + Chemotherapy Phase 3 (AURELIA Study) | Elahere Phase 3 (MIRASOL Study) | Elahere Phase 3 (SORAYA Study) | Olvi-Vec Phase 2 (VIRO-15 Study) |
|---------------------------------|--|-------------------------------------|--|---|
| Patient Population | Progressed <6 months after last platinum | FRα positive and platinum-resistant | FRα positive and platinum-resistant | Platinum –resistant or platinum-refractory |
| Prior Lines of Systemic Therapy | ≤2 L's (60% 1 line; 40% 2 lines) | ≤3 L's (14% 1L; 39% 2L; 47% 3L) | ≤3 L's (10% 1L; 39% 2L; 50% 3L) | 2-9 L's (median=4) |
| Number in Treated Arm | 179 (all platinum resistant) | 227 (all platinum resistant) | 104 (all platinum resistant) | 22* (11 platinum resistant; 11 platinum refractory) |
| ORR | 28% | 42% | 32% | 59% (54% in PI resistant; 64% in PI refractory) |
| CR | Unk | 5% | 5% | 9% (18% in PI resistant; 0% in PI refractory) |
| PR | Unk | 37% | 27% | 50% (36% in PI resistant; 64% in PI refractory) |
| PFS (months) | PFS=6.8 | PFS=5.6 | PFS=5.5 | PFS=11.4 |
| Reference | FDA Prescribing Information | FDA Prescribing Information | FDA Prescribing Information and Immunogen press release March 2022 | |

*October 22, 2024

Note: As the data presented is based on a cross-trial comparison and not a head-to-head clinical trial, such comparisons may not be reliable due to differences in study protocols, conditions and patient populations. Accordingly, cross-trial comparisons may not be reliable predictors of the relative efficacy or other characteristics of our candidates compared to others presented.

Self Launch Olvi-Vec for Ovarian Cancer in the US

Drivers of Market Penetration



Partnerships

Leverage partnership with GOG Foundation

- Preeminent US-based cooperative group in Gynecologic Oncology
- Composed of leading KOLs in the field
- Partners in the OnPrime/GOG-3076 Phase 3 registration trial



Self-Manufacturing

Large-Scale cGMP Manufacturing

- Control of Production Schedule
- Attractive COGs
- Ability to scale up modular process



Patients

Underappreciated Population

- ~238,484 Ovarian Cancer Patients in the US¹
- 70-80% will relapse with few therapeutic options
- Limited number of Gyn-Oncs enabling specialty sales team



Reimbursement

Compelling Value Proposition for Payors

- Significant unmet medical need
- Combination with generic/biosimilars
- Future label expansion

¹NIH Ovarian Cancer Fact Sheet



Systemic Administration Programs

Lung Cancers

Key Takeaways

- Funding commitment by Newsoara of the US-based Genelux Phase 2 trial in NSCLC
- Genelux has worldwide commercial rights (ex-Greater China) to all clinical data generated in China¹
- All patients in these trials will be treated systemically and have previously failed platinum-based therapy

Expected Milestones

- Ph1b SCLC: Interim readout 2H, 2024
- Ph2 NSCLC: Interim readout mid 2025

¹Newsoara has development and commercialization rights in Greater China

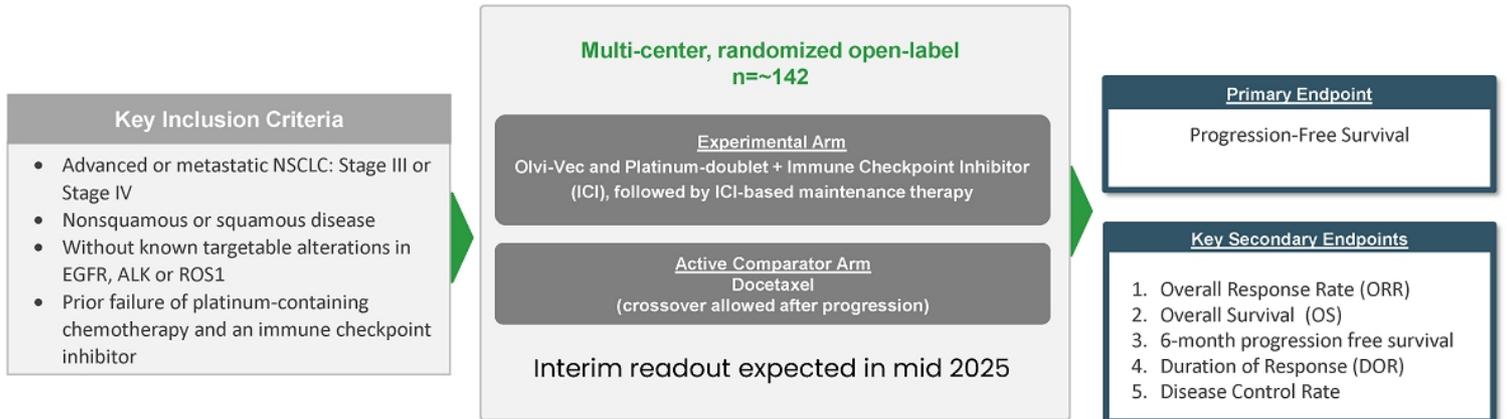
Ongoing and Planned Clinical Trials

| Sponsor | Trial Sites | Indication | Clinical Stage | Patients (est.) | Randomization | Status |
|---|-------------|---|----------------|-----------------|---------------|-----------|
|  | US | Recurrent/platinum-ICI failure NSCLC (rNSCLC) | Phase 2 | ~142 | 1:1 | Enrolling |

| | | | | | | |
|---|-------|---|------------|------|------------|-----------------------|
|  | China | Recurrent/platinum failure SCLC (rSCLC) | Phase 1b/2 | ~110 | Single Arm | Enrolling |
| | | Recurrent/platinum failure OC | Phase 1b/2 | ~150 | 2:1 | Regulatory Submission |
| | | Recurrent/platinum-ICI failure NSCLC | Phase 1b/2 | ~150 | 2:1 | Planned |

Phase 2 Trial in Recurrent Non-small Cell Lung Cancer

Patients with Non-small Cell Lung Cancer after First Progression while on Front-Line Immune Checkpoint Inhibitor-based Maintenance



Phase 1b/2 Trial in Recurrent Small Cell Lung Cancer

Heavily Pretreated Patients with Platinum-Relapse or Platinum-Refractory Small Cell Lung Cancer



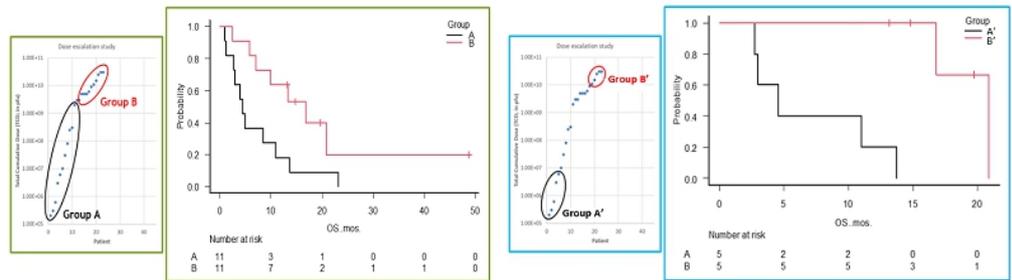
Systemic Administration Demonstrated Dose-dependent OS Benefit

Key Clinical Takeaways

Demonstrated feasibility and clinical benefit of multiple IV cycles

- Median 5 prior lines of therapy
- **Regimen:** various dosing levels and schedules (typically over 4-6 months)
- **Duration of Treatment (DoT):** Higher cumulative-dose patients assigned to cohorts with DoT shorter than (condensed schedule) or equal to the DoT of patients assigned to lower cumulative-dose cohorts
- **Well tolerated:** no-MTD reached with one DLT
- **Clinical Benefit:** statistically significant virus dose-dependent OS benefit in solid tumors with lung metastases

Dose Escalation Phase 1b Monotherapy Study in Solid Tumors Progressed from Last Prior Therapy



Group A (n=11): TCD 2×10^5 pfu – 2×10^8 pfu (lower TCD)
Median OS = 4.6 months (95%CI: 1.3-11.0)
Group B (n=11): TCD 3×10^9 pfu – 3×10^{10} pfu (higher TCD)
Median OS = 16.8 months (95%CI: 5.9-UND)

OS Significantly greater in Group B (16.8 mo) vs Group A (4.6 mo), $p=0.026$

Group A' (n=5): TCD 2×10^5 pfu – 1×10^6 pfu (lowest TCD)
Median OS = 4.6 months (95%CI: 2.7-UND)
Group B' (n=5): TCD 1×10^{10} pfu – 3×10^{10} pfu (highest TCD)
Median OS = 20.9 months (95%CI: 16.8-UND)

OS Significantly greater in Group B' (20.0 mo) vs Group A' (4.6 mo), $p=0.002$

Key Clinical Takeaways

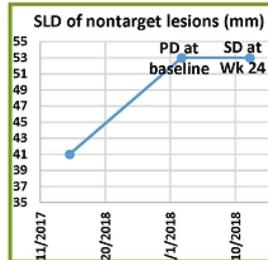
Anti-tumor effect of IV Immunochemotherapy

- High and Condensed Dosing (single cycle: bolus infusion on 5 consecutive days)
- Well tolerated: No DLT or MTD reached
- Monotherapy: Anti-tumor effects
- Combination therapy: Virus treatment revitalized tumors to subsequent chemotherapy with prolonged PFS and OS

Platinum refractory metastatic cervical cancer with lung mets

Case Report (Pt.#21A-06)

- ❖ Received 5 consecutive daily i.v. doses
 - Transient adverse reactions: fever, nausea, bone pain (Hx arthritis)
 - Stable disease with no tumor size increase

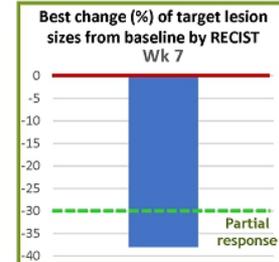


- ❖ Chemotherapy after disease progression
 - Partial Response
 - PFS: 70+ Weeks
 - OS: 53.4 Months

High-grade pancreatic cancer with lung & liver mets

Case Report (Pt.#21A-04)

- ❖ Received 5 consecutive daily i.v. doses
 - Transient adverse reactions: fever, nausea
 - 59% drop of CA19.9 tumor biomarker and Objective Response per RECIST, with PFS of 18 weeks



- ❖ Chemotherapy after disease progression
 - 83% drop of CA 19.9
 - Partial Response by RECIST
 - PFS: 31 wks

Industry Collaboration with Newsara BioPharma Co., Ltd



NEWSARA HIGHLIGHTS

7
Pipelines
12
Indications

5
Phase IIb/III
2
Phase II

Top 10
Blue-chip Biotech
Investors



Benny Li, PhD
Founder and Chief Executive Officer
20+ yrs. global and China local pharma
Former VP, GM of Takeda China
Development Center and SVP, Executive
GM of R&D at Hansoh Pharmaceuticals
Former Head of Clinical Development &
Medical Affairs in Asia at Alcon/Novartis

Newsara has paid \$11M to date and GNLX is eligible for additional development, regulatory and sales milestone payments and up to mid-double-digit percentages royalties on net sales



V2ACT Therapeutics is a joint venture between Genelux Corporation and TVAX Biomedical, Inc. established to develop and test V2ACT.

Vaccination increases the numbers of neoantigen-specific T cells in the body and Olvi-Vec kills cancer cells and potentiates T cells by increasing cancer tissue receptivity to adoptively transferred neoantigen-specific effector T cells.

Key Trial Takeaways

V2ACT Immunotherapy, combines an oncolytic immunotherapy and adoptive cell therapy

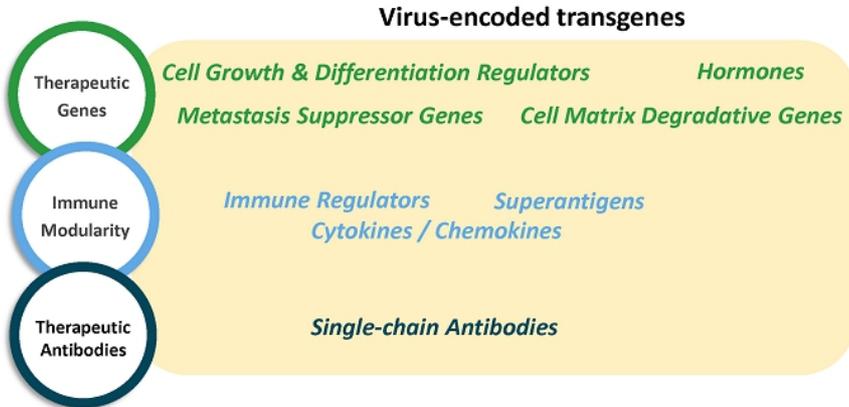
- Induces an acute inflammatory response in the tumor and converts tumor microenvironment from immunosuppressive to immunostimulatory;
- Anticipated to enhance effect of neoantigen specific effector T cells

| Technology | TVI Adoptive Cell Therapy | Olvi-Vec Oncolytic Immunotherapy |
|----------------|---|----------------------------------|
| Patients Dosed | ~ 130 | ~ 150 |
| Regulatory | Fast Track Designation / FDA Grant - glioblastoma | Phase 3 enrolling - ovarian |

Novel IO modality: United States Patent No. 11,633,442, issued in April 2023

Choice Platform Library: 500+ Vectors with 110+ Transgenes

Engineered and selected clonal isolated (non-GMO)
viral strains identified from
in vitro and *in vivo* selection criteria



✓ *In vitro* & *in vivo* tested: GLP Tox ready

Immune Modularity Molecules

- IL-6/sIL-6R
- IL-24

Cell Growth & Differentiation Regulators

- BMP-4

Cell Matrix-Degradative Genes

- hMMP9

Clonal Isolated Strains (non-GMO)

- LIVP1.1
- LIVP5.1.1
- V-VET1 (LIVP6.1.1)
- Cop15.1.1

Single-Chain Antibodies

- Anti-VEGF
- Anti-PD-1
- Anti-FAP
- Anti-PD-L1
- Anti-DLL4
- Anti-CTLA4
- Anti- $\alpha\beta 3$ -integrin

Intellectual Property: Market Exclusivity & Freedom to Operate



Patent Portfolio: 20 issued patents & 7 pending applications;
Olvi-Vec covered by Composition of Matter (2031*) and
Manufacturing (2038)



Olvi-Vec: No third-party royalties due



Long Duration of Regulatory / Marketing Exclusivity



*Reflects Patent Term Extension

Integrated R&D and Manufacturing Capabilities For Phase 3 And Launch

Key Takeaways

Facilities and Operations based in Southern California

GMP Manufacturing

- Large-scale manufacturing process
- Capacity for clinical studies and commercial launch needs

Translational Research

- Clinical Science capabilities to support development program
- Process development capabilities to support manufacturing

Headquarters

- Executive Office suite
- Right of First Refusal on 16,338 Sq. Ft of adjacent office space for build-out of Commercialization, Development & G&A functions



Facilities and Operations: Based in Southern California

Accomplished Leadership Team

Executive Team



Thomas Zindrick, JD
Chief Executive Officer



Lourie Zak
Chief Financial Officer



Paul Scigalla, MD, PhD
Chief Medical Officer



Sean Ryder, JD
General Counsel



Operations & R&D



Tony Yu, PhD
SVP, ClinDev
UC San Diego
MOORE'S CANCER CENTER



Joseph Cappello, PhD
Chief Technical Officer
THE UNIVERSITY OF UTAH
B BRAUN
SHARING EXPERTISE



Qian Zhang, MD, PhD
VP, Clinical Sciences
UC San Diego
MOORE'S CANCER CENTER



Ralph Smalling
Head, Regulatory Affairs
AMGEN



Cathy Gust, PhD
VP, Program Mgmt
AMGEN

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Director



JOHN SMITHER, CPA (Inactive)
Director

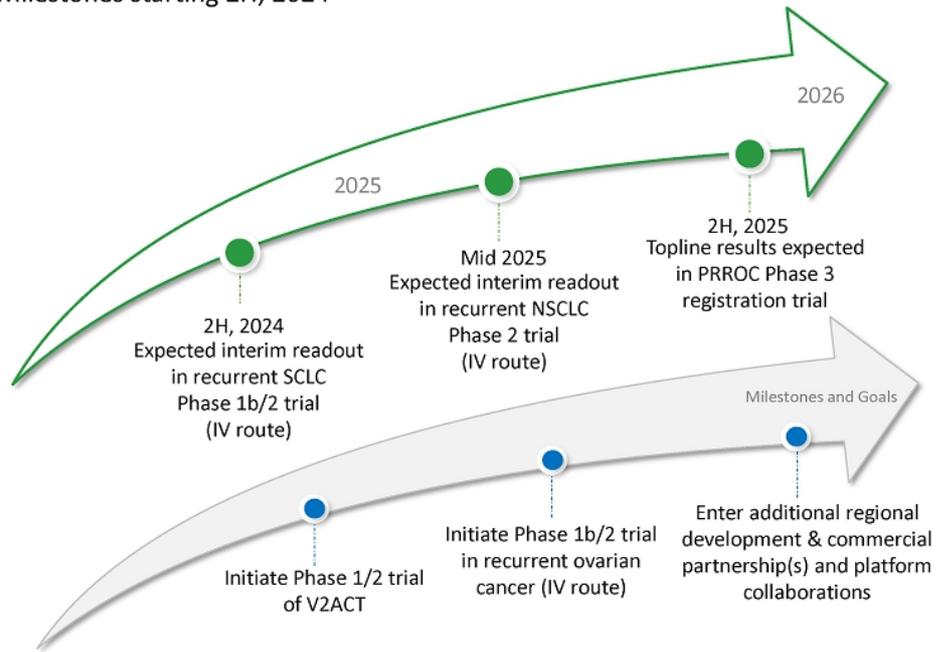


Genelux Has Executed on Multiple Milestones and is Positioned for the Future

Regular Cadence of Important Program Milestones starting 2H, 2024

Executed Milestones

- Runway past expected PRROC topline results, and recurrent SCLC and NSCLC interim readouts
- Syndicate of healthcare institutions for latest raise
- 20+ sites active in Phase 3 Trial in PRROC
- Phase 2 PRROC results published in JAMA Oncology
- Collaboration and License Agreement with Newsora
- Initiation of Phase 2 trial in recurrent NSCLC (US)
- Initiation of co-sponsored Phase 1b/2 trial in recurrent SCLC (China)



The logo for GENELUX features the word "GENELUX" in a bold, black, sans-serif font. The letter "G" is stylized with a green dot. The text is enclosed within a green, horizontal oval shape that has a slight gradient and a shadow effect.

Redefining Immuno-Oncology

Corporate Presentation | November 2024
Appendix



Accomplished Clinical Advisory Board

Medical Director,
Gynecologic
Oncology,
AdventHealth
Cancer Institute



Robert Holloway, MD
CHAIRMAN

Dr. Holloway is the principal investigator for VIRO-15 and has served on several committees of the Society of Gynecologic Oncology (SGO), including its Board of Directors.

Chief Medical
Officer, Vanium
Group



Robert Coleman, MD

Dr. Coleman currently serves as Special Advisor to the President of Gynecologic Oncology Group and is co-Director of GOG-Partners. In addition, he is immediate Past-President of the International Gynecologic Cancer Society.

Co-Director,
Gynecologic
Oncology, Hoag
Memorial Hospital
Presbyterian



Albert A. Mendivil, MD

Dr. Mendivil, site principal investigator for VIRO-15, serves as Co-Director of Gyn- Onc and Complex Pelvic Surgery, Hoag Hospital. He has been the principal investigator or site sub-investigator on 20+ clinical trials.

Deputy Director of
the University of
Cincinnati Cancer
Institute



Thomas J. Herzog, MD

Dr. Herzog is President of the GOG Foundation. He has served on the leadership board or council of SGO, the Foundation for Women's Cancer, and ACOG.

Professor and
Division Director,
Ohio State
University
Comprehensive
Cancer Center



David M. O'Malley, MD

Dr. O'Malley is the clinical trial advisor/lead for ovarian cancer within GOG Partners, a committee member for the NCI Gynecologic Cancer Steering Committee's Ovarian Task Force and the NRG Oncology.

Forsythe & Bear,
LLC



Alan Forsythe, PhD

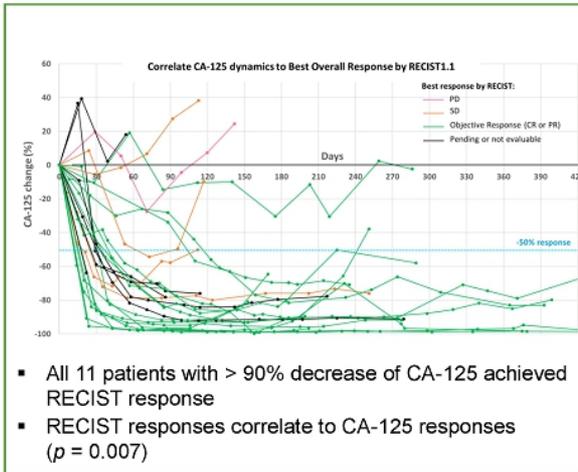
Dr. Forsythe has had a distinguished career in pharmaceutical drug development. As Vice President of Corporate Biomedical Information at Amgen, Alan led the Biostatistics, Epidemiology and HOER depts.

Olvi-Vec-primed Immunochemotherapy Anti-tumor Activity: CA-125 Biomarker

Rapid, Common and Durable Responses

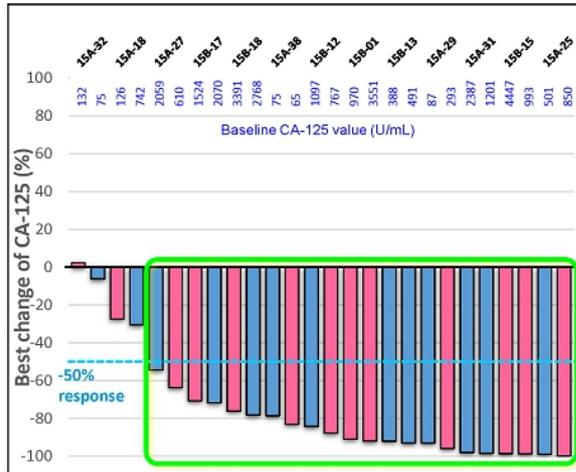
CA-125 Decrease

- All PRROC Patients: 96% (25/26)
- Platinum refractory patients: 85% (11/13)



ORR by CA-125

- All PRROC Patients: 85% (22/26)
- Platinum refractory patients: 85% (11/13)

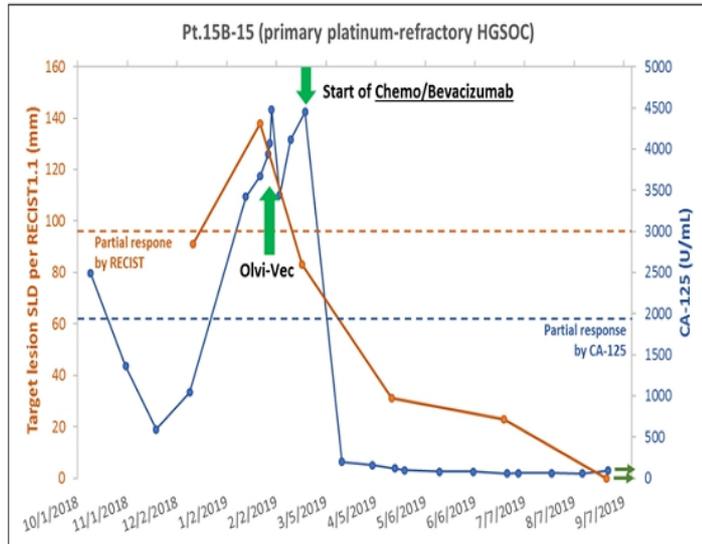
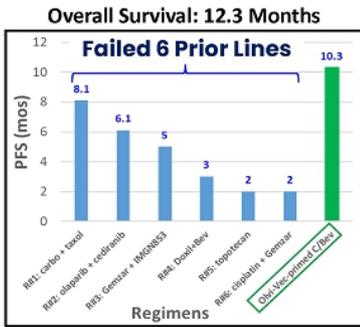


Olvi-Vec-Primed Immunochemotherapy Overcomes "Refractoriness"

Exemplary platinum-refractory patients, after platinum re-challenge, achieved **PFS exceeding any prior lines**

15B-15:

- Stage IIIB high-grade serous
- ECOG: 0
- BRCA negative
- PD-L1 negative



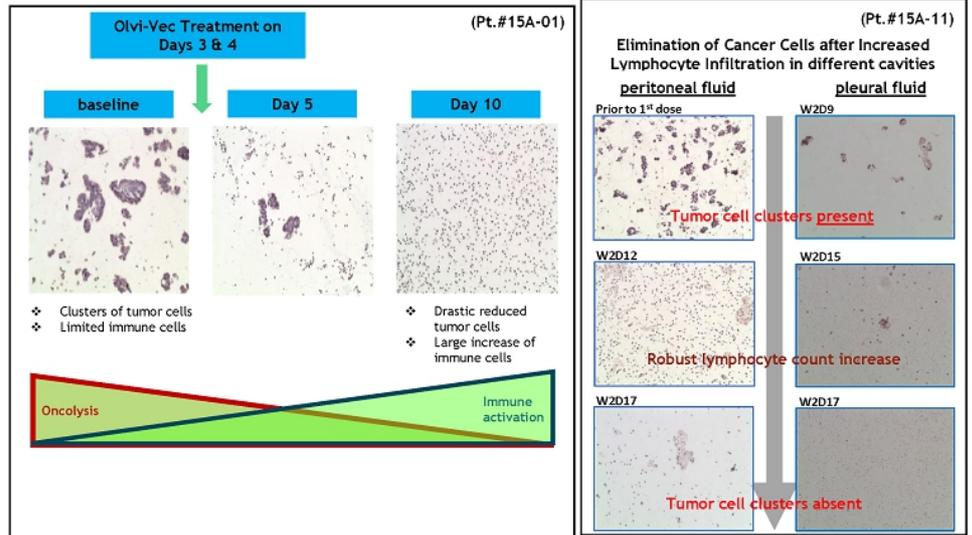
Olvi-Vec Demonstrated Oncolysis and Immune Activation

Data from Phase 1b Monotherapy portion of VIRO-15 trial

Key Takeaways

Olvi-Vec monotherapy shows decreased tumor cells and increased immune activation

- Olvi-Vec treatment was able to dramatically decrease or eliminate tumor cells in multiple patient samples
- The Activation of Immunosurveillance by Olvi-Vec after 2 doses was seen in multiple cavities as monotherapy



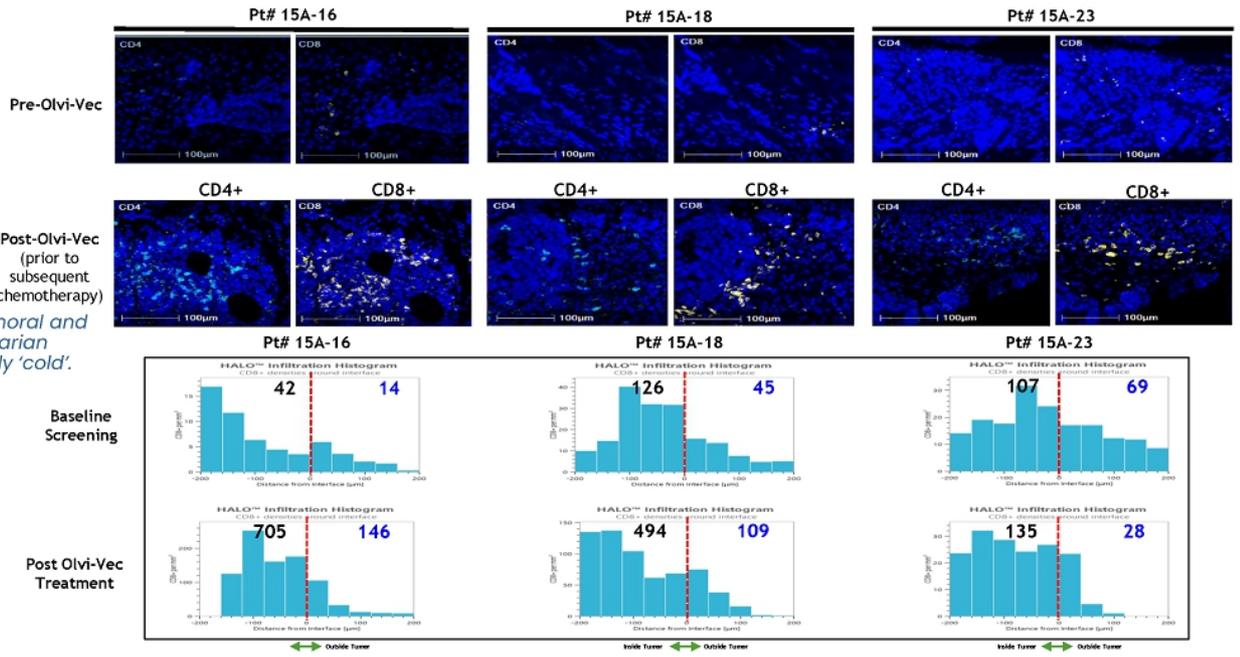
CD8+ T-cells: Infiltrating Lymphocytes are Prognostic for Response/Survival

Data from Phase 1b Monotherapy portion of VIRO-15 trial

**Olvi-Vec
Induced Infiltration
of CD8+ cells into
Tumors**

Endogenous TILs (intra-tumoral and stromal) are very low in ovarian cancer, i.e., immunologically 'cold'.

**Shift of CD8+
cells into
epithelial
tumor tissue**



Long-lasting, Tumor-specific T cell Response Corresponds to Tumor Reduction

Data from Phase Ib Monotherapy portion of VIRO-15 trial

Key Takeaways

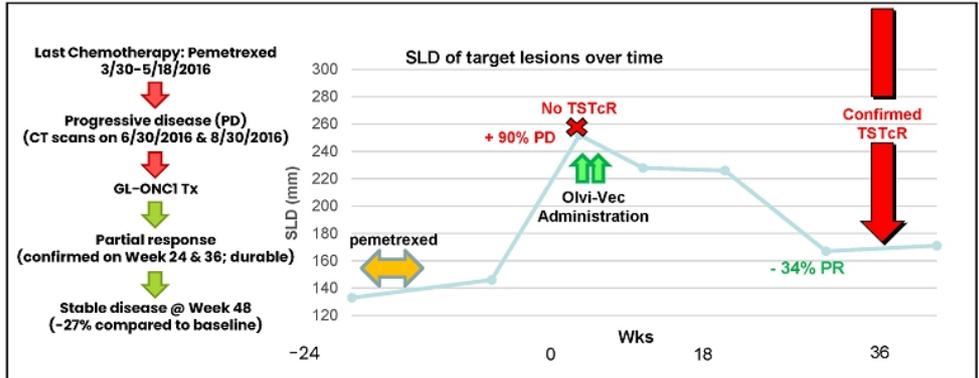
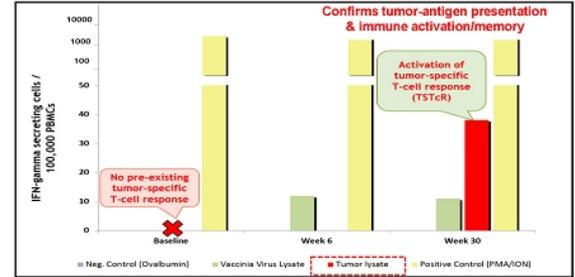
Off-the-Shelf Personalized Medicine: Single Agent generates Individualized Results

- Olvi-Vec induces favorable & long-lasting Tumor-specific T-cell Response (TSTcR) by ELISPOT analysis in patient in heavily treated patient w/ 9 prior regimens of chemo; no Tumor-specific T-cell response at baseline
- Documented OR from Olvi-Vec treatment after failure of last chemotherapy

Case Report (Pt #15A-05)

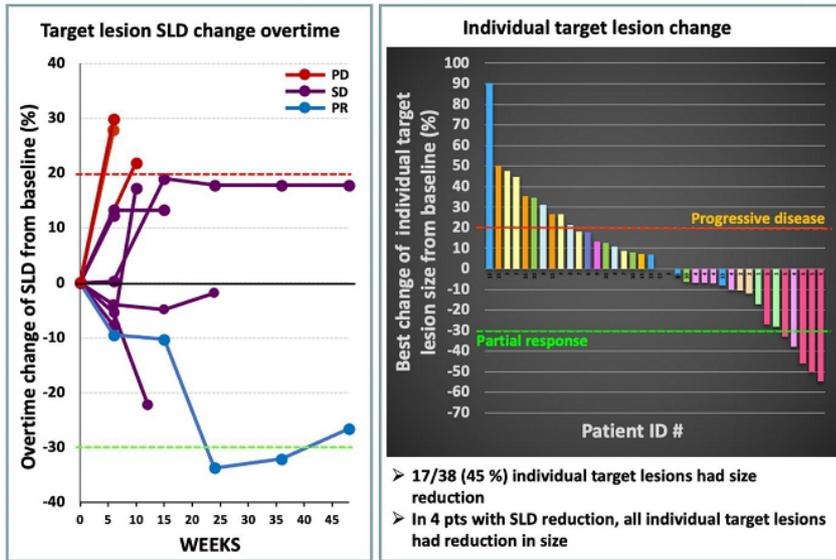
Heavily pre-treated:
9 prior regimens of chemo+Avastin;
no pre-existing tumor-specific T-cells

Post treatment:
Consequential amount (~3%) of all activatable T cells at Week 30 are tumor-specific T-cells



Olvi-Vec Demonstrated Anti-Tumor Response & Disease Control Observed

Data from Phase 1b Monotherapy portion of VIRO-15 trial

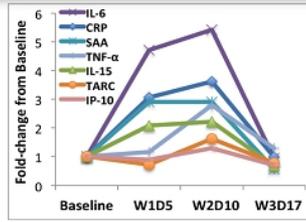


Olvi-Vec: Ideal Backbone for Combination Therapy

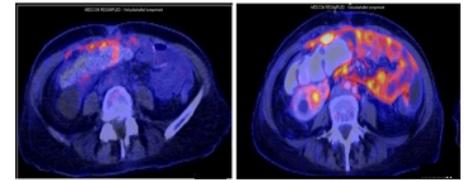
Converts Tumor Microenvironment to Inflammatory "Hot Spot"

Induction of acute inflammatory cytokines (Th1-type related)

VIRO-15 Study



NCT01443260/TUE Study



Baseline

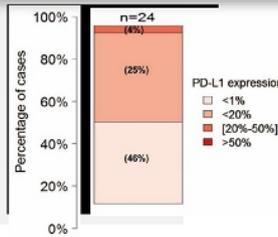
Massive inflammatory response after (C1D24) single dose of virus

Up Regulates Immunomodulatory Target Proteins, such as PD-L1

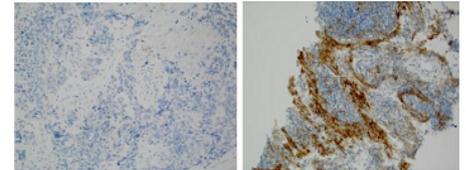
Endogenous PD-L1 expression in ovarian tumor is low, hence limiting target by

anti-PD-1/PD-L1 therapy

Rodriguez-Freixinos et al. J Clin Oncol 36, 2018 (suppl; abstr 5595)



PD-L1: VIRO-15 Study (monotherapy)



Baseline

Post treatment (20d)
Strong PD-L1 staining at the tumor-stromal interface