# 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): June 3, 2024**

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

| **Delaware** | **001-41599** | **77-0583529** |
|---|---|---|
| **(State or other jurisdiction of incorporation)** | **(Commission File Number)** | **(I.R.S. Employer Identification No.)** |

| | |
|---|---|
| **2625 Townsgate Road, Suite 230**<br>**Westlake Village, California**<br>**(Address of principal executive offices)** | **91361**<br>**(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 June 4, 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, except as expressly set forth by specific reference in such filing to this Current Report on Form 8-K.

**Item 8.01 Other Events.**

On June 3, 2024, the Underwriters (as defined below) exercised in part their option to purchase (i) an additional 625,000 shares (the "Shares") of the Company's common stock, par value $0.001 per share (the "Common Stock") and (ii) accompanying warrants to purchase 625,000 shares of Common Stock (the "Warrants"), with an exercise price of $5.25 per share, at a combined offering price of $4.00 per share and accompanying Warrant, pursuant to an underwriting agreement dated as of May 23, 2024 (the "Underwriting Agreement") by and between the Company and Guggenheim Securities, LLC, as representative of the several underwriters named therein (the "Underwriters", and such exercise, the "Overallotment Exercise").

The net proceeds to the Company from the Overallotment Exercise were approximately $2.35 million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by the Company. All of the Shares and the Warrants were sold by the Company.

The securities described above were offered and issued pursuant to an effective shelf registration statement on Form S-3 (File No. 333-276847) and the related prospectus and prospectus supplement.

Each Warrant has an initial exercise price per share of $5.25, subject to certain adjustments as provided in the Warrant. The Warrants may be exercised at any time until exercised in full. A holder (together with its affiliates and other attribution parties) may not exercise any portion of a Warrant to the extent that immediately prior to or after giving effect to such exercise the holder would own more than 9.99% of the Company's outstanding Common Stock immediately after exercise, which percentage may be changed at the holder's election to a lower or higher percentage not in excess of 19.99% (if exceeding such percentage would result in a change of control under Nasdaq Listing Rule 5635(b) or any successor rule) upon 61 days' notice to the Company subject to the terms of the Warrants.

The foregoing description of the terms of the Warrants does not purport to be complete and is qualified in its entirety by reference to the form of Warrant, which is filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the U.S. Securities and Exchange Commission on May 24, 2024, and which is incorporated herein by reference. A copy of the opinion of Cooley LLP relating to the legality of the issuance and sale of the securities in the Overallotment Exercise is filed as Exhibit 5.1 hereto.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

| Exhibit No. | Description |
|---|---|
| 5.1 | Opinion of Cooley LLP |
| 23.1 | Consent of Cooley LLP (included in Exhibit 5.1) |
| 99.1 | Corporate Presentation, dated June 4, 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: June 4, 2024

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

**Exhibit 5.1**

Cooley

Jason L. Kent
+1 212 479 6044
jkent@cooley.com

June 4, 2024

Genelux Corporation
2625 Townsgate Road, Suite 230
Westgate Village, California 91361

Ladies and Gentlemen:

We have acted as counsel to Genelux Corporation, a Delaware corporation (the "***Company***"), in connection with the sale by the Company of (i) 625,000 shares (the "***Shares***") of the Company's common stock, par value $0.001 ("***Common Stock***"), and (ii) warrants (the "***Warrants***") to purchase up to 625,000 shares of Common Stock (the "***Warrant Shares***"), pursuant to a Registration Statement on Form S-3 (Registration Statement No. 333-276847) (**the "*Registration Statement*"**), filed with the Securities and Exchange Commission (the "***Commission***") under the Securities Act of 1933, as amended (the "***Securities Act***"), the base prospectus included in the Registration Statement (the "***Base Prospectus***"), and the prospectus supplement relating to the Shares, the Warrants and the Warrant Shares filed with the Commission pursuant to Rule 424(b) under the Securities Act (together with the Base Prospectus, the "***Prospectus***").

In connection with this opinion, we have examined and relied upon (a) the Registration Statement and the Prospectus, (b) the form of Warrant filed as an exhibit to a Current Report on Form 8-K with the Commission on May 24, 2024, (c) the Company's certificate of incorporation and bylaws, each as currently in effect, and (d) such other documents, records, opinions, certificates, memoranda and instruments as in our judgment are necessary or appropriate to enable us to render the opinion expressed below. We have assumed the genuineness of all signatures, the authenticity of all documents submitted to us as originals, the conformity to originals of all documents submitted to us as copies, the accuracy, completeness and authenticity of certificates of public officials and the due authorization, execution and delivery of all documents by all persons other than the Company where authorization, execution and delivery are prerequisites to the effectiveness thereof. As to certain factual matters, we have relied upon a certificate of an officer of the Company and have not independently verified such matters.

With regard to our opinion as to the Warrants and the Warrant Shares, we express no opinion to the extent that future issuances of securities of the Company, antidilution adjustments to outstanding securities of the Company or other matters cause the Warrants to be exercisable for more shares of Common Stock than the number available for issuance by the Company. Further, we have assumed the exercise price of the Warrants will not be adjusted to an amount below the par value per share of the Common Stock.

Our opinion is expressed only with respect to the General Corporation Law of the State of Delaware and, as to the Warrants constituting binding obligations of the Company, the laws of the State of New York. We express no opinion to the extent that any other laws are applicable to the subject matter hereof and express no opinion and provide no assurance as to compliance with any federal or state securities law, rule or regulation.

With regard to our opinion concerning the Warrants constituting binding obligations of the Company:

(i) Our opinion is subject to, and may be limited by, (a) applicable bankruptcy, reorganization, insolvency, moratorium, fraudulent conveyance, debtor and creditor, and similar laws which relate to or affect creditors' rights generally, and (b) general principles of equity (including, without limitation, concepts of materiality, reasonableness, good faith and fair dealing) regardless of whether considered in a proceeding in equity or at law;

(ii) Our opinion is subject to the qualification that (a) the enforceability of provisions for indemnification or limitations on liability may be limited by applicable law and by public policy considerations, and (b) the availability of specific performance, an injunction or other equitable remedies is subject to the discretion of the court before which the request is brought;

(iii) We express no opinion with respect to any provision of the Warrants that: (a) relates to the subject matter jurisdiction of any federal court of the United States of America or any federal appellate court to adjudicate any controversy related to the Warrants; (b) specifies provisions may be waived in writing, to the extent that an oral agreement or implied agreement by trade practice or course of conduct has been created that modifies such provision; (c) contains a waiver of an inconvenient forum; (d) provides for liquidated damages, default interest, late charges, monetary penalties, prepayment or make-whole payments or other economic remedies; (e) relates to advance waivers of claims, defenses, rights granted by law, or notice, opportunity for hearing, evidentiary requirements, statutes of limitations, trial by jury, service of process or procedural rights; (f) restricts non-written modifications and waivers; (g) provides for the payment of legal and other professional fees where such payment is contrary to law or public policy; (h) relates to exclusivity, election or accumulation of rights or remedies; or (i) provides that provisions of the Warrants are severable to the extent an essential part of the agreed exchange is determined to be invalid and unenforceable; and

(iv) We express no opinion as to whether a state court outside of the State of New York or a federal court of the United States would give effect to the choice of New York law or jurisdiction provided for in the Warrants.

On the basis of the foregoing, in reliance thereon and subject to the qualifications set forth herein, we are of the opinion that (i) the Shares, when sold and issued against payment therefor in accordance with the Registration Statement and the Prospectus, will be validly issued, fully paid and nonassessable, (ii) the Warrants, when duly executed and delivered by the Company against payment therefor as described in the Registration Statement and the Prospectus, will be binding obligations of the Company, and (iii) the Warrant Shares, when issued and paid for in accordance with the terms of the Warrants, will be validly issued, fully paid and nonassessable.

This opinion is limited to the matters expressly set forth in this letter, and no opinion should be implied, or may be inferred, beyond the matters expressly stated. This opinion speaks only as to law and facts in effect or existing as of the date hereof and we undertake no obligation or responsibility to update or supplement this letter to reflect any facts or circumstances that may hereafter come to our attention or any changes in law that may hereafter occur.

We consent to the reference to our firm under the heading "Legal Matters" in the Prospectus and to the filing of this opinion as an exhibit to a Current Report on Form 8-K to be filed with the Commission for incorporation by reference in the Registration Statement. In giving such consents, we do not thereby admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Commission thereunder.

Sincerely,

Cooley LLP

By: */s/ Jason L. Kent*
Jason L. Kent

Exhibit 99.1


GENELUX
Redefining Immuno-Oncology
Corporate Presentation June 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 March 31, 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.

We have filed a registration statement (including a base prospectus) and will file a preliminary prospectus supplement with the SEC for the offering to which this presentation relates. Before you invest, you should read the base prospectus in that registration statement, the preliminary prospectus supplement related to the offering (when available) and other documents we have filed with the SEC for more complete information about the Company and the offering. You may get these documents for free by visiting EDGAR on the SEC website at: http://www.sec.gov. This presentation shall not constitute an offer to sell or the solicitation of an offer to buy these securities, nor shall there be any sale of these securities in any state or jurisdiction in which such offer, solicitation, or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

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 1b/2 trial via systemic in recurrent small cell lung cancer (SCLC)*
*Planned Phase 2 trial via systemic in recurrent non-small cell lung cancer (NSCLC)*

***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***

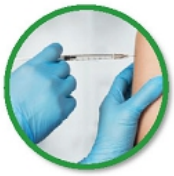
*US launch in Ovarian Cancer initially; strategic partnerships for ex-US rights*

***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
- Potential utility in multiple cancers (demonstrated in 20 pre-clinical liquid & solid tumor models, e.g., ovarian, lung, breast, colon, kidney, prostate)

### Antitumor Effect and Well Tolerated

- Strong 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)*

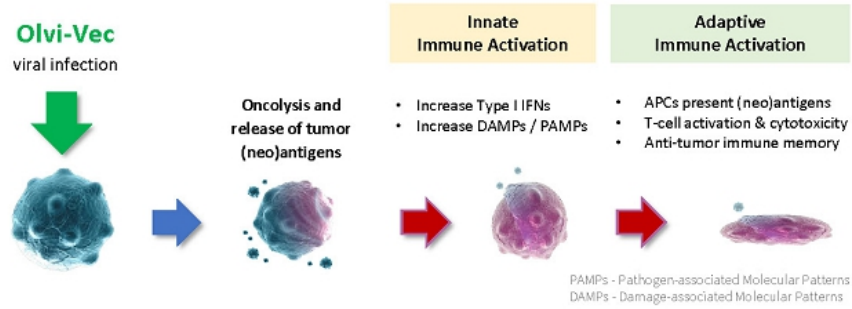
| Olvi-Vec | Indication | Design | Preclinical | Phase 1 | Phase 2 | Phase 3 | Anticipated Milestones | Collaborators |
|---|---|---|---|---|---|---|---|---|
| Regional Route | *Ovarian Cancer (platinum-resistant/ refractory)* | *Olvi-Vec (i.pe) +Platinum-based regimen* | | *Ph3 OnPrime/GOG-3076 Study 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 Regulatory Submission* | | | *Expected to initiate in 1H, 2024* | |
| | *Small Cell Lung Cancer (recurrent/platinum failure)* | *Olvi-Vec (IV) +Platinum-based regimen* | | *Ph1b/2 Enrolling* | | | *Expected interim readout in 2H, 2024* | NEWSOARA (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)




**'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**

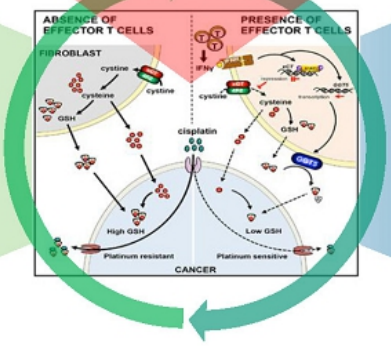
- Increase of proinflammatory cytokines/chemokines
- Influx of CD8+ effector T cells
- M2 to M1 transition of tumor-associated macrophages
- Decrease of immune suppression
- Changes of tumor gene expression profile
- Immunogenic tumor cell death
- Vascular collapse

# Olvi-Vec-Primed Immunochemotherapy: Reversing Platinum Resistance

**Olvi-Vec-Induced Hot Tumor**

**Pro-therapeutic gene expression**
*[VIRO-15 Monotherapy Data]*

- Positive regulation of T-cell activating and trafficking[1]
- Expression profiles (e.g., STAT1) correlated to better prognosis[2]
- Promotion of sensitization[3] / response to chemotherapy[4]




**Chemotherapy synergy**

- Immunogenic cell death and presentation of oncogenic neoantigens
- Depletion of suppressor cells[5]
- Increase susceptibility to cytotoxic T-lymphocytes

**"Prime & Boost"**

[1]Song et al. (Mol Ther (2007) 15(8):1558-1562)
[2]Wang et al., Cell. 2016; 165(5): 1092–1105
[3]Mantovani et al., J Exp Med. 2015;212(4):435–445
[4]Ahmed et al., Mol Aspects Med. 2014;39:170–25
[5]Weir et al., Cancers (Basel) (2011) 3(3):3114-3142 Emens et al., Cancer Immunol Res (2015) 3(5):436-443)

# A Maturing Modality with Phase 3 Companies Validating OV Potential

GENELUX

*Next Generation Regional & Systemic Administration*

**Best-in-Class**
**Potential across multiple tumor types**

**Phase 2 Ovarian Cancer**
**Apparent tumor re-sensitization to platinum-based therapy**

**Phase 1b Solid Tumors**
**Dose-dependent mOS in primary & metastatic lung-diseased 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 | Daiichi-Sankyo | CG ONCOLOGY |
|---|---|---|
| FDA/EMA Approval in Melanoma | PMDA Approval in malignant glioma | 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
- 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 / (1) | Phase 1 | Monotherapy (Dose Escalation) | 11 | Single Arm | Completed[1] |
| US / (2) | Phase 2 | Combination (platinum-based regimen) | 27 | Single Arm | Completed[2] |
| US / (~30) | Phase 3 | Combination (platinum-based regimen) | 186 | 2:1 | Enrolling[3] |

[1] Monyam *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 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 Monotherapy***[1]

### 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: $6x10^9$ 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 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

[1]Manyam *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*

**Key Inclusion Criteria**

- High-grade serous, endometrioid or clear-cell ovarian cancer which includes: (1) platinum-resistant (recurrence or progression in < 6 months) or (2) platinum-refractory (progression while on platinum-based therapy) with at least two prior lines of therapy
- ECOG Performance status is at 0 or 1

**Interventional Single Group Assignment**
**n=27**

**Design**

Olvi-Vec via intraperitoneal infusion in multiple doses, after systemic chemotherapy administered with or without bevacizumab

**Endpoints**

Primary: Median progression-free survival (mPFS); Objective Response Rate (ORR) by RECIST 1.1 and by tumor biomarker Cancer Antigen-125.
Secondary: Median overall survival (mOS)

**Data Presentations**

1. 2020 Digital Annual Meeting of International Gynecologic Cancer Society

   Oral Plenary Session

2. JAMA Oncology

   Selected for Journal podcast series interview

**OnPrime Phase 3 Trial**

Ongoing Pivotal Phase 3 for the treatment of PRROC patients, using the same Experimental Arm treatment regimen

JAMA Oncology

*Results of the VIRO-15 Phase 2 Trial were published in JAMA Oncology* (Link)

# Phase 2: Clinically-Meaningful Responses in Heavily Pretreated Patients

## 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

**Overall Response Rate (ORR) & Progression-Free Survival (PFS)***

| | 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◊◊) (33 - 74) | **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) | **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) | **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 patents 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***

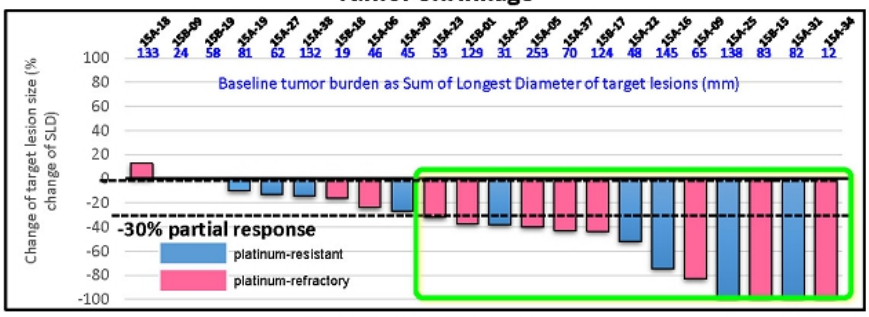
Tumor Shrinkage

- 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

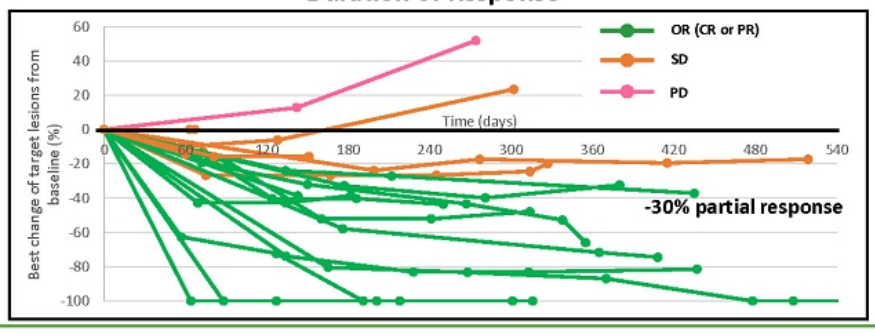
Duration of Response (DOR)

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

**Tumor Shrinkage**




**Duration of Response**

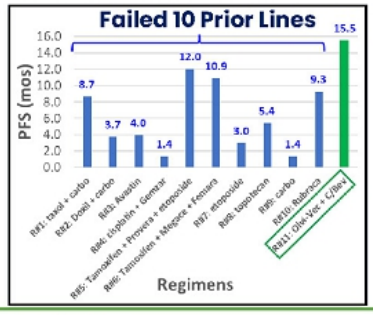


# Olvi-Vec-Primed Immunochemotherapy Overcomes "Refractoriness"

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

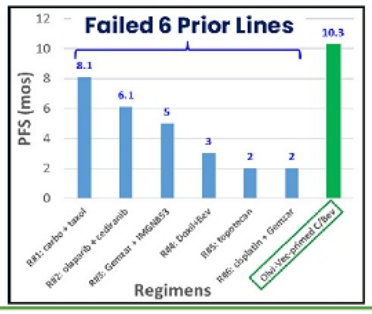
**15B-01:**
- Stage IIIB papillary serous
- ECOG: 0
- BRCA negative
- PD-L1 negative

**Overall Survival: 23.2 Months**



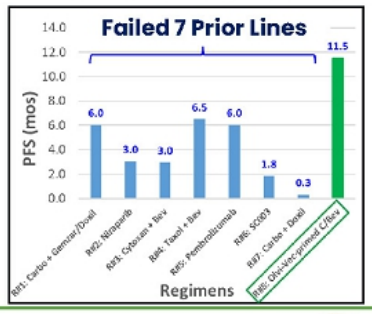

**15B-15:**
- Stage IIIB high-grade serous
- ECOG: 0
- BRCA negative
- PD-L1 negative

**Overall Survival: 12.3 Months**




**15B-17:**
- Stage IIIC high-grade serous
- ECOG: 1
- BRCA negative

**Overall Survival: 15.7 Months**



# Durable Survival Benefit

## Key Clinical Takeaways

***Encouraging mOS and Long-term survival data***

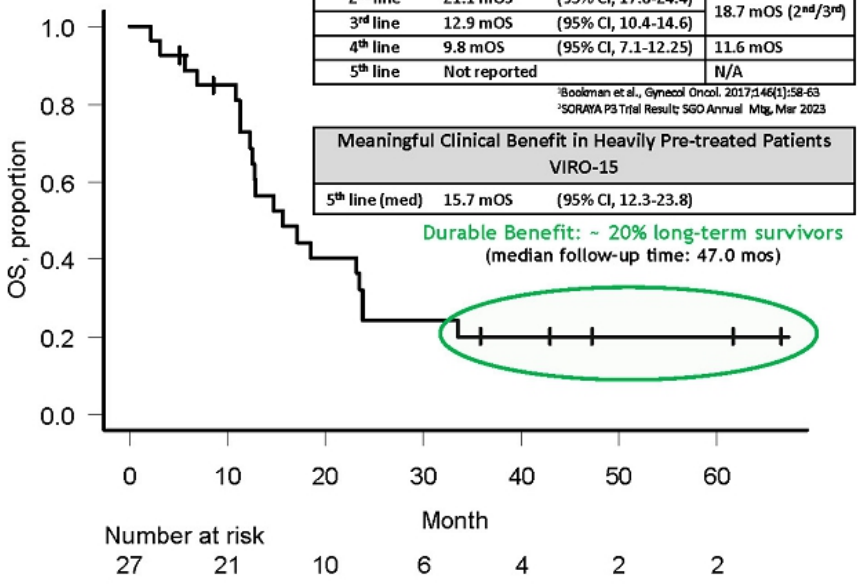
*20% long-term survivors consistent with clinically beneficial immunotherapies*

- 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

| Prognosis Worsens with each Successive Line | | | |
|---|---|---|---|
| Historical Data[1] | | | ELAHARE[2] |
| 2nd line | 21.1 mOS | (95% CI, 17.8-24.4) | 18.7 mOS (2nd/3rd) |
| 3rd line | 12.9 mOS | (95% CI, 10.4-14.6) | |
| 4th line | 9.8 mOS | (95% CI, 7.1-12.25) | 11.6 mOS |
| 5th line | Not reported | | N/A |

[1]Bookman et al., Gynecol Oncol. 2017;146(1):58-63
[2]SORAYA P3 Trial Result; SGO Annual Mtg, Mar 2023

| Meaningful Clinical Benefit in Heavily Pre-treated Patients VIRO-15 | | |
|---|---|---|
| 5th line (med) | 15.7 mOS | (95% CI, 12.3-23.8) |



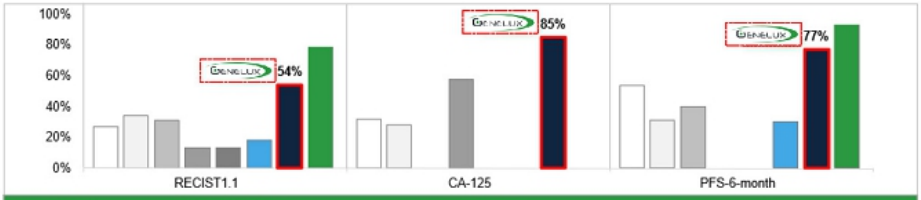
# Seeking to Reset Life Clock of Heavily Pre-treated Patients

## Key Clinical Takeaways

***Olvi-Vec addresses a broad and underserved pool of patients***

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

*While clinical remissions are obtainable, a majority of patients will relapse. Genelux looks to take an all-comers approach*




| Study | # or prior lines | Regimen |
|---|---|---|
| **Platinum-resistant / refractory patients** | | |
| AURELIA[1] | ≤ 2 prior lines | Chemo + Avastin (i.e., CT+Bev) |
| B-GEMOX[2] | 1-2 (21%), 3-4 (63%), ≥ 5 (16%) | Oxali + Gem + Avastin |
| FORWARD II[3] | Median 3 prior lines | Mirvetuximab soravtansine + pembrolizumab (median/high FRα group) |
| VB-111[4] | ≤ 3 prior lines | VB-111 + paclitaxel |
| JAVELIN-200 | ≤ 3 prior lines | Avelumab + PLD |
| TOPACIO[5] | ≤ 4 prior lines | Niraparib + pembrolizumab |
| VIRO-15 | **Median 4 prior lines** | **Olvi-Vec / Chemo ± Avastin** |
| **Platinum-sensitive patients** | | |
| OCEANS[6] | *No prior chemo in recurrent setting* | Carbo + Gem + Avastin |


References
(1) Pujade-Lauraine et al, J Clin Oncol 2014;32:1302-1308.
(2) Ikeda et al, Int J Gynecol Cancer 2013;23:355-360.
(3) Matulonis et al, ESMO 2018.
(4) Arend et al, Gynecol Oncol. 2020;157:578-584.
(5) Konstantinopoulos et al, J Clin Oncol 2018;36(S15)106.
(6) Aghajanian et al, Gynecol Oncol. 2015;139(1):10–18.


Footnote: 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.

# 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.*

**Key Inclusion Criteria**

- High-grade serous, endometrioid, or clear-cell ovarian cancer
- Platinum-resistant or -refractory disease
- Received prior bevacizumab (or biosimilar) treatment
- Received a minimum of 3 prior lines of systemic therapy with no maximal limit
- Performance status ECOG is at 0 or 1, and life expectancy of at least 6 months

**Multi-center, randomized open-label[1]**
**n=186**

**Experimental Arm**
Olvi-Vec and Platinum + single agent chemo + Bevacizumab, followed by maintenance therapy

**Active Comparator Arm [2]**
Single-agent chemo (+ optional platinum) + Bevacizumab, followed by maintenance therapy

Topline results expected in 2H, 2025

**Primary Endpoint**

Progression-Free Survival

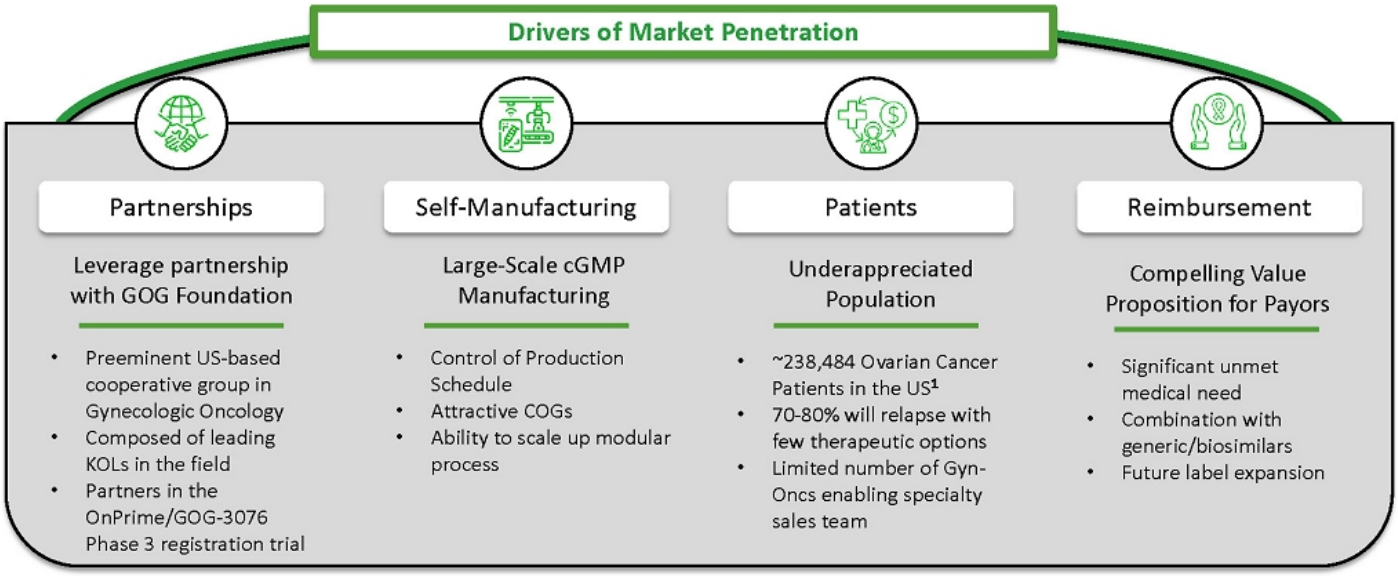
**Key Secondary Endpoints**

1. Treatment-emergent AEs
2. Duration of Response (DOR)
3. Overall Response Rate (ORR)
4. Overall Survival (OS)

*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 J ournals.sagepub.com/home/hic

# Self Launch Olvi-Vec for Ovarian Cancer in the US




[1]NIH Ovarian Cancer Fact Sheet


# Systemic Administration Programs

## Lung Cancers

# Systemic Administration Program

## 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 China[1]
- All patients in these trials will be treated systemically and have previously failed platinum-based therapy

Expected Milestones

- Ph2 NSCLC: Initiate 1H, 2024
- Ph1b SCLC: Interim readout 2H, 2024

[1] Newsoara 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 | Phase 2 | ~142 | 1:1 | Regulatory Submission |
| NEWSOARA | China | Recurrent/platinum failure SCLC | 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 |

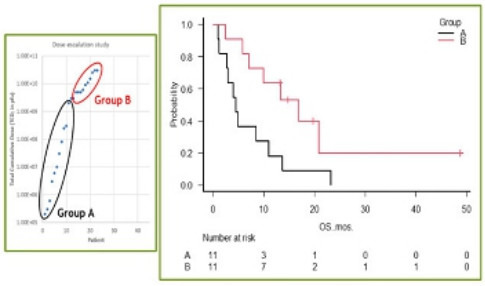
# Systemic Administration Demonstrated Dose-dependent OS Benefit

## Key Clinical Takeaways

***Demonstrated feasibility and clinical benefit of multiple IV cycles***

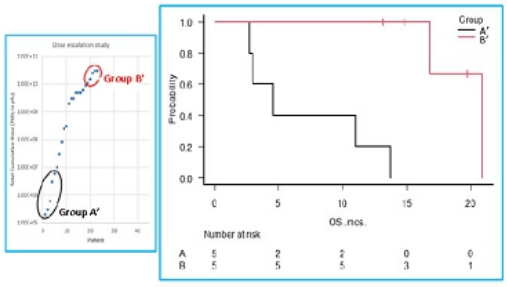
- Median 5 prior lines of therapy
- Regimen: various dosing levels and schedules (typically over 4-6 months)
- Well tolerated: no-MTD reached with one DLT
- Duration of Treatment (DoT): Higher cumulative-dose patients assigned to cohorts with DoT shorter than (condensed schedule) or equal to the DoT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

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




**Group A :** (n=11; **lower-dose group** with TCD ranging from $2\times10^5$ pfu - $2\times10^9$ pfu)
**Group B :** (n=11; **higher-dose group** with TCD ranging from $3\times10^9$ pfu - $3\times10^{10}$ pfu)

**Groups lower vs higher TCD:**
median Overall Survival at **4.6 months** (95% CI: 1.3 – 11.0) vs **16.8 months** (95% CI: 5.9 – NA);
$p = 0.026$; a statistically significant clinical benefit favoring the higher dose group.




**Group A':** (n=5; **lowest-dose group** with TCD ranging from $2\times10^5$ pfu - $1\times10^6$ pfu)
**Group B':** (n=5; **highest-dose group** with TCD ranging from $1\times10^{10}$ pfu - $3\times10^{10}$ pfu)

**Groups lowest vs highest TCD:**
median Overall Survival at **4.6 months** (95% CI: 2.7 – NA) vs **20.9 months** (95% CI: 16.8 – NA);
$p = 0.002$; a statistically significant clinical benefit favoring the highest dose group.

The ROYAL MARSDEN NHS Foundation Trust
UNIVERSITY OF SURREY
ICR The Institute of Cancer Research

# Systemic Administration + Chemo Generated Encouraging Data

## Key Clinical Takeaways

***Anti-tumor effect of IV Immunochemotherapy***

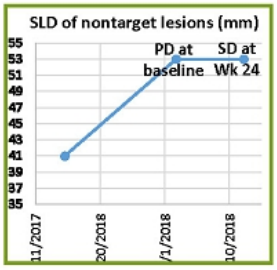
- High and Condensed Dosing (single cycle: bolus infusion on 5 consecutive days)
- Well tolerated: No DLT or MTD reached
- Monotherapy: Anti-tumor effects
- Combination therapy: Virus treatment revitalized tumors to subsequent chemotherapy with prolonged PFS and OS

AdventHealth | Cancer Institute : Expanded Access Program

### 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

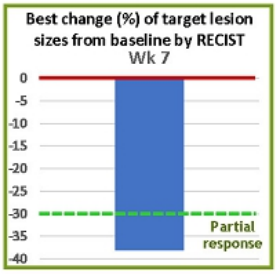



- Chemotherapy after disease progression
  - Partial Response
  - PFS: 70+ Weeks
  - OS: 53.4 Months

### High-grade pancreatic cancer with lung & liver mets

Case Report (Pt.#21A-04)

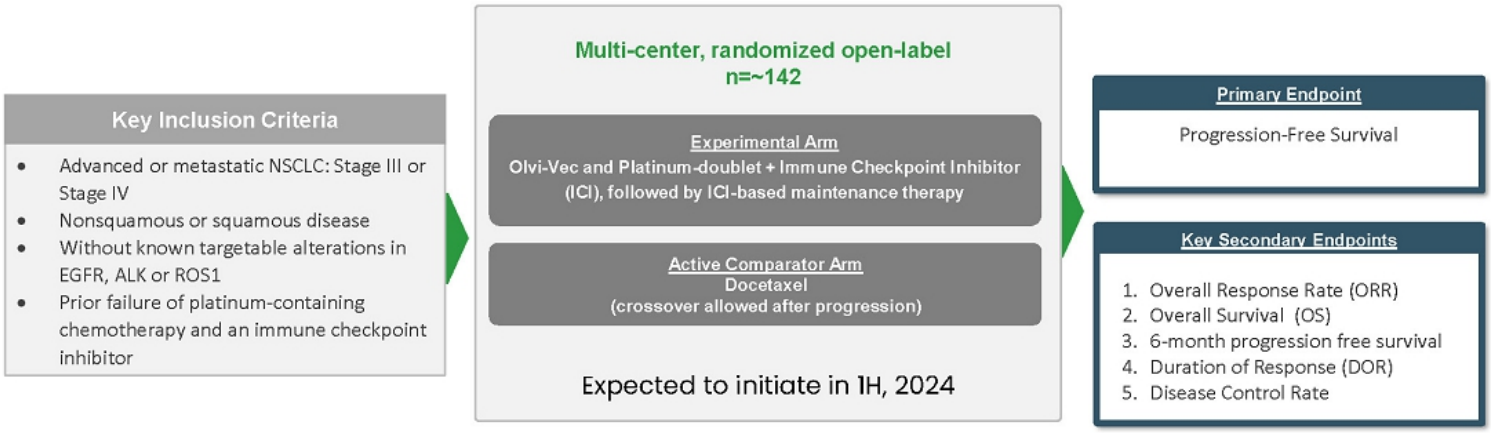
- Received 5 consecutive daily i.v. doses
  - Transient adverse reactions: fever, nausea
  - 59% drop of CA19.9 tumor biomarker and Objective Response per RECIST, with PFS of 18 weeks




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

# 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*

**Key Inclusion Criteria**

- Prior failure of platinum-containing chemotherapy and/or immunotherapy, platinum-containing chemotherapy and/or Anlotinib with disease progresses or relapses.
- ECOG Performance status is at 0 or 1

**Multi-center, randomized open-label**
**n=~110**

**Design**

**Olvi-Vec via multiple consecutive day intravenous doses, followed by systemic administered of platinum and etoposide**

Interim results expected in 2H, 2024

**Phase 1b Endpoints**

**Primary Endpoint**
- Safety and tolerability

**Secondary Endpoints**
- ORR by RECIST 1.1
- Progression-free Survival (PFS)
- Duration of Response (DoR)
- Disease Control Rate (DCR)

**Phase 2 Endpoints**

**Primary Endpoint**
- ORR by RECIST 1.1 (by investigator and by BICR)

**Secondary Endpoints**
- Safety
- Progression-free Survival (PFS)
- Duration of Response (DoR)
- Disease Control Rate (DCR)

# Industry Collaboration with Newsoara BioPharma Co., Ltd


**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

NEWSOARA
HIGHLIGHTS

**7** Pipelines
**12** Indications

**5** Phase IIb/III
**2** Phase II

**Top 10**
Blue-chip Biotech Investors

Newsoara 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 LLC: Joint Venture between GNLX and TVAX BioMedical

## 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

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

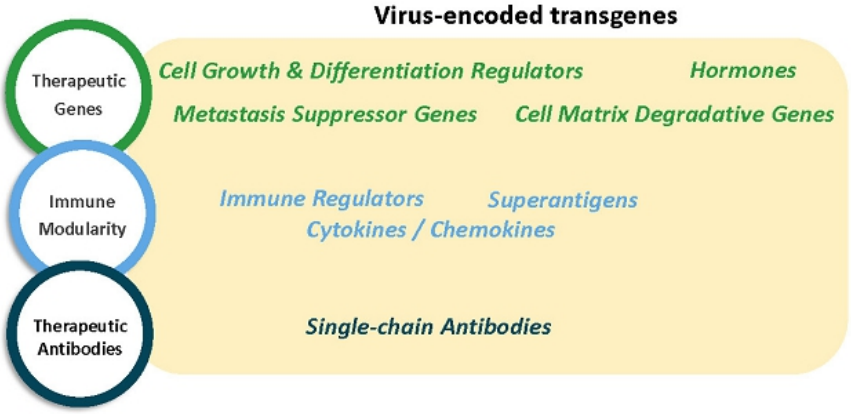
Vaccination increases the numbers of neoantigen-specific T cells in the body and Olvi-Vec kills cancer cells and potentiates T cells by increasing cancer tissue receptivity to adoptively transferred neoantigen-specific effector T cells.

| 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)

- **LIVP1.1.1**
- **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-αvβ3-integrin**

# Intellectual Property: Market Exclusivity & Freedom to Operate

Patent Portfolio: 33 issued patents & 7 pending;
Olvi-Vec covered by Composition of Matter (2031*)
and Manufacturing (2038)

Olvi-Vec: No third-party royalties due

Long Duration of Regulatory / Marketing Exclusivity

**Strong IP & Regulatory Designations**

*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

## Board of Directors

**THOMAS ZINDRICK, JD**
Chairman of the Board

**JAMES L. TYREE, MBA**
Lead Independent Director

**MARY MIRABELLI, MBA**
Director

**JOHN THOMAS, MBA, PhD**
Director

**JOHN SMITHER, CPA (Inactive)**
Director

## Operations & R&D

**Tony Yu, PhD**
SVP, ClinDev

**Joseph Cappello, PhD**
Chief Technical Officer

**Caroline Jewett**
Head, Quality

**Ralph Smalling**
Head, Regulatory Affairs

**Qian Zhang, MD, PhD**
VP, Clinical Sciences

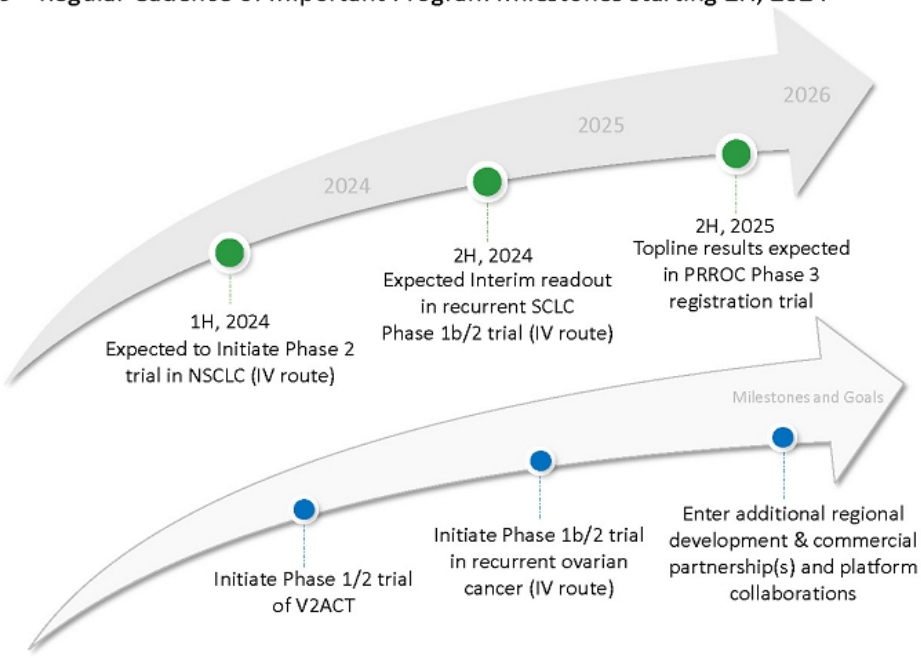
**Cathy Gust, PhD**
VP, Program Mgmt

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

Expected Operating Runway into 1Q 2026 – Regular Cadence of Important Program Milestones starting 2H, 2024

## Executed Milestones

- Runway past PRROC topline and rSCLC interim readouts
- 20+ sites active in Phase 3 Trial in PRROC
- Phase 2 results published in JAMA Oncology
- Collaboration and License agreement with Newsoara
- Initiation of Phase 1b/2 trial in recurrent SCLC (China)
- Issuance of V2ACT US Patent



GENELUX

*Redefining Immuno-Oncology*

Corporate Presentation | June 2024
Appendix

# Accomplished Clinical Advisory Board

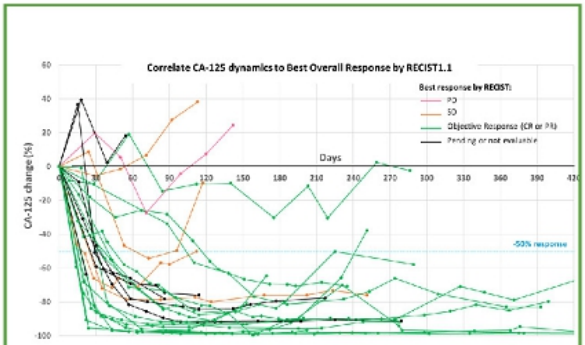
| | | |
|---|---|---|
| Medical Director, Gynecologic Oncology, AdventHealth Cancer Institute  | **Robert Holloway, MD**<br>CHAIRMAN | Dr. Holloway is the principal investigator for VIRO-15 and has served on several committees of the Society of Gynecologic Oncology (SGO), including its Board of Directors. |
| Chief Medical Officer, Vanium Group  | **Robert Coleman, MD** | Dr. Coleman currently serves on the Board of Directors 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***

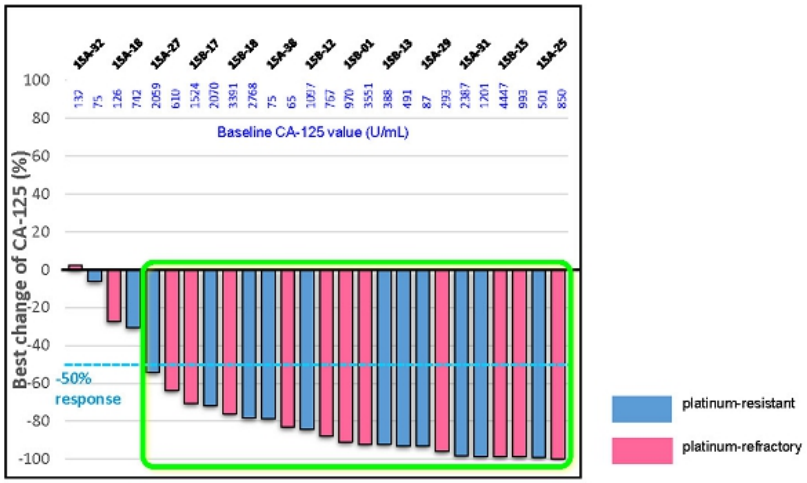
- All PRROC Patients: 96% (25/26)
- Platinum refractory patients: 85% (11/13)




- All 11 patients with > 90% decrease of CA-125 achieved RECIST response
- RECIST responses correlate to CA-125 responses ($p$ = 0.007)

***ORR by CA-125***

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



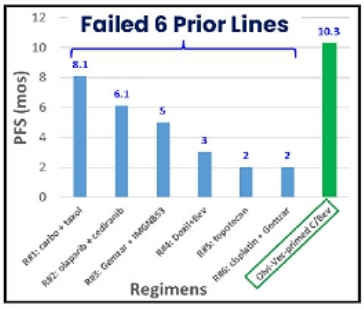
# Olvi-Vec-Primed Immunochemotherapy Overcomes "Refractoriness"

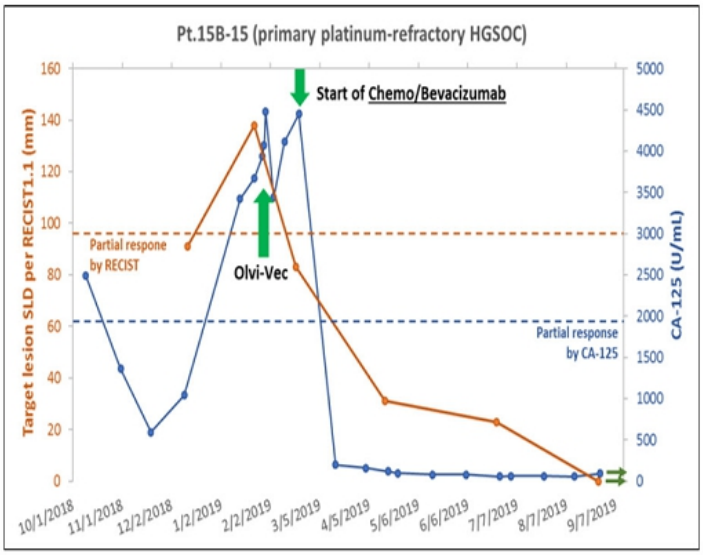
Exemplary platinum-refractory patients, after platinum re-challenge, achieved ***PFS exceeding any prior lines***

**15B-15:**

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

**Overall Survival: 12.3 Months**



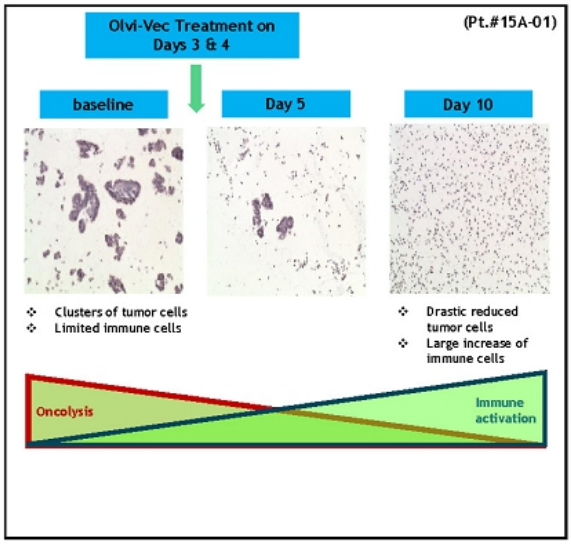
# Olvi-Vec Monotherapy Demonstrated Oncolysis and Immune Activation

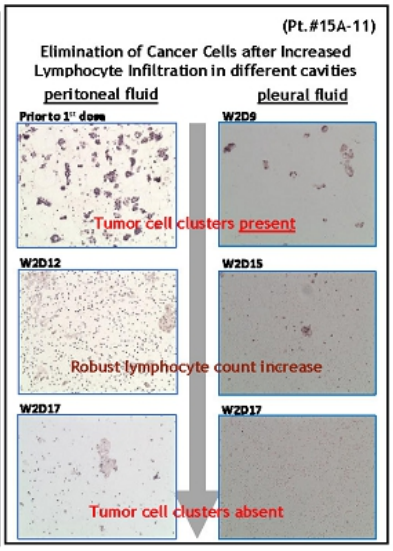
## Data from Phase 1b Monotherapy portion of VIRO-15 trial

### 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

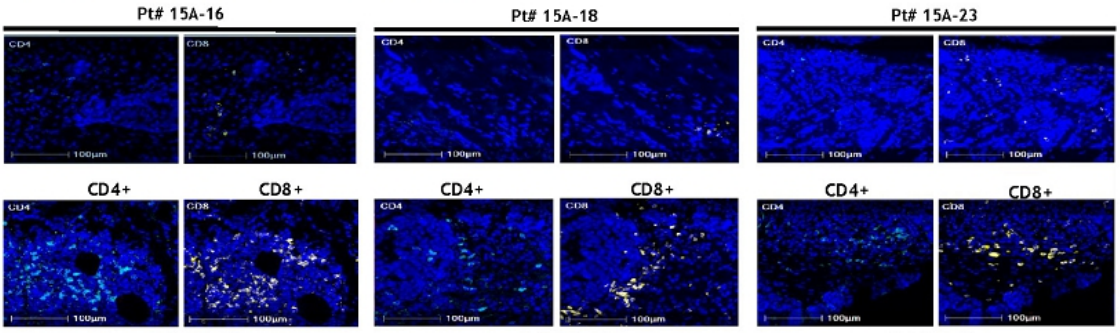


# CD8+ T-cells: Infiltrating Lymphocytes are Prognostic for Response/Survival

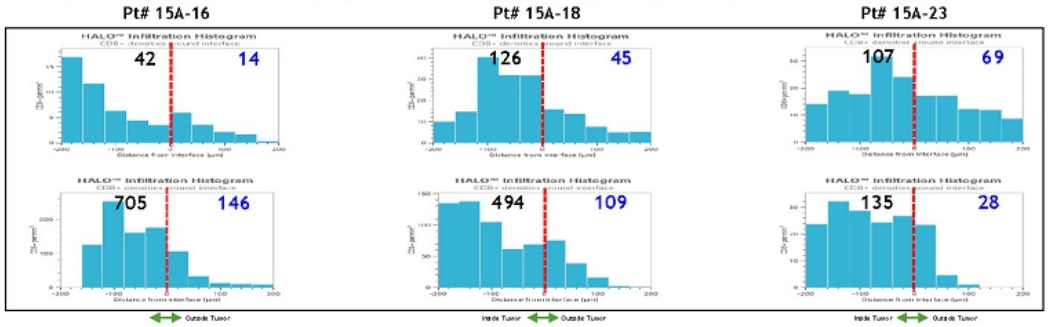
## Data from Phase 1b Monotherapy portion of VIRO-15 trial

**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 1b Monotherapy portion of VIRO-15 trial

### Key Takeaways

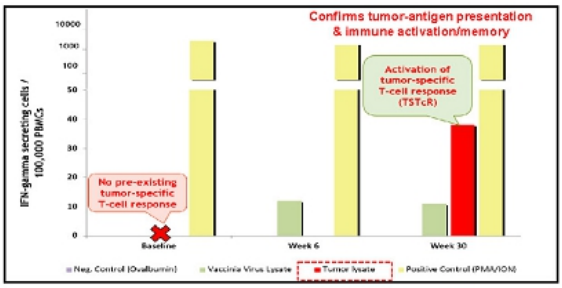
***Off-the-Shelf Personalized Medicine: Single Agent generates Individualized Results***

- 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

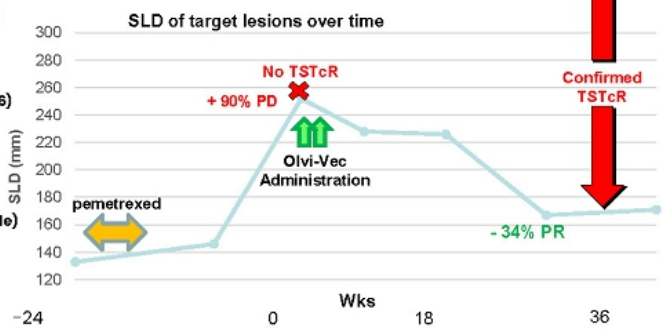
**Case Report (Pt #15A-05)**

**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**




Last Chemotherapy: Pemetrexed 3/30-5/18/2016
↓
Progressive disease (PD) (CT scans on 6/30/2016 & 8/30/2016)
↓
GL-ONC1 Tx
↓
Partial response (confirmed on Week 24 & 36; durable)
↓
Stable disease @ Week 48 (-27% compared to baseline)

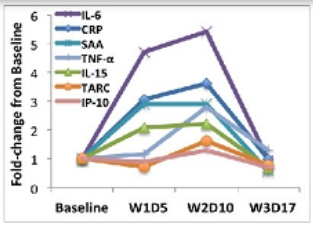


# Olvi-Vec: Ideal Backbone for Combination Therapy

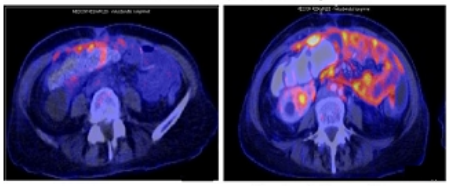
## Converts Tumor Microenvironment to Inflammatory "Hot Spot"

**Induction of acute inflammatory cytokines (Th1-type related)**

*VIRO-15 Study*




*NCT01443260/TUE Study*

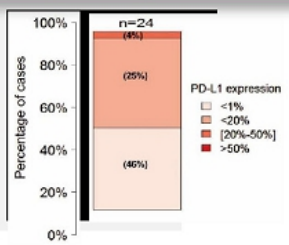


**Baseline** | **Massive inflammatory response after (C1D24) single dose of virus**

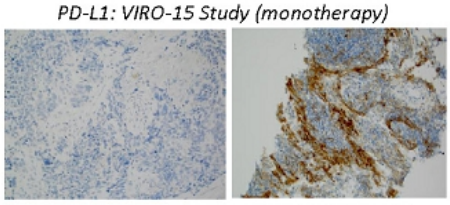
## Up Regulates Immunomodulatory Target Proteins, such as PD-L1

**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