# **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): April 1, 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 Iownsgate 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 simu	ultaneously satisfy the filing obligation of the	registrant under any of the following provisions:				
☐ Written communications pursuant to Rule 425 under the Securities Act	t (17 CFR 230.425)					
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (1	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  Common stock, par value \$0.001 per share	Trading Symbol(s) GNLX	Name of each exchange on which registered 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 registran provided pursuant to Section 13(a) of the Exchange Act. $\Box$	nt has elected not to use the extended transi	ition period for complying with any new or revised financial accounting standards				

#### Item 7.01 Regulation FD Disclosure.

On April 1, 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 <u>Corporate Presentation, dated April 1, 2024</u>

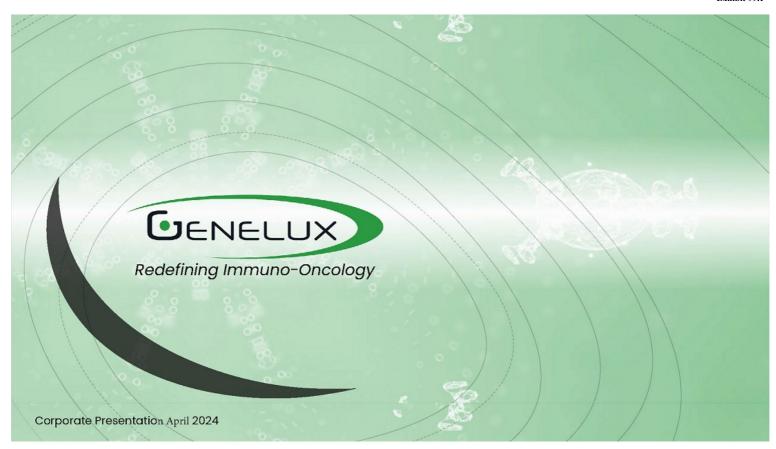
Cover Page Interactive Data File (embedded within the Inline XBRL document).

# 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

By: /s/ Thomas Zindrick, J.D.
Thomas Zindrick, J.D.
President and Chief Executive Officer Date: April 1, 2024



# Forward Looking Statements

This presentation contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1934, 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 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 strate

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 Annual Report on Form 10-K for the year ended December 31, 2023 and in our other filings with the 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," "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 \*s and \*m\* 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.



# Olvi-Vec: De-risked late-stage Clinical Program focused on Platinum Resensitization

Ongoing pivotal Phase 3 trial in late-stage platinum resistant/refractory ovarian cancer (PRROC)
Ongoing Phase 1b/2 trial in recurrent small cell lung cancer (SCLC)
Planned Phase 2 trial 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 in the U.S. for Ovarian Cancer

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
- In Ovarian Cancer trial, catheter placement is prior to chemotherapy, with removal 2 days after initial placement
- IV therapy currently being used in small cell lung cancer Phase 1b/2 trial



# Antitumor Effect and Well Tolerated

- Strong data in Phase 1b/2 trial in platinum-resistant/refractory ovarian cancer
- No Maximum Tolerated Dose (MTD) observed
- Potential utility in multiple cancers (demonstrated in 20 pre-clinical tumor models), including metastatic disease



# 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 platinumbased chemotherapy in multiple tumor types



# Program Builds on Completed Trials to Exploit Competitive Advantages

# Estimated Billion Dollar Plus annual Olvi-Vec Commercial Opportunity (US)

Olvi-Vec	Indication	Design	Preclinical	Phase 1	Phase 2	Phase 3	Anticipated Milestones	Collaborators
Regional Route	Ovarian Cancer (platinum-resistant/ refroctory)	Oivi-Vec (i.pe) +Platinum-based regimen	Ph3 OnPrin		dy Actively Enrolli DA Fast Track Design		Topline results expected in 2H, 2025	GOG FOUNDATION' (Cooperative Group)
	Non-Small Cell Lung Cancer (recurrent/platinum-ICI failure)	Oivi-Vec (IV) +Platinum/Checkpoint inhibitor-based regimen	Ph2 Regulat	ory Submission			Expected to initiate in 1H, 2024	
	Small Cell Lung Cancer (recurrent/platinum failure)	Olvi-Vec (IV) +Platinum-based regimen	Ph1b/2 Enrol	lling			Expected interim readout in 2H, 2024	
Systemic Route	Ovarian Cancer (recurrent/platinum failure)	Olvi-Vec (IV) +Platinum-based regimen	Ph1b/2 Regulatory Submission	•				NEWSOARA Greater China)
Noute	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					(Worldwide Rights Ex- Greater China)





# Selective Replication In Tumors Unleashes Immune System Against Cancer

# **Key Takeaways**

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

- Kills cancer cells directly, including cancer stem cells
- Enhances (neo)antigen presentation and stimulates a tumor-specific immune response
- Converts tumor microenvironment from immunosuppressive (cold state) to immunoreactive (hot state)

# Olvi-Vec

# viral infection



Oncolysis and release of tumor (neo)antigens





#### Innate Immune Activation

Increase Type I IFNs

- Activation Immune Activation
  - APCs present (neo)antigens
     T-cell activation & cytotoxicity

Adaptive

Anti-tumor immune memory



Increase DAMPs / PAMPs





PAMPs - Pathogen-associated Molecular Patterns DAMPs - Damage-associated Molecular Patterns

#### '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

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

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

# ADSENCE OF EFFECTOR TCELLS FIROBLAST Critice Options Options Critice Options Options Critice Options Options Options Critical Options Options

**Olvi-Vec-Induced Hot Tumor** 

# Chemotherapy synergy

- Immunogenic cell death and presentation of oncogenic neoantigens
- Depletion of suppressor cells<sup>5</sup>
- Increase susceptibility to cytotoxic T-lymphocytes

"Prime & Boost"



# A Maturing Modality with Phase 3 Companies Validating OV Potential

# **G**ENELUX

Next Generation

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

# Clinical Advantages of Olvi-Vec

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

**AMGEN** 

FDA/EMA Approval in Melanoma



<u>Limitations of 1st Gen Viruses</u>

Commercial/Late-stage I<sup>st</sup> Generation viruses confirm modality's potential Limited to local delivery and scope of

addressable cancers

Phase 3 monotherapy trial [interim data] in bladder cancer







# Ovarian Cancer Program: Regional (Intraperitoneal) Delivery

# **Key Takeaways**

- · Phase I tested condensed dosing schedule and demonstrated tolerability with evidence of antitumor activity
- Phase 2 demonstrated promising Objective 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 <sup>1</sup>
US / (2)	Phase 2	Combination (platinum-based regimen)	27	Single Arm	Completed <sup>2</sup>
US / (~30)	Phase 3	Combination (platinum-based regimen)	186	2:1	Enrolling <sup>3</sup>



<sup>&</sup>lt;sup>1</sup> Manyam et al., <u>Gynecol Oncol</u>, 2021;163(3):481–489. <sup>2</sup> Holloway et al., <u>JAMA Oncol</u>, 2023 Jul 1;9(7):903–908. <sup>3</sup> Holloway et al., <u>Int.J. Gynecol Cancer</u>, 2023 Sep. 4;33(9):1458–1463.

# Phase lb: 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.
  - 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: 6x10<sup>9</sup> 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

<sup>1</sup>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

<u>Design</u>

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**

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



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)	<b>54</b> % (13 <sup>0</sup> /24) (33 - 74)	<b>7.6 mos</b> (3.7 - 9.6)	<b>85</b> % (22/26) (65 - 96)	<b>11.0 mos</b> (6.7 - 13.0)	<b>15.7 mos</b> (12.3 - 23.8)
Platinum-resistant (n=14) (95% CI)	55% (6/11) (26 - 84)	<b>7.6 mos</b> (3.7 - NA)	<b>85</b> % (11/13) (55 - 98)	10.0 mos (6.4 - NA)	<b>18.5 mos</b> (11.3 – 23.8)
Platinum-refractory (n=13) (95% CI)	<b>54</b> % (7/13) (27 - 81)	<b>8.0 mos</b> (3.7 - NA)	<b>85</b> % (11/13) (55 - 98)	11.4 mos (4.3 -13.2)	<b>14.7 mos</b> (10.8 – 33.6)

<sup>\*</sup>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

# Demonstrated Deep and Durable Tumor Shrinkage

-60

-80

-100

# **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 platinumrefractory patients

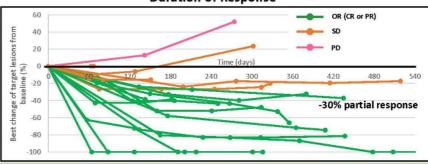


**Tumor Shrinkage** 

# **Duration of Response**

platinum-resistan

platinum-refractory



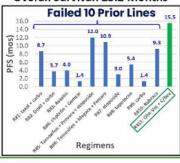


# Olvi-Vec-Primed Immunochemotherapy Overcomes "Refractoriness"

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

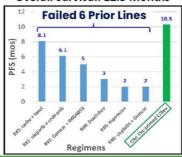


#### Overall Survival: 23.2 Months



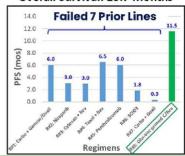


# Overall Survival: 12.3 Months





#### Overall Survival: 15.7 Months



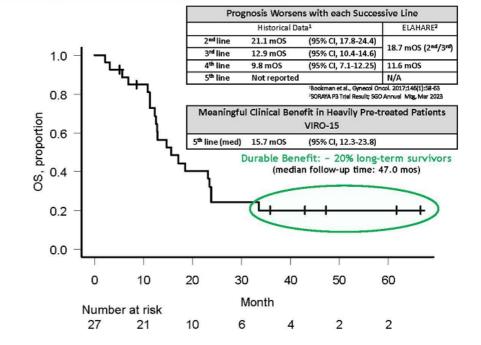


# **Key Clinical Takeaways**

# Encouraging mOS and Long-term survival data

20% long-term survivors consistent with commercially successful 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





# "All-comers" Approach May Reset Life Clock of Heavily Pre-treated Patients

100%

# **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)

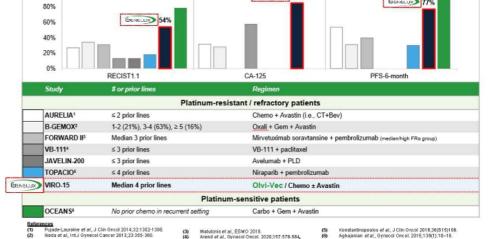
Olvi-Vec Phase 2 results approach

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

GENELUX 85%



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



GENELUX 77%

# 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 in the tumor microenvironment

- · 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-label1 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,

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

International Journal of Gynecological Cancer, Holloway RW, et al. 2023;33:1458-1463.

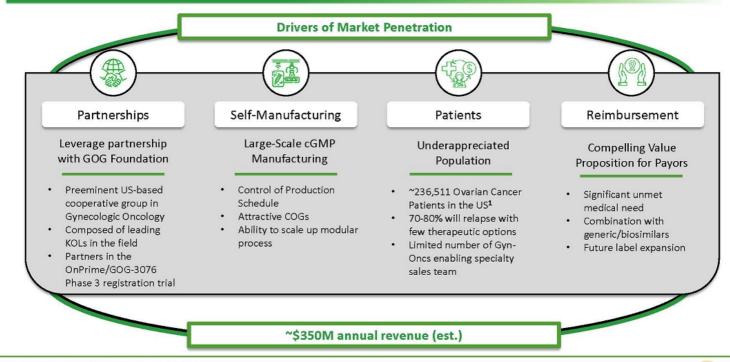
Protocol smended to make platform optional in the Active Comparator Arm with Intent to Implement upon receipt of IRB approvals.

Journal of Investigative Medicine High Impact Case Reports, Volume 6:1-3, 2018

DOI:10.1177/2324709618760080 J ournals.sagepub.com/nome/hic



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





1. NIH Ovarian Cancer Fact Sheet

# 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<sup>1</sup>
- 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

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



Newsoara has development and commercialization rights in Greater China

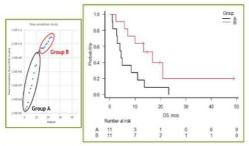
# Systemic Administration Demonstrated Dose-dependent OS Benefit

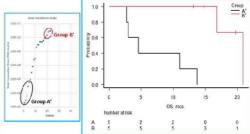
# **Key Clinical Takeaways**

#### 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
- 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 2×10° pfu - 2×10° pfu) Group B: (n=11; higher-dose group with TCD ranging from 3×10° pfu - 3×10¹0 pfu)

Groups lower vs higher TCD: median Overall Survival at 4.6 months (95% CI: 1.3-11.0) vs  $\frac{16.8 \text{ months}}{16.8 \text{ months}}$  (95% CI: 1.3-11.0) vs  $\frac{16.8 \text{ months}}{16.8 \text{ months}}$  (95% CI: 1.3-11.0) vs  $\frac{16.8 \text{ months}}{16.8 \text{ months}}$  (95% CI: 1.3-11.0) vs  $\frac{16.8 \text{ months}}{16.8 \text{ months}}$  (95% CI: 1.3-11.0) vs  $\frac{16.8 \text{ months}}{16.8 \text{ months}}$  (95% CI: 1.3-11.0) vs  $\frac{16.8 \text{ months}}{16.8 \text{ months}}$  (95% CI: 1.3-11.0) vs  $\frac{16.8 \text{ months}}{16.8 \text{ months}}$  (95% CI: 1.3-11.0) vs  $\frac{16.8 \text{ months}}{16.8 \text{ months}}$  (95% CI: 1.3-11.0) vs  $\frac{16.8 \text{ months}}{16.8 \text{ months}}$  (95% CI: 1.3-11.0) vs  $\frac{16.8 \text{ months}}{16.8 \text{ months}}$  (95% CI: 1.3-11.0) vs  $\frac{16.8 \text{ months}}{16.8 \text{ months}}$  (95% CI: 1.3-11.0) vs  $\frac{16.8 \text{ months}}{16.8 \text{ months}}$  (95% CI: 1.3-11.0) vs  $\frac{16.8 \text{ months}}{16.8 \text{ months}}$  (95% CI: 1.3-11.0) vs  $\frac{16.8 \text{ months}}{16.8 \text{ months}}$  (95% CI: 1.3-11.0) vs  $\frac{16.8 \text{ months}}{16.8 \text{ months}}$  (95% CI: 1.3-11.0) vs  $\frac{16.8 \text{ months}}{16.8 \text{ months}}$  (95% CI: 1.3-11.0) vs  $\frac{16.8 \text{ months}}{16.8 \text{ months}}$  (95% CI: 1.3-11.0) vs  $\frac{16.8 \text{ months}}{16.8 \text{ months}}$  (95% CI: 1.3-11.0) vs  $\frac{16.8 \text{ months}}{16.8 \text{ months}}$  (95% CI: 1.3-11.0) vs  $\frac{16.8 \text{ months}}{16.8 \text{ months}}$  (95% CI: 1.3-11.0) vs  $\frac{16.8 \text{ months}}{16.8 \text{ months}}$  (95% CI: 1.3-11.0) vs  $\frac{16.8 \text{ months}}{16.8 \text{ months}}$  (95% CI: 1.3-11.0) vs  $\frac{16.8 \text{ months}}{16.8 \text{ months}}$  (95% CI: 1.3-11.0) vs  $\frac{16.8 \text{ months}}{16.8 \text{ months}}$  (95% CI: 1.3-11.0) vs  $\frac{16.8 \text{ months}}{16.8 \text{ months}}$  (95% CI: 1.3-11.0) vs  $\frac{16.8 \text{ months}}{16.8 \text{ months}}$  (95% CI: 1.3-11.0) vs  $\frac{16.8 \text{ months}}{16.8 \text{ months}}$  (95% CI: 1.3-11.0) vs  $\frac{16.8 \text{ months}}{16.8 \text{ months}}$  (10% CI: 1.3-11.0) vs  $\frac{16.8 \text{ months}}{16.8 \text{ months}}$  (10% CI: 1.3-11.0) vs  $\frac{16.8 \text{ months}}{16.8 \text{ months}}$  (10% CI: 1.3-11.0) vs  $\frac{16.8 \text{ months}}{16.8 \text{ months}}$  (10% CI: 1.3-11.0) vs  $\frac{16.8 \text{ months}}{16.8 \text{ month$ 

Group A\*: (n=5; lowest-dose group with TCD ranging from 2×10° pfu - 1×10° pfu) Group B\*: (n=5; highest-dose group with TCD ranging from 1×10³° pfu - 3×10¹° pfu) Groups lowest vs highest TCD: median Overall Survival at 4.6 months (95% Cl: 2.7 – NA) vs 20.9 months (95% Cl: 16.8 – NA);

ρ = 0.002; a statistically significant clinical benefit favoring the highest dose group.









# Systemic Administration + Chemo Generated Encouraging Data

# **Key Clinical Takeaways**

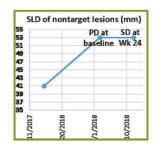
#### Anti-tumor effect of IV Immunochemotherapy

- 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

# Advent Health | Cancer : Expanded Access Program

# <u>Platinum refractory metastatic</u> <u>cervical cancer with lung mets</u>

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



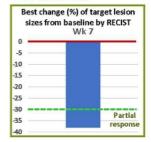
- \* Chemotherapy after disease progression
  - Partial Response
  - > PFS: 70+ Weeks
  - > OS: 53.4 Months

# 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

#### Key Inclusion Criteria

- Advanced or metastatic NSCLC: Stage III or Stage IV
- Nonsquamous or squamous disease
- Without known targetable alterations in EGFR, ALK or ROS1
- Prior failure of platinum-containing chemotherapy and an immune checkpoint inhibitor

# Multi-center, randomized open-label n=~142

### Experimental Arm

Olvi-Vec and Platinum-doublet + Immune Checkpoint Inhibitor (ICI), followed by ICI-based maintenance therapy

# Active Comparator Arm

Docetaxel (crossover allowed after progression)

Expected to initiate in 1H, 2024

#### Primary Endpoint

Progression-Free Survival

# Key Secondary Endpoints

- 2. Overall Survival (OS)
- 3. 6-month progression free survival
- 4. Duration of Response (DOR)

1. Overall Response Rate (ORR)

5. Disease Control Rate



# 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)



# Validating 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 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.

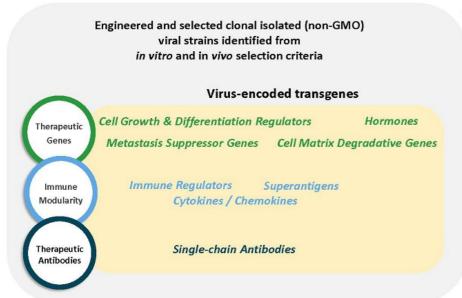
Vaccination increases the numbers of neoantigen-specific T cells in the body and Olvi-Vec kills cancer cells and potentiates T cells by increasing cancer tissue receptivity to adoptively transferred neoantigen-specific effector T cells.

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



# √ In vitro & in vivo tested: GLP Tox ready

Immune Modularity Molecules

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

Cell Growth & Differentiation Regulators

o BMP-4

Cell Matrix-Degradative Genes

o hMMP9

Clonal Isolated Strains (non-GMO)

 V-VET1 (LIVP6.1.1) o LIVP1.1.1

o LIVP5.1.1 o Cop15.1.1

# Single-Chain Antibodies

 Anti-VEGF o Anti-PD-1

o Anti-FAP o Anti-PD-L1

Anti-DLL4
 Anti-CTLA4
 Anti-ανβ3-

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: Worldwide operating freedom; 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

- Iranslational 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





# 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

# RELSINN mesoblast

# THOMAS ZINDRICK, JD

Chairman of the Board



**Board of Directors** 

JAMES L. TYREE, MBA Lead Independent Director



hfma

MARY MIRABELLI, MBA Director

🎎 La Sierra

HCA#

JOHN THOMAS, MBA, PhD



JOHN SMITHER, CPA (Inactive) AMGEN KYTHERA EY Director





# Operations & R&D



Tony Yu, PhD SVP, Clin Dev UC San Diego



Joseph Cappello, PhD Chief Technical Officer UNIVERSITY B BRAUN



Caroline Jewett Head, Quality AMGEN



Ralph Smalling Head, Regulatory Affairs **AMGEN** 



Qian Zhang, MD, PhD VP, Clinical Sciences UC San Diego

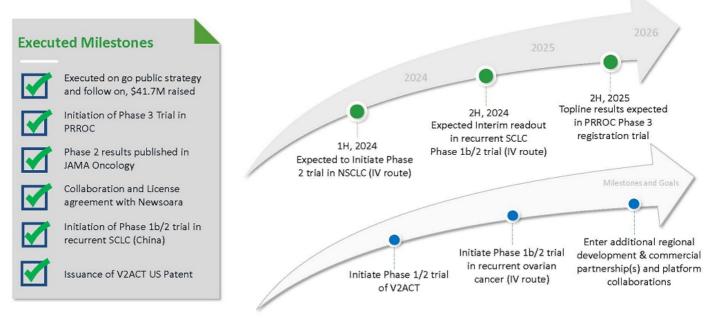


Cathy Gust, PhD VP, Program Mgmt AMGEN



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

Expected Operating Runway into 2Q 2025







# Olvi-Vec: De-risked late-stage Clinical Program focused on Platinum Resensitization

Ongoing pivotal Phase 3 trial in late-stage platinum resistant/refractory ovarian cancer (PRROC)
Ongoing Phase 1b/2 trial in recurrent small cell lung cancer (SCLC)
Planned Phase 2 trial 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**

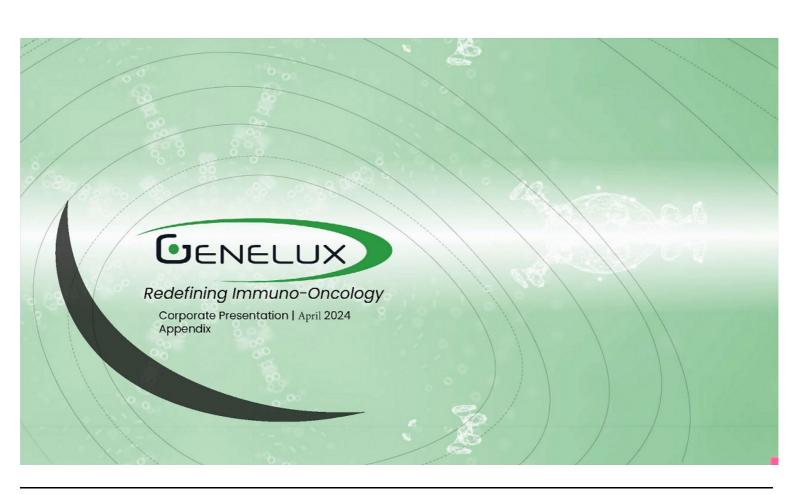
US launch in Ovarian Cancer initially; strategic partnerships for ex-US rights



#### Estimated Billion Dollar Plus Annual Market Opportunity in the U.S. for Ovarian Cancer

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





# Accomplished Clinical Advisory Board





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.



Robert Coleman, MD Member

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.



Albert A. Mendivil, MD Member

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.



Thomas J. Herzog, MD Chief Executive Officer

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.



David M. O'Malley, MD Chief Medical Officer

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.



Alan Forsythe, PhD Chief Financial Officer 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.

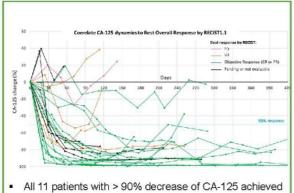


# Olvi-Vec-primed Immunochemotherapy Anti-tumor Activity: CA-125 Biomarker

Rapid, Common and Durable Responses

#### CA-125 Decrease

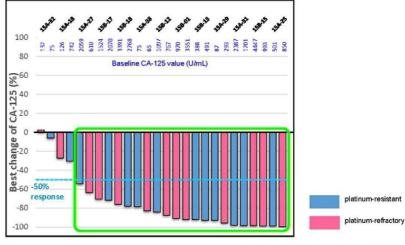
- o All PRROC Patients: 96% (25/26)
- o Platinum refractory patients: 85% (11/13)



- 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

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



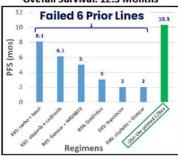


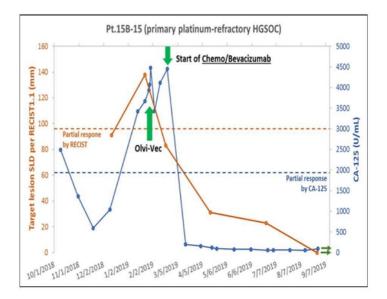
# Olvi-Vec-Primed Immunochemotherapy Overcomes "Refractoriness"

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





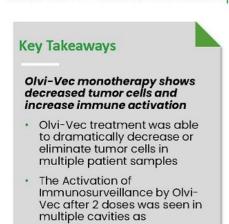




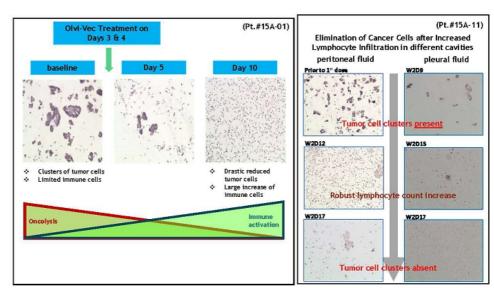
GENELUX

# Olvi-Vec Monotherapy Demonstrates Oncolysis and Immune Activation

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



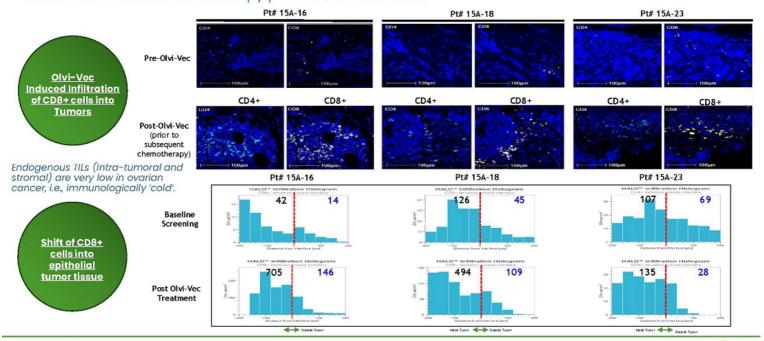
monotherapy





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

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





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

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

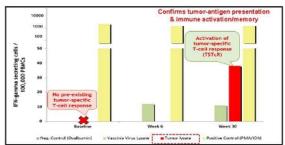
# Off-the-Shelf Personalized Medicine: Single Agent generates Individualized Results

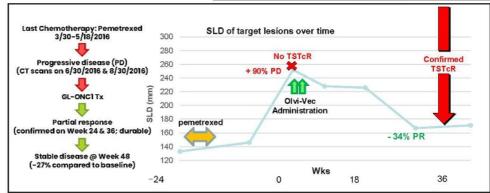
**Key Takeaways** 

- Olvi-Vec induces favorable & long-lasting Tumor-specific Tcell 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





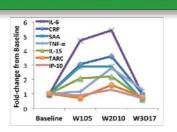


# Olvi-Vec: Ideal Backbone for Combination Therapy

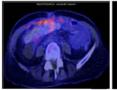
# Converts Tumor Microenvironment to Inflammatory "Hot Spot"

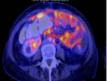
Induction of acute inflammatory cytokines (Th1-type related)

VIRO-15 Study



#### NCT01443260/TUE Study





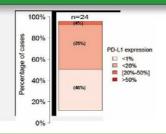
Baseline

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

