

The logo features the word "GENELUX" in a bold, black, sans-serif font. The letter "G" is stylized with a green dot in its center. The text is enclosed within a green, horizontal, pill-shaped oval that has a slight gradient and a shadow effect. A large, black, curved swoosh element is positioned to the left of the logo, extending from the bottom left towards the center.

**GENELUX**

*Redefining Immuno-Oncology*

# Forward Looking Statements

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# Highlights



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

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



## **CHOICE™ Platform; Broad and Diverse Discovery Engine**

Library with over 500 novel vaccinia strains and 110+ transgenes



## **Validating Strategic Partnership**

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



## **Focused Commercial Strategy**

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



## **Estimated Billion Dollar Plus Annual Market Opportunity**

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

# The Most Advanced Non-local Delivery Oncolytic Immunotherapy

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



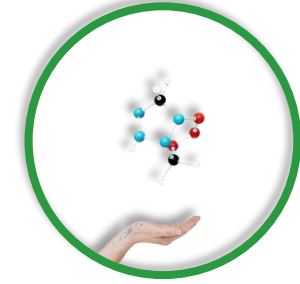
## Physician-preferred routes of delivery

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



## Antitumor Effect and Well Tolerated

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



## Ideal Backbone of Combination Therapy

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

# Program Builds on Completed Trials to Exploit Competitive Advantages

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

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

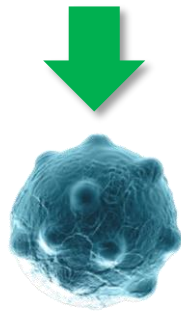
# Olvi-Vec Seeks to Unleash Immune System Against Cancer

## Key Takeaways

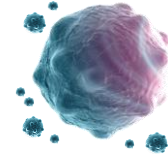
Olvi-Vec is being developed as a robust immune modulator that utilizes a triple mode of action to mount a personalized attack against cancer cells throughout the body and aims to:

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

**Olvi-Vec**  
viral infection

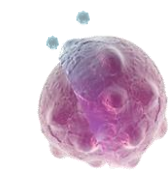


**Oncolysis and  
release of tumor  
(neo)antigens**



**Innate  
Immune Activation**

- Increase Type I IFNs
- Increase DAMPs / PAMPs



**Adaptive  
Immune Activation**

- APCs present (neo)antigens
- T-cell activation & cytotoxicity
- Anti-tumor immune memory



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**

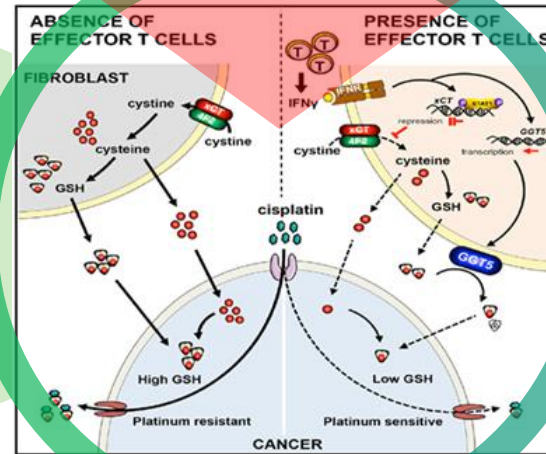
- Increase of proinflammatory cytokines/chemokines
- Influx of CD8+ effector T cells
- M2 to M1 transition of tumor-associated macrophages
- Decrease of immune suppression
- Changes of tumor gene expression profile
- Immunogenic tumor cell death
- Vascular collapse

# Olvi-Vec-Primed Immunochemotherapy: Reversing Platinum Resistance

## Olvi-Vec-Induced Hot Tumor

### 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>



### Chemotherapy synergy

- Immunogenic cell death and presentation of oncogenic neoantigens<sup>6</sup>
- Depletion of suppressor cells<sup>5</sup>
- Increase susceptibility to cytotoxic T-lymphocytes<sup>6</sup>

“Prime & Boost”

<sup>1</sup>Song et al. (*Mol Ther* (2007) 15(8):1558-1563)

<sup>2</sup>Wang et al., *Cell*. 2016; 165(5): 1092-1105

<sup>3</sup>Mantovani et al., *J Exp Med*. 2015;212(4):435-445

<sup>4</sup>Ahmed et al., *Mol Aspects Med*. 2014;39:110-25

<sup>5</sup>Weir et al., *Cancers (Basel)* (2011) 3(3):3114-3142 Emens et al., *Cancer Immunol Res* (2015) 3(5):436-443

<sup>6</sup>Emens et al., *Cancer Immunol Res* (2015) 3 (5): 436-443.

# A Maturing Modality with Phase 3 Companies Validating OV Potential



*Next Generation  
Regional & Systemic  
Administration*

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

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

**Phase 1b Solid Tumors**  
**Dose-dependent mOS in metastatic lung-diseased  
solid tumor patients after multiple IV doses**

## Potential Clinical Advantages of Olvi-Vec

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

## Limitations of 1<sup>st</sup> Gen Viruses

- Limited to local delivery and scope of addressable cancers

**AMGEN**

FDA/EMA Approval  
in Melanoma



Daiichi-Sankyo

PMDA Approval in  
malignant glioma



Phase 3 monotherapy  
trial [interim data] in  
bladder cancer





# Regional Administration Program

Ovarian Cancer

# Ovarian Cancer Program: Regional (Intraperitoneal) Delivery

## Key Takeaways

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

### **Expected Milestones**

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

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

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

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>

<sup>1</sup> Manyam *et al.*, *Gynecol Oncol.* 2021;163(3):481-489.

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

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

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

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

## 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<sup>1</sup> n=186

### Experimental Arm

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

### Active Comparator Arm<sup>2</sup>

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”.<sup>3</sup>*

<sup>1</sup> International Journal of Gynecological Cancer, Holloway RW, et al. 2023;33:1458–1463.

<sup>2</sup> Protocol amended to make platinum optional in the Active Comparator Arm with intent to implement upon receipt of IRB approvals.

<sup>3</sup> Journal of Investigative Medicine High Impact Case Reports, Volume 6: 1–3, 2018  
DOI: 10.1177/2324709618760080 J ournals.sagepub.com/home/hic

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

## Key Clinical Takeaways

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

## Olvi-Vec Monotherapy<sup>1</sup>



### Patient Background & Study Treatment

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



### Tolerability:

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



### Antitumor activity:

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



### Translational Evidence:

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

<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

#### 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<sup>1</sup>

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

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

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

### Key Clinical Takeaways

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

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

	ORR by RECIST1.1**	Duration of Response	ORR by CA-125	Median PFS	Median Overall Survival (OS)
<b>All patients (n= 27)</b> (95% CI)	<b>54%</b> (13 <sup>◊</sup> /24 <sup>◊◊</sup> ) (33 - 74) <b>CR=8%</b> <b>PR=46%</b>	<b>7.6 mos</b> (3.7 - 9.6)	<b>85%</b> (22/26 <sup>◊◊◊</sup> ) (65 - 96)	<b>11.0 mos</b> (6.7 - 13.0)	<b>15.7 mos</b> (12.3 - 23.8)
<b>Platinum-resistant (n=14)</b> (95% CI)	<b>55%</b> (6/11) (26 - 84) <b>CR=18%</b> <b>PR=36%</b>	<b>7.6 mos</b> (3.7 - NA)	<b>85%</b> (11/13) (55 - 98)	<b>10.0 mos</b> (6.4 - NA)	<b>18.5 mos</b> (11.3 - 23.8)
<b>Platinum-refractory (n=13)</b> (95% CI)	<b>54%</b> (7/13) (27 - 81) <b>CR=0%</b> <b>PR=54%</b>	<b>8.0 mos</b> (3.7 - NA)	<b>85%</b> (11/13) (55 - 98)	<b>11.4 mos</b> (4.3 -13.2)	<b>14.7 mos</b> (10.8 - 33.6)

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

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

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

◊◊Three of 27 patients were not evaluable as defined by RECIST 1.1 criteria due to no measurable disease. However, these 3 patients were evaluable by the Gynecological Cancer InterGroup (GCIg) CA-125 criteria, showing 2 partial responses and 1 complete response as best response.

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

# Demonstrated Deep and Durable Tumor Shrinkage

## Key Clinical Takeaways

### Refractory patients performed as well as resistant patients

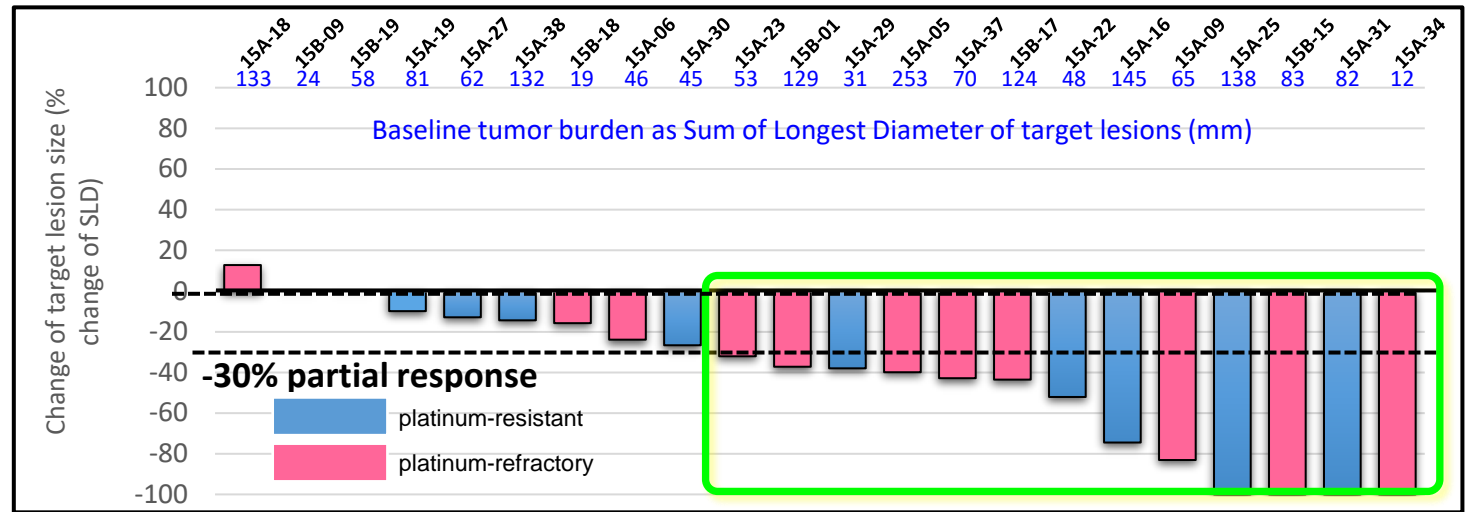
#### Tumor Shrinkage

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

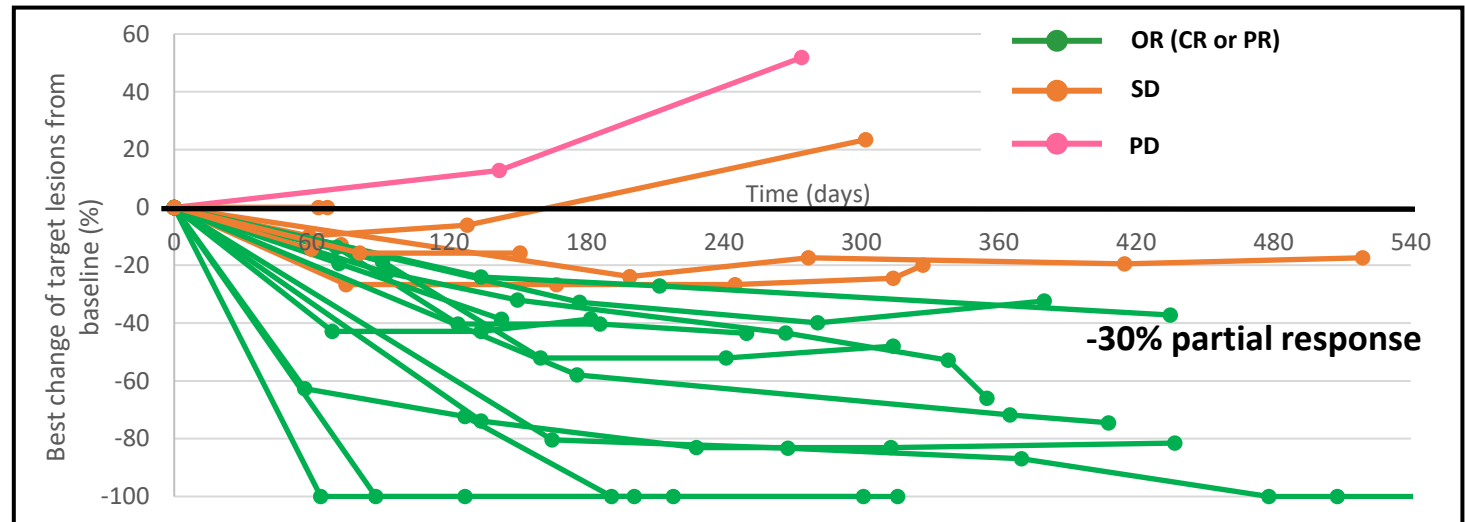
#### Duration of Response (DOR)

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

## 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

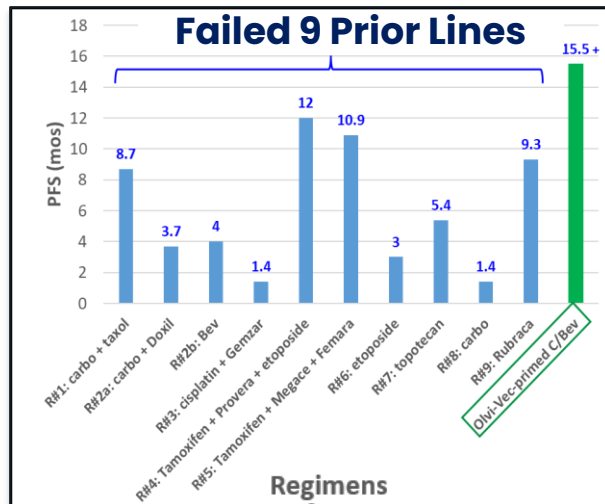
## 15B-15:

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

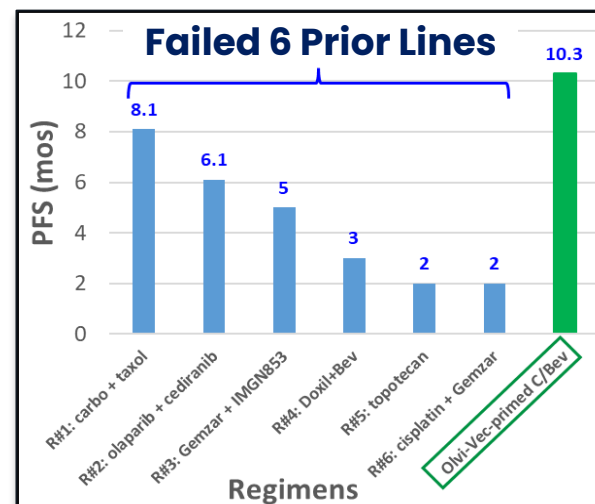
## 15B-17:

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

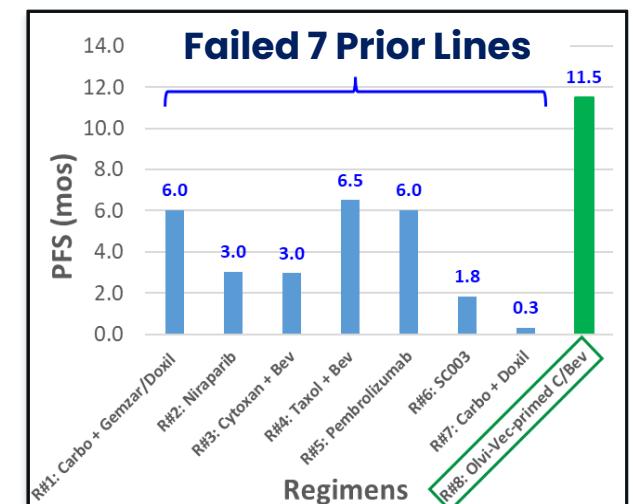
**Overall Survival: 23.2 Months**



**Overall Survival: 12.3 Months**



**Overall Survival: 15.7 Months**





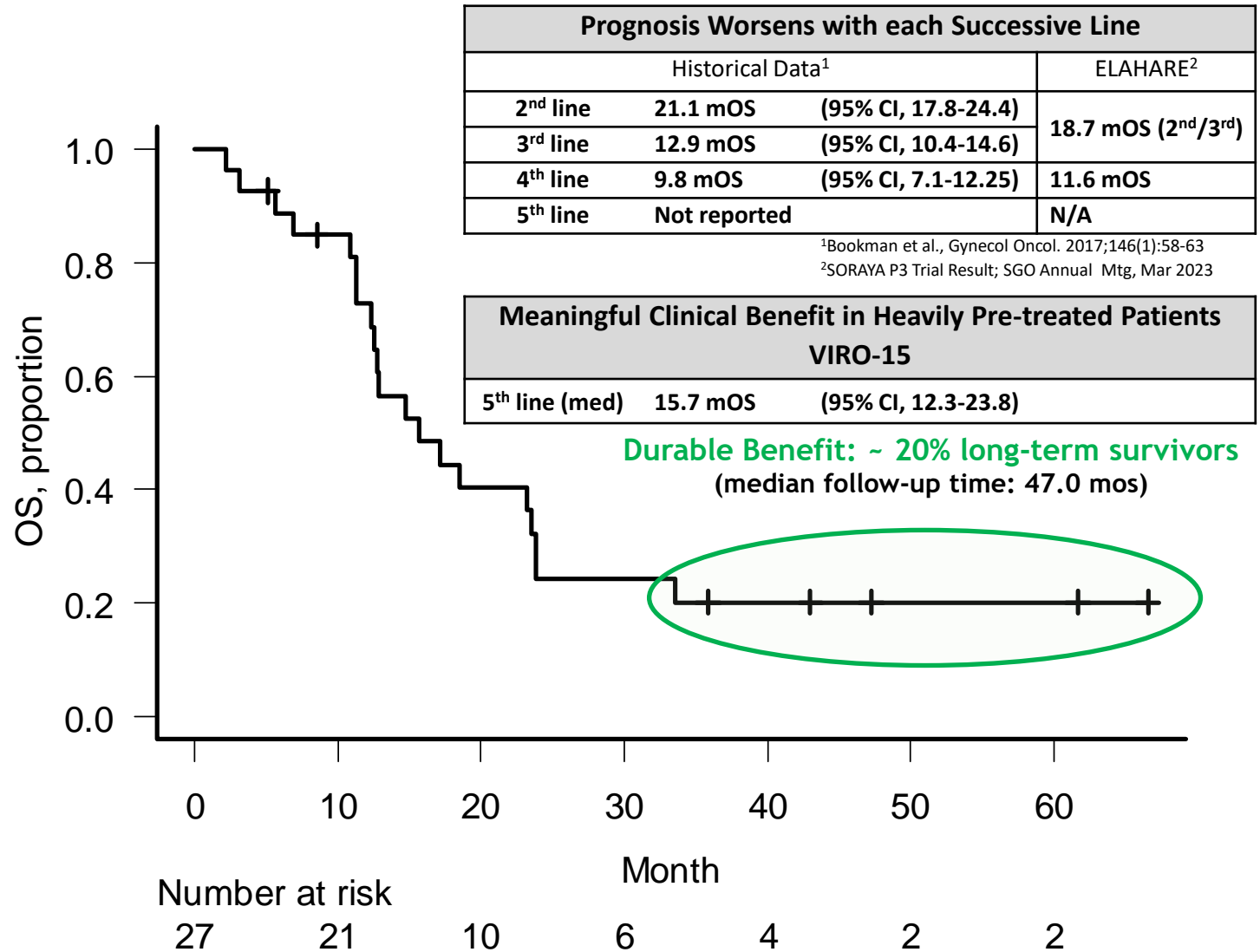
# Durable Survival Benefit

## Key Clinical Takeaways

### Encouraging mOS and Long-term survival data

20% long-term survivors consistent with clinically beneficial immunotherapies

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



# Phase 2 Compared to Approved Standard of Care in Earlier Lines

## Key Clinical Takeaways

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

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

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

\*October 22, 2024

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

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

## Drivers of Market Penetration



### Partnerships

Leverage partnership with GOG Foundation

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



### Self-Manufacturing

Large-Scale cGMP Manufacturing

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



### Patients

Underappreciated Population

- ~238,484 Ovarian Cancer Patients in the US<sup>1</sup>
- 70-80% will relapse with few therapeutic options
- Limited number of Gyn-Oncs enabling specialty sales team



### Reimbursement

Compelling Value Proposition for Payors

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

<sup>1</sup>NIH Ovarian Cancer Fact Sheet



# Systemic Administration Programs

Lung Cancers

# Systemic Administration Program


## Key Takeaways


- Funding commitment by Newsora 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

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

## Ongoing and Planned Clinical Trials

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

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

<sup>1</sup> Newsora has development and commercialization rights in Greater China

# 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)

Interim readout expected in mid 2025

### Primary Endpoint

Progression-Free Survival

### Key Secondary Endpoints

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

- After receiving platinum containing chemotherapy scheme +/- immunotherapy, platinum containing chemotherapy scheme +/- anlotinib and other treatment recommended by the guidelines in the past, the 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

Interimreadout 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)

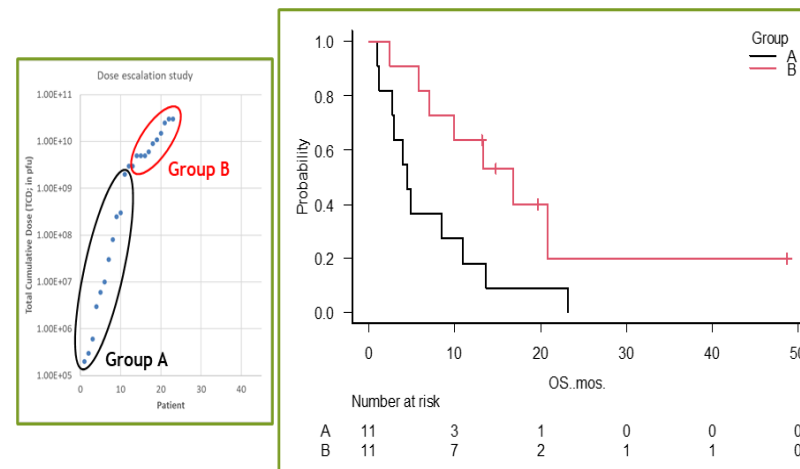
# Systemic Administration Demonstrated Dose-dependent OS Benefit

## Key Clinical Takeaways

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

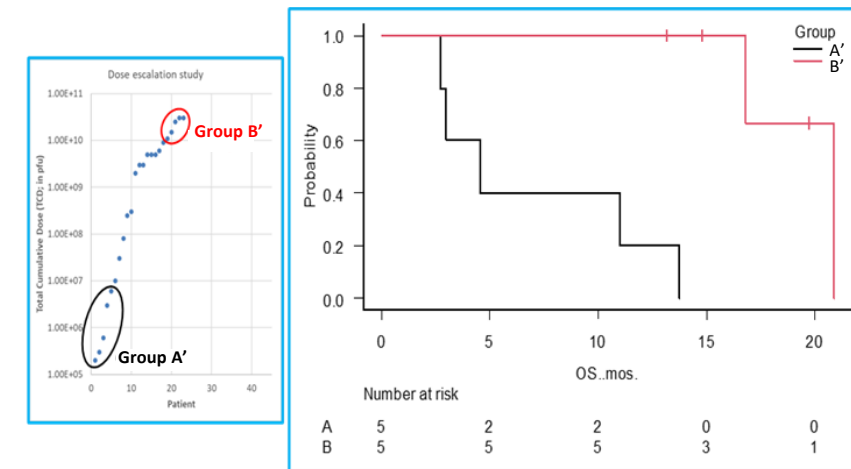
- Median 5 prior lines of therapy
- Regimen: various dosing levels and schedules (typically over 4-6 months)
- Duration of Treatment (DoT): Higher cumulative-dose patients assigned to cohorts with DoT shorter than (condensed schedule) or equal to the DoT of patients assigned to lower cumulative-dose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

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



Group A (n=11): TCD  $2 \times 10^5$  pfu –  $2 \times 10^6$  pfu (**lower TCD**)  
Median OS = 4.6 months (95%CI: 1.3-11.0)  
Group B (n=11): TCD  $3 \times 10^9$  pfu –  $3 \times 10^{10}$  pfu (**higher TCD**)  
Median OS = 16.8 months (95%CI: 5.9-UND)

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



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

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



# Systemic Administration + Chemo Generated Encouraging Data

## Key Clinical Takeaways

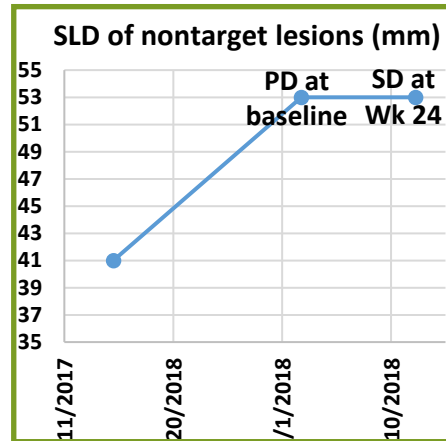
### Anti-tumor effect of IV Immunochemotherapy

- 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

### Platinum refractory metastatic cervical cancer with lung mets

Case Report (Pt #21A-06)

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

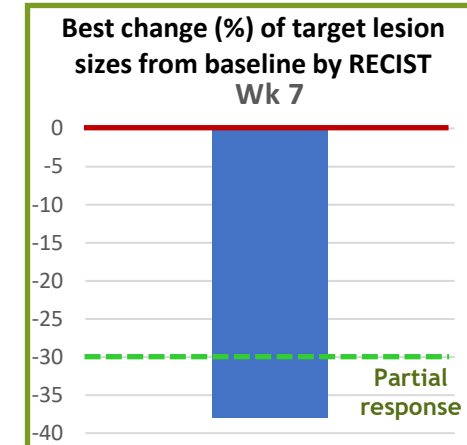


- ❖ Chemotherapy after disease progression
  - Partial Response
  - PFS: 70+ Weeks
  - OS: 53.4 Months

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

Case Report (Pt.#21A-04)

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



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

# Industry Collaboration with Newsoara BioPharma Co., Ltd



## NEWSQARA HIGHLIGHTS

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

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

**Top 10**  
Blue-chip Biotech  
Investors



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

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



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

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

## Key Trial Takeaways

### ***V2ACT Immunotherapy, combines an oncolytic immunotherapy and adoptive cell therapy***

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

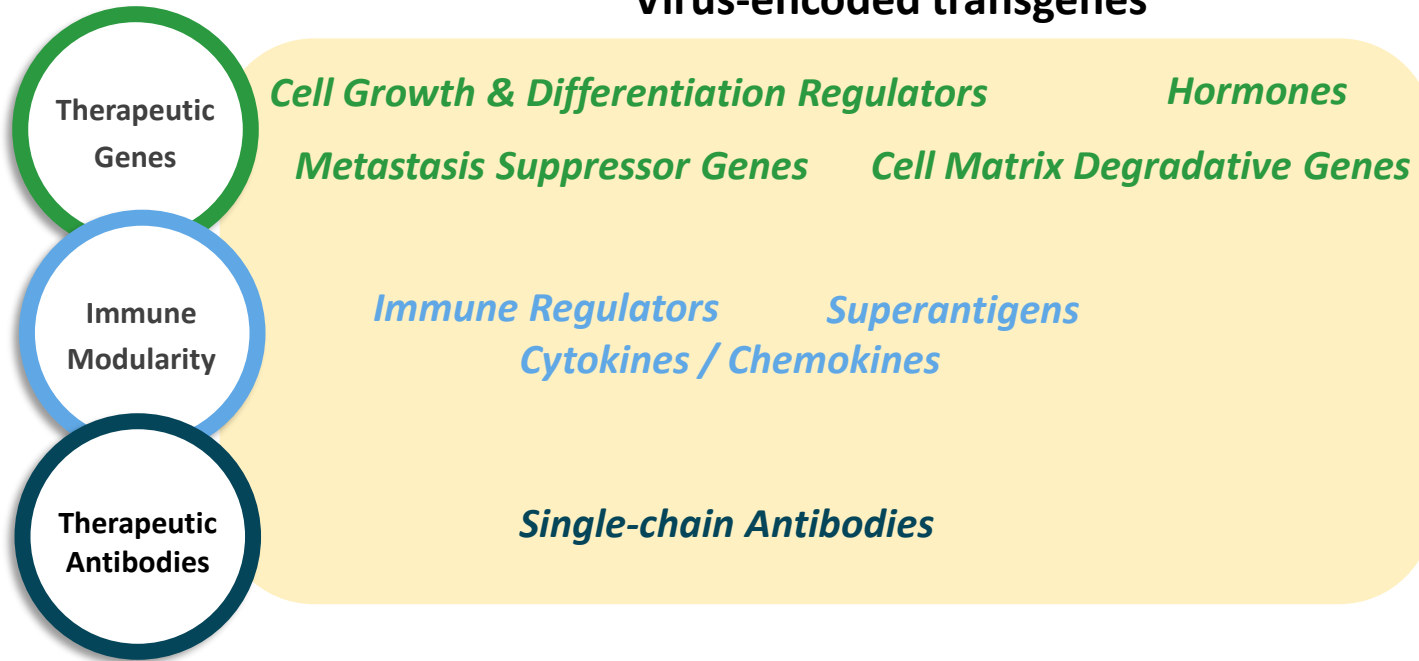
Technology	TVI Adoptive Cell Therapy	Olvi-Vec Oncolytic Immunotherapy
Patients Dosed	~ 130	~ 150
Regulatory	Fast Track Designation / FDA Grant - glioblastoma	Phase 3 enrolling - ovarian

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

# Choice Platform Library: 500+ Vectors with 110+ Transgenes

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

## Virus-encoded transgenes



✓ *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- $\alpha$ v $\beta$ 3-integrin*

# Intellectual Property: Market Exclusivity & Freedom to Operate



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



Olvi-Vec: No third-party royalties due



Long Duration of Regulatory / Marketing Exclusivity



\*Reflects Patent Term Extension

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

## Key Takeaways

### **Facilities and Operations based in Southern California**

#### GMP Manufacturing

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

#### Translational Research

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

#### Headquarters

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



Facilities and Operations: **Based in Southern California**

# Accomplished Leadership Team

## Executive Team



**Thomas Zindrick, JD**  
Chief Executive Officer



**Lourie Zak**  
Chief Financial Officer



**Paul Scigalla, MD, PhD**  
Chief Medical Officer



**Sean Ryder, JD**  
General Counsel



## 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



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



**Ralph Smalling**  
Head, Regulatory Affairs



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

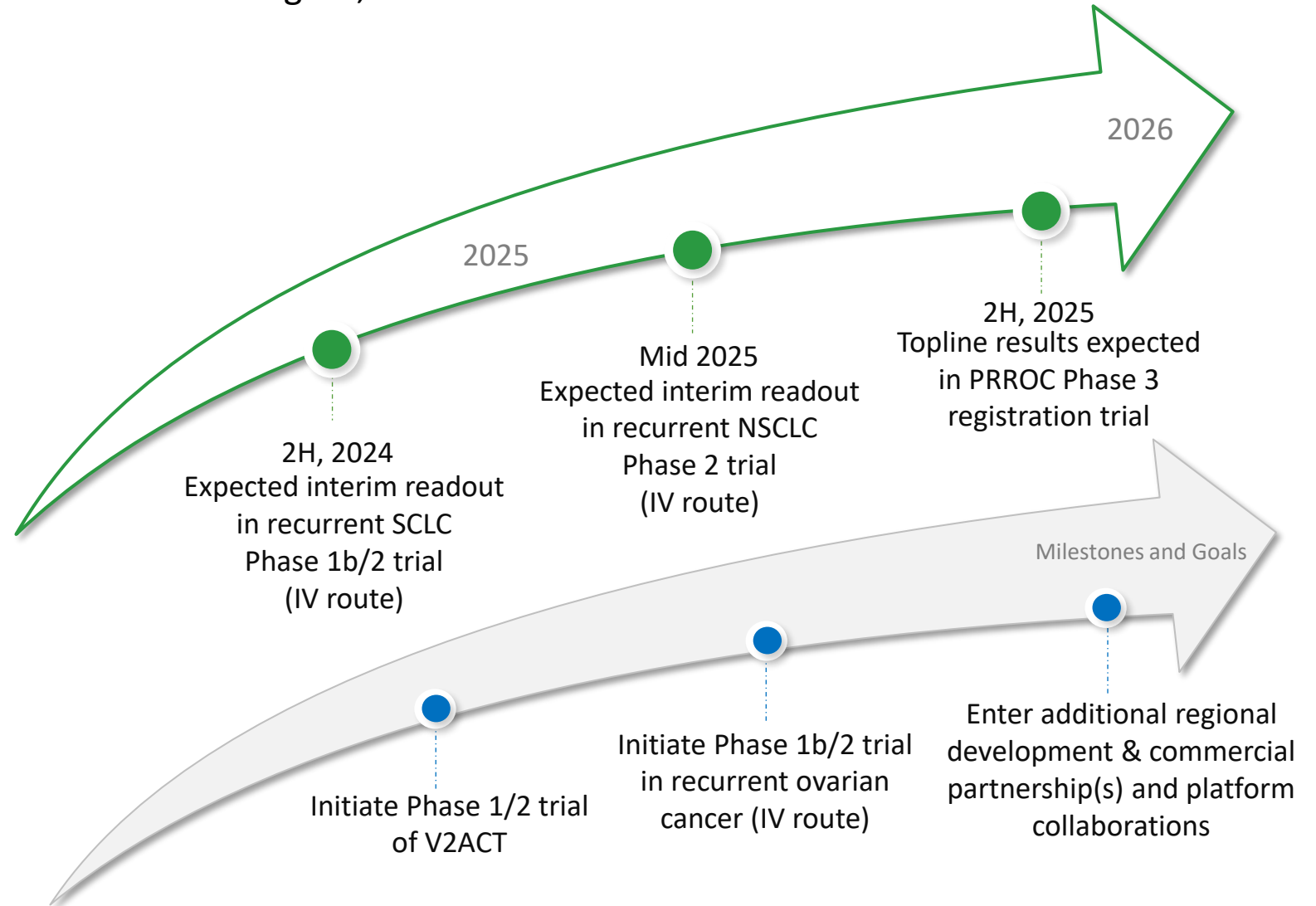


# Genelux Has Executed on Multiple Milestones and is Positioned for the Future

Regular Cadence of Important Program Milestones starting 2H, 2024

## Executed Milestones

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





The logo for GENELUX features the word "GENELUX" in a bold, black, sans-serif font. The letter "G" is stylized with a green dot in its upper-left quadrant. The text is enclosed within a green, horizontal, oval-shaped swoosh that tapers at both ends. A thick, black, curved swoosh is positioned on the left side of the slide, partially overlapping the green swoosh of the logo.

**GENELUX**

*Redefining Immuno-Oncology*

Corporate Presentation | November 2024  
Appendix

# Accomplished Clinical Advisory Board

Medical Director,  
Gynecologic  
Oncology,  
AdventHealth  
Cancer Institute



**Robert Holloway, MD**  
CHAIRMAN

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

Chief Medical  
Officer, Vanium  
Group



**Robert Coleman, MD**

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

Co-Director,  
Gynecologic  
Oncology, Hoag  
Memorial Hospital  
Presbyterian



**Albert A. Mendivil, MD**

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

Deputy Director of  
the University of  
Cincinnati Cancer  
Institute



**Thomas J. Herzog, MD**

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

Professor and  
Division Director,  
Ohio State  
University  
Comprehensive  
Cancer Center



**David M. O'Malley, MD**

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

Forsythe & Bear,  
LLC



**Alan Forsythe, PhD**

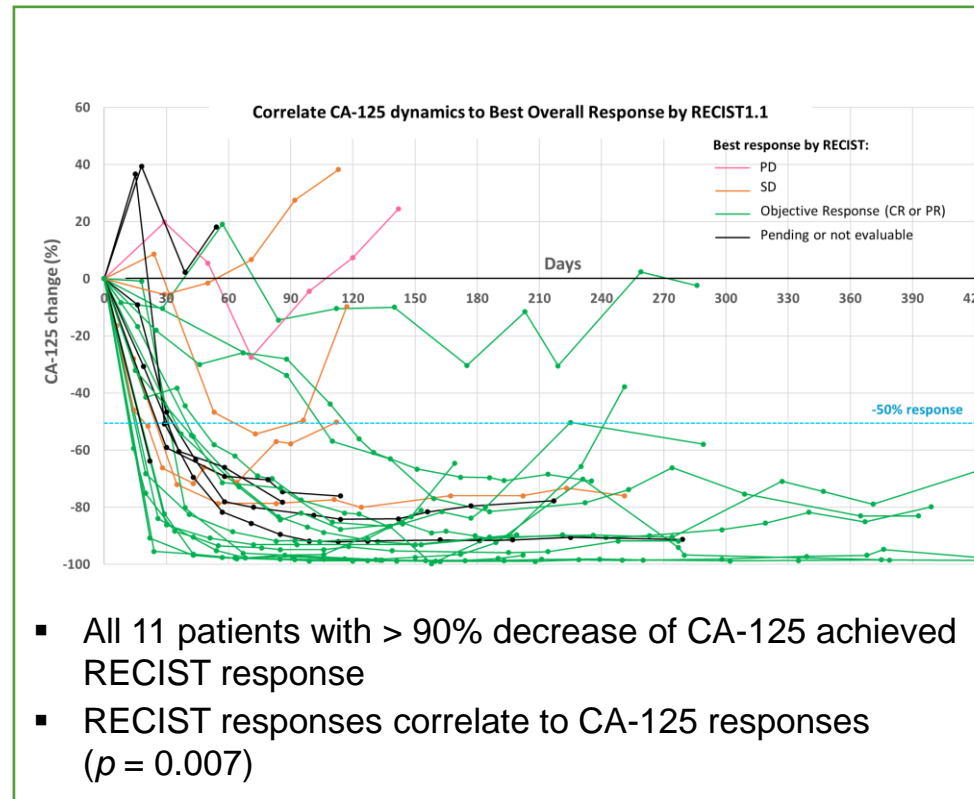
Dr. Forsythe has had a distinguished career in pharmaceutical drug development. As Vice President of Corporate Biomedical Information at Amgen, Alan led the Biostatistics, Epidemiology and HOER depts.

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

## Rapid, Common and Durable Responses

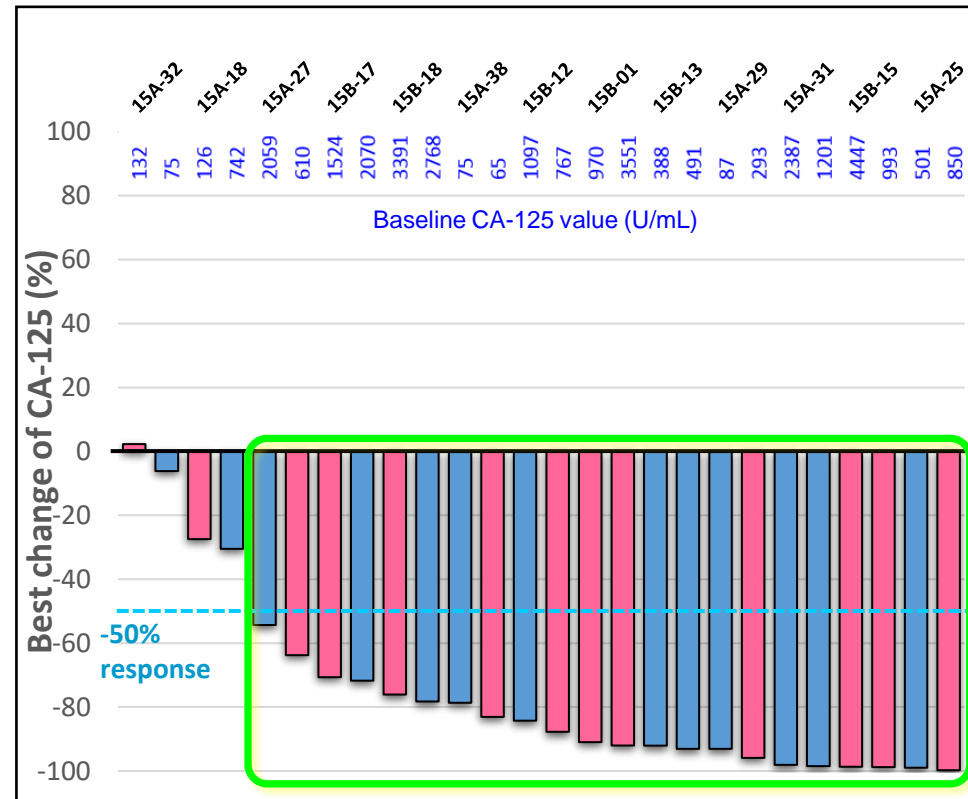
### CA-125 Decrease

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



### ORR by CA-125

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



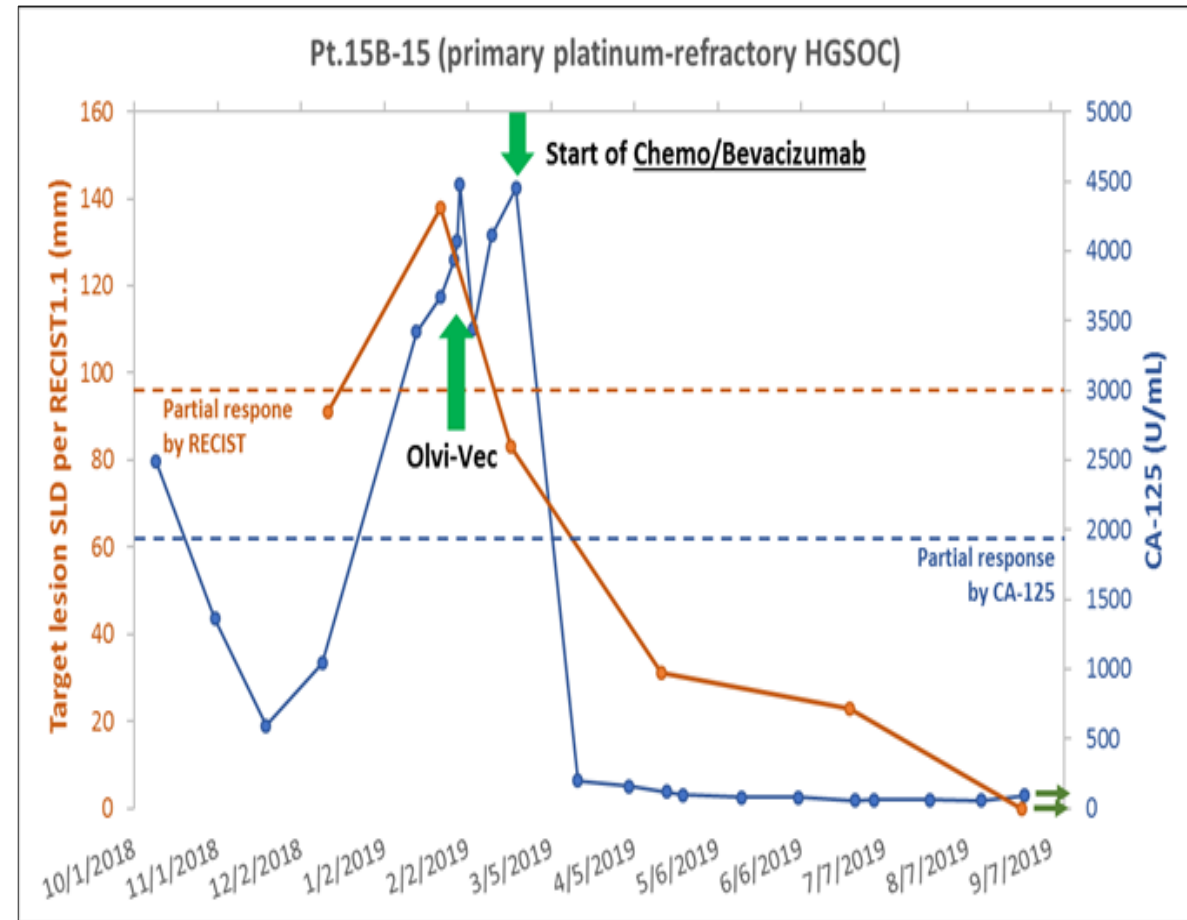
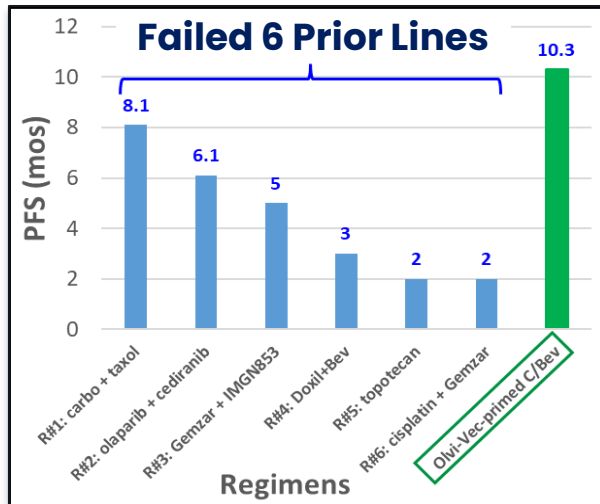
# Olvi-Vec-Primed Immunochemotherapy Overcomes "Refractoriness"

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

**15B-15:**

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

Overall Survival: 12.3 Months



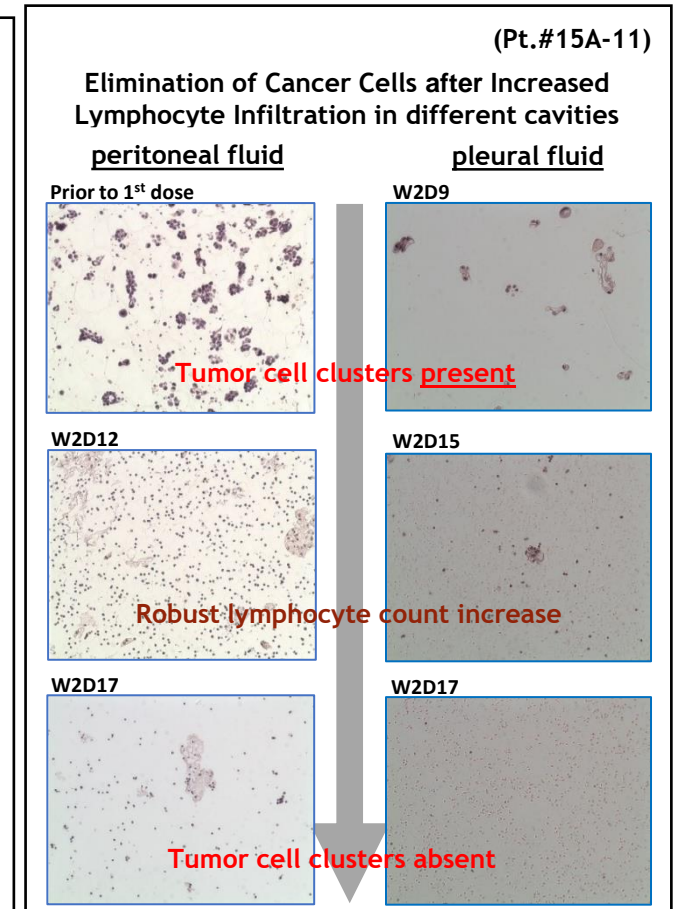
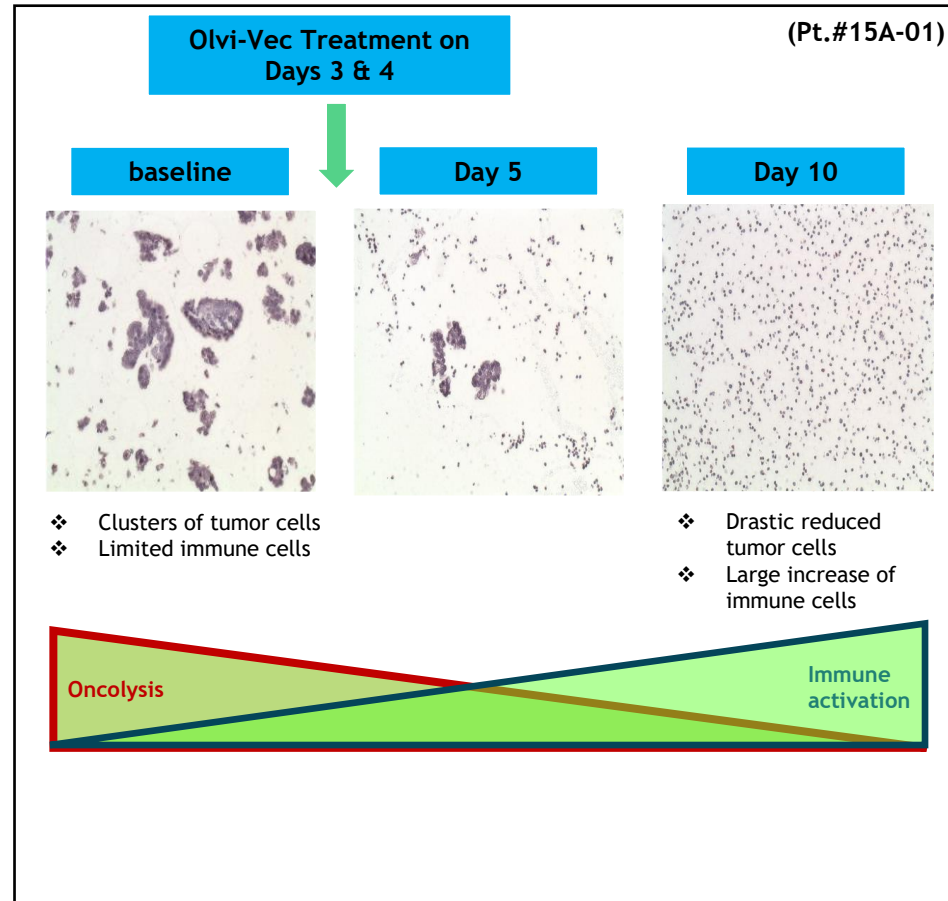
# Olvi-Vec Demonstrated Oncolysis and Immune Activation

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

## Key Takeaways

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

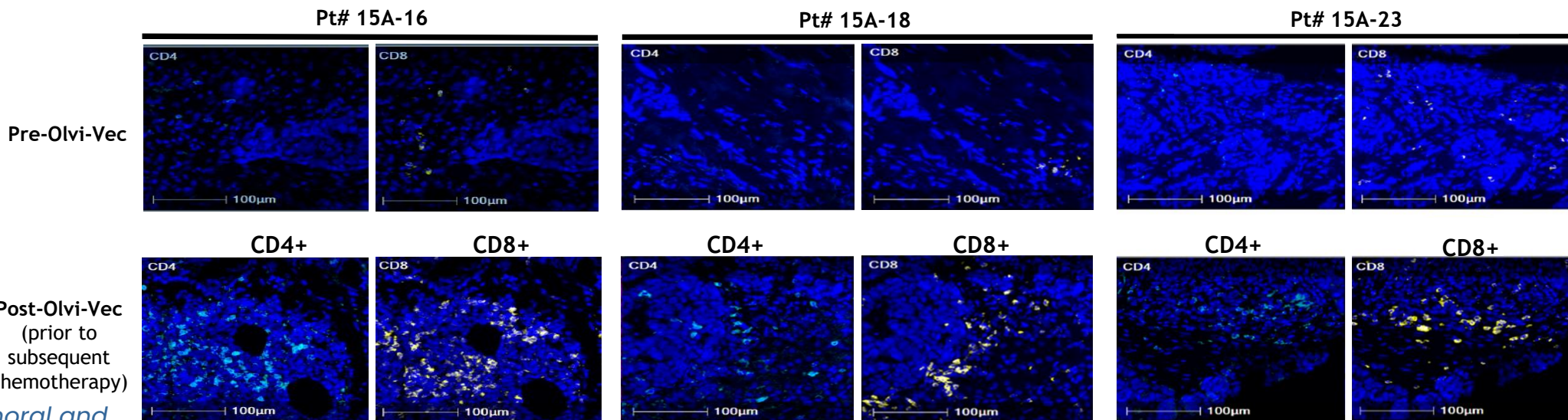
- Olvi-Vec treatment was able to dramatically decrease or eliminate tumor cells in multiple patient samples
- The Activation of Immunosurveillance by Olvi-Vec after 2 doses was seen in multiple cavities as monotherapy



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

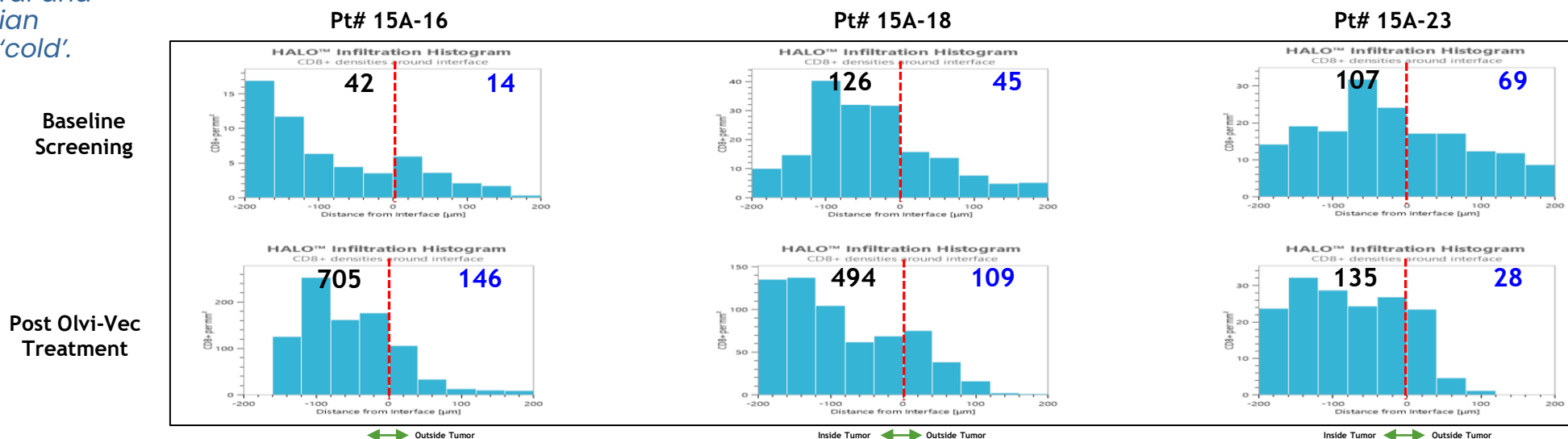
Data from Phase 1b Monotherapy portion of VIRO-15 trial

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



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

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



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

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

## Key Takeaways

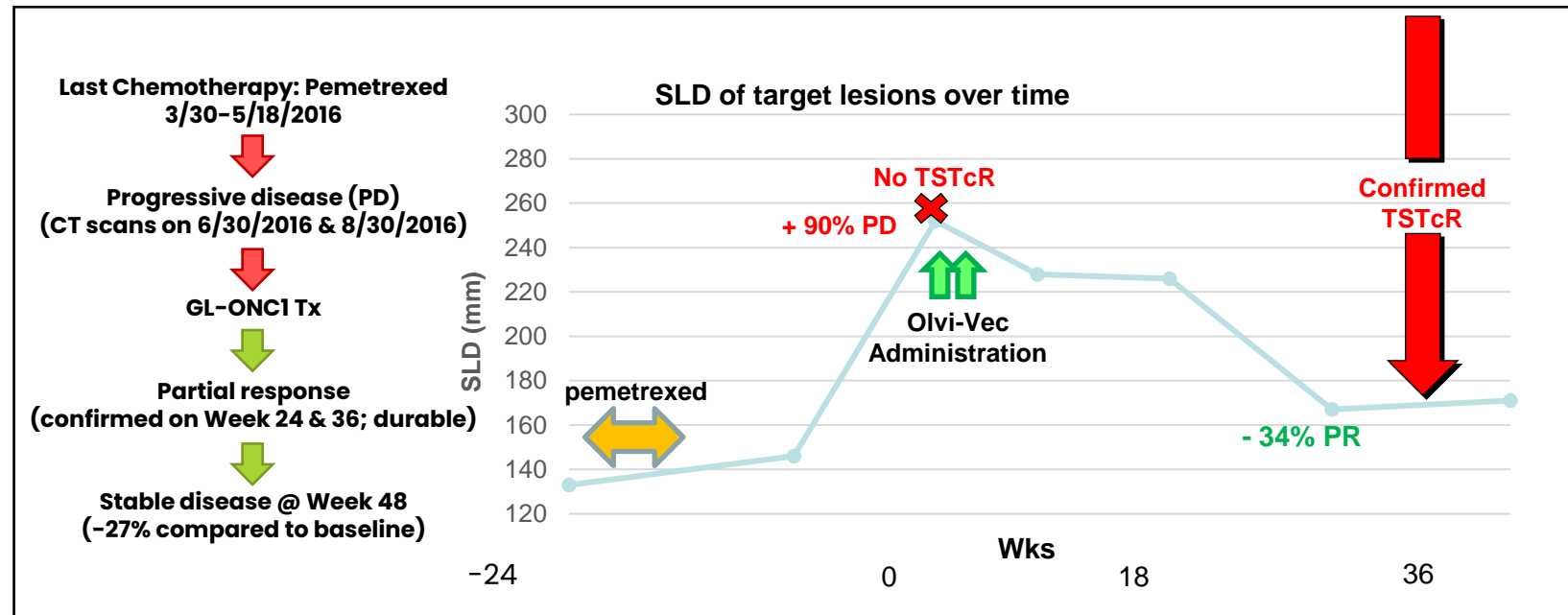
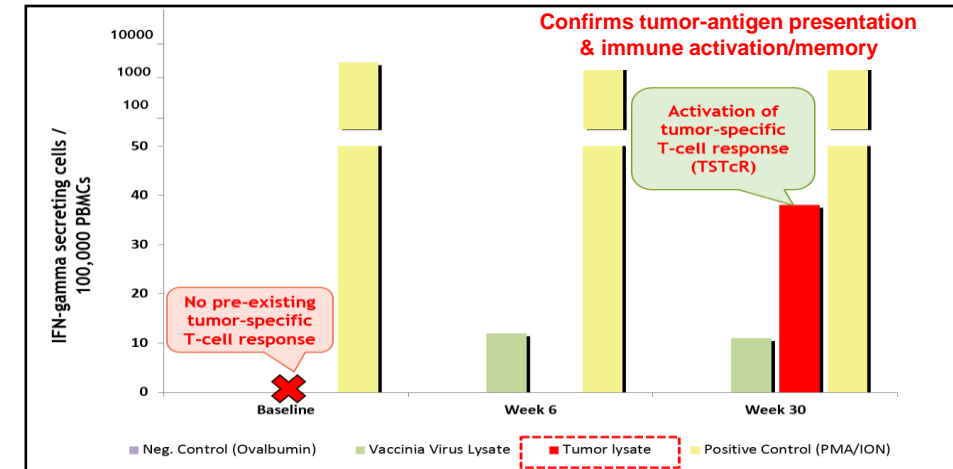
**Off-the-Shelf Personalized Medicine: Single Agent generates Individualized Results**

- 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)

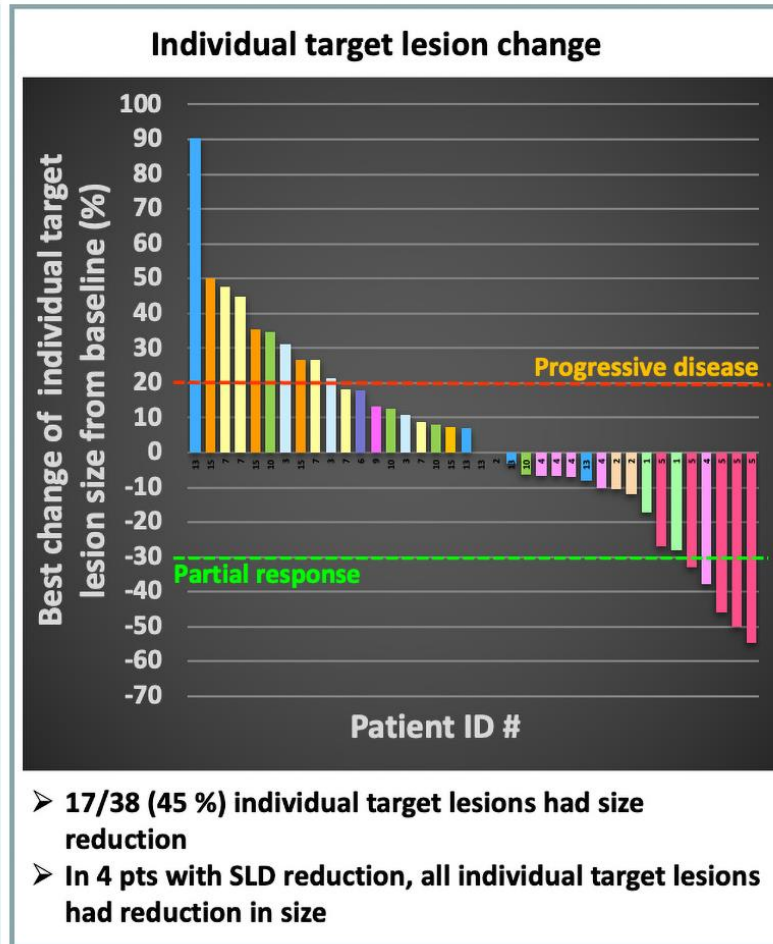
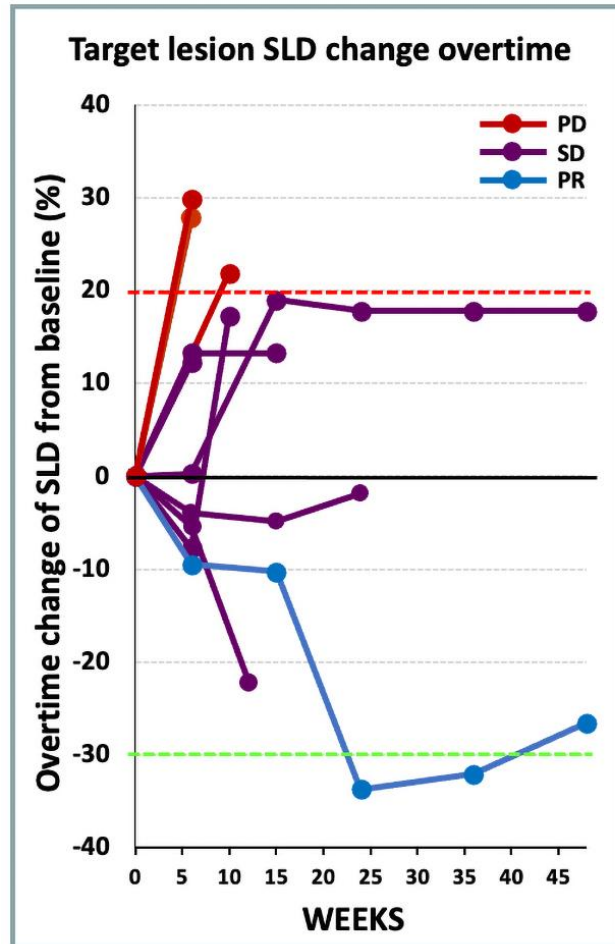
**Heavily pre-treated:**  
9 prior regimens of chemo+Avastin;  
no pre-existing tumor-specific T-cells

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



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

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



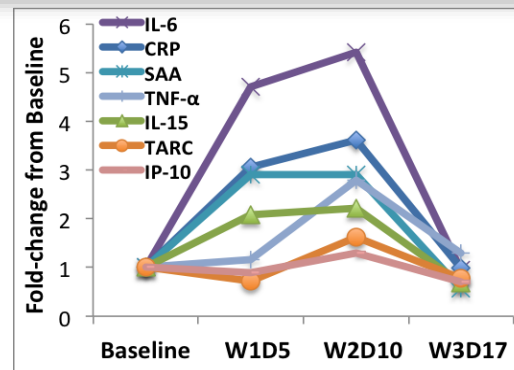


# Olvi-Vec: Ideal Backbone for Combination Therapy

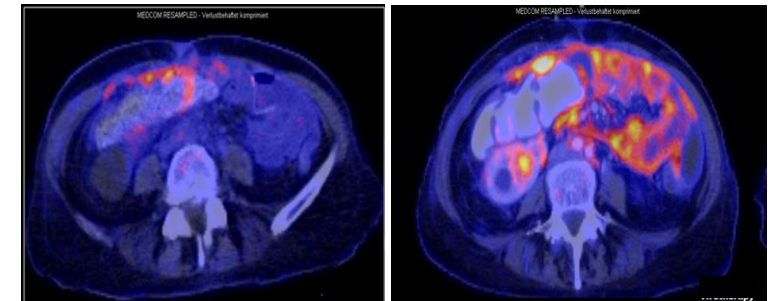
## Converts Tumor Microenvironment to Inflammatory "Hot Spot"

Induction of acute inflammatory cytokines (Th1-type related)

*VIRO-15 Study*



*NCT01443260/TUE Study*



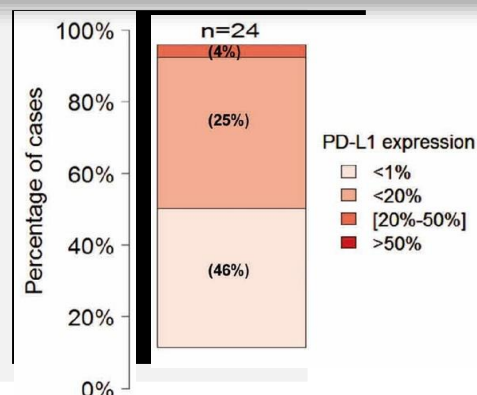
Baseline

Massive inflammatory response after (C1D24) single dose of virus

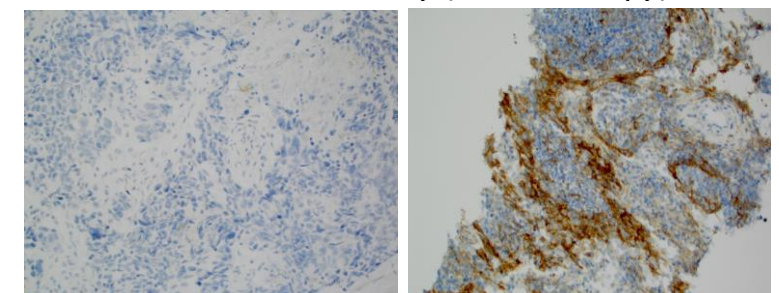
## Up Regulates Immunomodulatory Target Proteins, such as PD-L1

Endogenous PD-L1 expression in ovarian tumor is low, hence limiting target by anti-PD-1/PD-L1 therapy

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



*PD-L1: VIRO-15 Study (monotherapy)*



Baseline

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