# UNITED STATES <br> SECURITIES AND EXCHANGE COMMISSION <br> Washington, D.C. 20549 

## FORM 8-K

| CURRENT REPORT <br> Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 <br> Date of Report (Date of earliest event reported): December 12, 2023 |  |
| :---: | :---: |
| Genelux Corporation <br> (Exact name of registrant as specified in its charter) |  |
| Delaware 001-41599 <br> (Commission <br> (State or other jurisdiction File Number) <br> of incorporation)  | $\begin{gathered} \text { 77-0583529 } \\ \text { (I.R.S. Employer } \\ \text { Identification No.) } \end{gathered}$ |
| 2625 Townsgate Road, Suite 230 Westlake Village, California (Address of principal executive offices) | $\begin{gathered} 91361 \\ \text { (Zip Code) } \end{gathered}$ |
| Registrant's telephone number, including area code: (805) 267-9889 <br> Not Applicable <br> (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:
$\square$ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
$\square \quad$ Soliciting material pursuant to Rule $14 \mathrm{a}-12$ under the Exchange Act (17 CFR 240.14a-12)
$\square$ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
$\square$ 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:

 of 1934 (§ $240.12 \mathrm{~b}-2$ of this chapter).

[^0] provided pursuant to Section 13(a) of the Exchange Act. $\square$

On December 12, 2023, Genelux Corporation (the "Company") made available the slide 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 Slide presentation, dated December 12, 2023.
$104 \quad$ 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

# Genelux <br> Redefining Immuno-Oncology 

## 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: 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; 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. 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 our Quarterly Report on Form 10-Q for the quarter ended September 30, 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," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will" or "would," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these identifying words. You should not put undue reliance on any forward-looking statements. Forward-looking statements should not be read as a guarantee of future performance or results, and will not necessarily be accurate indications of the times at, or by, which such performance or results will be achieved, if at all. Except as required by law, Genelux does not undertake any obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future developments or otherwise.
Trade names, trademarks and service marks of other companies appearing in this presentation are the property of their respective owners. Solely for convenience, the trademarks and tradenames referred to in this presentation appear without the ${ }^{\circ}$ and ${ }^{\text {Tm }}$ 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

Ongoing pivotal trial in late-stage Ovarian Cancer, SCLC and planned Phase 2 trial Adjuvant Maintenance NSCLC

CHOICE ${ }^{T M}$ Platform; Broad and Diverse Discovery Engine
Library with over 500 novel vaccinia strains and 110+ transgenes

Validating Strategic Partnerships
Newsoara Biopharma (Greater China rights) initiated a Phase 1b/2 clinical trial with Olvi-Vec in small-cell lung cancer


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.
Potential beyond this in numerous clinical settings

## 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 trials, catheter placement is prior to chemotherapy, with removal 2 days after initial placement.
- IV therapy currently being used in small cell lung cancer Phase 1 trial.



## Antitumor Effect and Well Tolerated

- Strong data in Phase $1 \mathrm{~b} / 2$ study in platinum-resistant/refractory ovarian cancer (PRROC)
- No Maximum Tolerated Dose (MTD) observed+
- Potential utility in multiple cancers (demonstrated in 20 pre-clinical tumor models), including metastatic disease


## Program Builds on Completed Trials to Exploit Competitive Advantages

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

| Olvi-Vec | Human Health | Design | Preclinical | Phase 1 | Phase 2 | Phase 3 | Notes | Collaborators |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| Regional Route | Ovarian Cancer (platinum-resistant/refractory) | Olvi-Vec (i.pe) + Chemotherapy | Ph3 OnPrime/GOG-3076 Study Actively Enrolling |  |  |  | Topline results expected in 2 H , 2025 | $\underset{\text { (Cooperative Group) }}{\mathbf{G O G}}$ |
|  | Non-Small Cell Lung Cancer (Adjuvant Maintenance) | Olvi-Vec (IV) + Chemotherapy | Ph2 Regulatory Submission |  |  |  | Expected to Initiate in 1 H 2024 |  |
| Systemic Route | Small Cell Lung Cancer (recurrent) <br> Ovarian Cancer (recurrent) <br> Non-Small Cell Lung Cancer (relapsed/recurrent) | Olvi-Vec (IV) + Chemotherapy <br> Olvi-Vec (IV) + Chemotherapy <br> Olvi-Vec (IV) + Chemotherapy | Ph1b/2 enroll <br> Phib/2 Regulatory Submission <br> Planned |  |  |  | Expected to readout in 2 H 2024 | NEWSGARA -xan"n <br> (Greater China) |
| V2ACT <br> Immunotherapy |  |  | Preclinical | Phase 1 | Phase 2 | Phase 3 |  |  |
| Systemic Route | Pancreatic Cancer | Olvi-Vec (IV) + Adoptive Cell Therapy | Regulatory Submission |  |  |  |  | VACT <br> (Worldwide Rights ExGreater 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 |
| - Enhances (neo)antigen |
| presentation and stimulates a |
| tumor-specific immune response |
| Converts tumor |
| microenvironment from |
| immunosuppressive (cold state) |
| to immunoreactive (hot state) |

## Olvi-Vec-Primed Immunochemotherapy: Overcoming Drug Resistance

## Olvi-Vec-Induced Hot Tumor

```
Pro-therapeutic gene expression
    Positive regulation of T-cell activating
    and trafficking
> Expression profiles correlated to better
    prognosis in cancer patients
> Promotion of sensitization/
    response to chemotherapy
```


## A Maturing Modality with Phase 3 Companies validating OV Potential



## Phase lb: Anti-tumor Activity as Monotherapy Leading into Combination



## Olvi-Vec Monotherapy

## 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: $6 \times 10^{9} \mathrm{pfu}$, same dose as Phase ॥/III


## 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 $>2 x$ 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


## Completed Phase 2 Tested Olvi-Vec-primed Immunochemotherapy

## Heavily Pretreated Patients with <br> Platinum-Resistant or Platinum-Refractory Ovarian Cancer



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

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 median PFS of the patients immediately preceding line of therapy was $\sim 4.5$ months
- Based on historical data, the median PFS 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 OS |
| :---: | :---: | :---: | :---: | :---: | :---: |
| All patients <br> ( $\mathrm{n}=27$ ) <br> ( $95 \% \mathrm{Cl}$ ) | $\begin{gathered} 54 \%\left(13^{\circ} / 24\right) \\ (33-74) \end{gathered}$ | $\begin{gathered} 7.6 \mathrm{mos} \\ (3.7-9.6) \end{gathered}$ | $\begin{gathered} 85 \%(22 / 26) \\ (65-96) \end{gathered}$ | $\begin{gathered} 11.0 \mathrm{mos} \\ (6.7-13.0) \end{gathered}$ | $\begin{gathered} 15.7 \text { mos } \\ (12.3-23.8) \end{gathered}$ |
| Platinum-resistant ( $\mathrm{n}=14$ ) <br> ( $95 \% \mathrm{Cl}$ ) | $\begin{gathered} 55 \%(6 / 11) \\ (26-84) \end{gathered}$ | $\begin{gathered} 7.6 \mathrm{mos} \\ (3.7-\mathrm{NA}) \end{gathered}$ | $\begin{gathered} 85 \%(11 / 13) \\ (55-98) \end{gathered}$ | $\begin{aligned} & 10.0 \mathrm{mos} \\ & (6.4-\mathrm{NA}) \end{aligned}$ | $\begin{gathered} 18.5 \mathrm{mos} \\ (11.3-23.8) \end{gathered}$ |
| Platinum-refractory $(n=13)$ <br> ( $95 \% \mathrm{Cl}$ ) | $\begin{gathered} 54 \%(7 / 13) \\ (27-81) \end{gathered}$ | $\begin{gathered} 8.0 \mathrm{mos} \\ (3.7-\mathrm{NA}) \end{gathered}$ | $\begin{gathered} 85 \%(11 / 13) \\ (55-98) \end{gathered}$ | $\begin{gathered} 11.4 \mathrm{mos} \\ (4.3-13.2) \end{gathered}$ | $\begin{gathered} 14.7 \mathrm{mos} \\ (10.8-33.6) \end{gathered}$ |

*Baseline for ORR \& PFS evaluation is the timepoint immediately prior to starting post-OlviVec 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
${ }^{\circ}$ Including 3 unconfirmed; 2 in resistant and 1 in refractory groups

## 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


Duration of Response


## 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


## Durable Survival Benefit



## "Allcomers" Approach May 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


## 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


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

## 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
- Clinical Benefit: statistically significant overall survival (OS) benefit in primary and metastatic lung diseases

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


## 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
$\%$ Cancer AdventHealth Institute

Recurrent 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

Expanded Access Program
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


## Genelux has Partnered with Newsoara BioPharma Co., Ltd



## Key Takeaways

- Newsoara will fund the USbased Genelux Phase 2 trial in NSCLC
- Newsoara has development and commercialization rights in Greater China
- Systemic Trial Milestones
- Initiate Phase 2 NSCLC: 1H, 2024
- Phase lb SCLC readout: 2H, 2024


## Systemic Program: Clinical Trials

| Sponsor | Trial Sites | Indication | Clinical Stage | Patients (est.) | Randomization | Status |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| [0] | US | Adjuvant <br> Maintenance NSCLC | Phase II | ~142 | 1:1 | Regulatory Submission |
|  | China | Recurrent SCLC | Phase IIII | $\sim 150$ | Single Arm | Enrolling |
|  |  | Recurrent OC | Phase I/II | $\sim 150$ | 2:1 | Regulatory Submission |
|  |  | Recurrent NSCLC | Phase IIII | $\sim 150$ | 2:1 | Planned |

Genelux will have worldwide commercial rights (excluding Greater China) to all data generated from clinical trials of Olvi-Vec in China.

## 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


## VACT

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 <br> Therapy | Olvi-Vec Oncolytic <br> Immunotherapy |
| :---: | :---: | :---: |
| Patients Dosed | $\sim 130$ | $\sim 150$ |
| Regulatory | Fast Track Designation / FDA <br> Grant <br> - glioblastoma | Phase 3 enrolling <br> - ovarian |

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

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



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

| Key Takeaways |
| :--- |
| Facilities and Operations based |
| in Southern California |
| GMP Manufacturing |
| G 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 |



## 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

Cell Growth \& Differentiation Regulators
Hormones
Genes
Genes

Immune Modularity

Therapeutic Antibodies

Metastasis Suppressor Genes Cell Matrix Degradative Genes

Immune Regulators Superantigens
Cytokines / Chemokines

Single-chain Antibodies
$\checkmark$ In vitro \& in vivo tested: GLP Tox ready
Immune Modularity Molecules

- $11-6 / s / L-6 R$

IL-24
Cell Growth \& Differentiation Regulators

- BMP-4

Cell Matrix-Degradative Genes

- hMMP9

Clonal Isolated Strains (non-GMO)

| $\circ$ | LIVP1.1. | $\circ$ V-VETI (LIVP6.1.1) |
| :--- | :--- | :--- |
| $\circ$ | LIVP5.1.1 | $\circ$ |
|  |  |  |

Single-Chain Antibodies

| Anti-VEGF | Anti-DLL4 |
| :--- | :--- | :--- |
| Anti-PD-1 | Anti-CTLA4 |
| Anti-FAP | Anti- $\alpha$ Vß3- |
| Anti-PD-L1 | integrin |



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

## Strong IP \& <br> Regulatory <br> Designations

## Executive Team



## Operations \& R\&D



Tony Yu, PhD SVP. ClinDev $\underset{\text { UCSanDigg }}{\text { Mmiscmornome }}$


Joseph Cappello, PhD Chief Technical Officer Tiinnergity bibraun


Caroline Jewett Head, Quality AMGEN


Ralph Smalling Head. Regulatory Affairs AMGEN


Qian Zhang. MD. PhD VP. Clinical Sciences UCSmbx. (i)


Cathy Gust
VP, Program Mgmt AMGEN

## 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

AMGEN aeromics DNX
${ }^{\text {Hen Bristal Myers Squibo }}$
PPfizer $\square$ abbott
hfma

La Sierra (ifi)

JOHN SMITHER, CPA (Inactive) AMMEN KYTHERA EY Director


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



## Olvi-Vec: De-risked late-stage Clinical Program

Ongoing pivotal trial in late-stage Ovarian Cancer, SCLC and planned Phase 2 trial Adjuvant Maintenance NSCLC

CHOICE ${ }^{T M}$ Platform; Broad and Diverse Discovery Engine
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## Validating Strategic Partnerships

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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.
Potential beyond this in numerous clinical settings


## Accomplished Clinical Advisory Board



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.

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.

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.

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

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

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.

## 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


Overall Survival: 12.3 Months



## Olvi-Vec Monotherapy Demonstrates Oncolysis and Immune Activation



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



## Long-lasting, Tumor-specific T cell response corresponds to tumor reduction



## Olvi-Vec: Ideal Backbone for Combination Therapy

Converts Tumor Microenvironment to Inflammatory "Hot Spot"

Induction of acute inflammatory cytokines
(Thi-type related)
VIRO-15 Study


NCTO1443260/TUE Study


Baseline


Massive inflammatory response after cycle 1 of virus treatment

Up Regulates Immunomodulatory Target Proteins, such as PD-L1

Endogenous PD-LI expression in ovarian tumor is low, hence limiting target by
anti-PD-1/PD-LI therapy
Rodriquez-Freixinos et al. J Clin Oncol 36, 2018 (suppl; abstr 5595)



[^0]:    

