

Redefining Immuno-Oncology

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We have filed a registration statement (including a prospectus) on Form S-1 (File No. 333-265828) with the SEC for the offering to which this communication relates. Before you invest, you should read the prospectus in that registration statement and other documents we have filed with the SEC for more complete information about Genelux and this offering. You may get these documents for free by visiting EDGAR on the SEC Web site at www.sec.gov. Alternatively, the issuer or any underwriter participating in the offering will arrange to send you the prospectus if you request it by contacting The Benchmark Company, 150 East 58<sup>th</sup> Street, New York, NY 10155, by email at Prospectus@benchmarkcompany.com or by phone at (212) 312-6700.

**Genelux** is a Phase 3 biopharmaceutical company developing powerful therapeutics for patients suffering from difficult-to-treat cancers. The Company is focused on the development of next-generation oncolytic viral immunotherapies that are designed to generate a personalized multi-prong attack to overwhelm a tumor's sophisticated defense mechanisms.

## OUR LEAD PRODUCT CANDIDATE

**Olvi-Vec** (olvimulogene nanivacirepvec), is a proprietary, modified strain of the vaccinia virus (VACV), a stable DNA virus with a large engineering capacity having the potential to:

- Directly kill cancer cells
- Stimulate a tumor-specific immune response
- Ability to transform immunologically "cold" tumors into "hot" tumors allowing for responsiveness for immunotherapy

# **OUR SCIENCE**

Platform technology (**Choice**<sup>TM</sup>) is the foundation of our oncolytic immunotherapy product development program; and is designed to allow us to generate new product candidates rapidly from conception through the initiation of clinical trials.

## Seasoned Leaders with Extensive Business & Clinical Development Experience

#### The Genelux Team

#### **Executive Leadership**

- Thomas Zindrick, JD Chair, President & CEO
  - 30+ years industry experience (Former – Amgen, VP)
- James L. Tyree, MBA Lead Independent Director
  - 35+ years industry experience (Former - Abbott Global Pharmaceuticals, EVP)

#### • Paul Scigalla, MD, PhD – Chief Medical Officer

 35+ years industry experience (Former - Pfizer, VP; Boehringer Mannheim, SVP)

#### Doug Samuelson – Chief Financial Officer

 30+ years industry experience (Former – Wellness Center USA, CFO)

#### • Sean Ryder, JD– General Counsel

 20+ years industry experience (Former – Helsinn Therapeutics (US), VP)

#### **Operations**

- Joseph Cappello, PhD Head of Operations
  - 30+ years industry experience
- Caroline Jewett Head of Quality
  - 30+ years industry experience

#### R&D

- Tony Yu, PhD Head of Development
   20+ years industry experience
- Qian Zhang, MD, PhD Assoc. VP, Research
  - $\circ$  15+ years industry experience
- Ralph Smalling, MS Head of Regulatory Affairs
   35+ years industry experience

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#### Advanced Clinical Program

- Phase 3 registration trial actively recruiting patients (late-stage ovarian cancer)
  - Proof of Concept confirmed in Phase 2 trial
- Phase 2 trial actively being prepared for initiation (recurrent non-small cell lung cancer; i.v. route)
  - Dose-dependent survival benefit in Phase 1b monotherapy study

## Broad Technology Platform

- $\circ$  Potential utility against broad range of tumor types and metastatic disease
- Physician-preferred/familiar route(s) of administration, e.g., intravenous delivery
- 500+ novel strains generated via our proprietary CHOICE<sup>™</sup> platform

## Large Market Opportunity

- Five-year US sales forecast estimated at \$1B+ (post-marketing approval of Olvi-Vec)
- o Potential in multiple clinical settings offer significant revenue upside

#### Validating Strategic Partnerships

- o Newsoara BioPharma Co. Ltd. (Chinese rights) anticipates initiating 3 Phase 1/2 clinical trials with Olvi-Vec
- ELIAS Animal Health (Worldwide rights) anticipates initiating canine efficacy studies with V-VET1



#### Identified Commercial Strategy

- o US launch in ovarian cancer; strategic partnership for larger indications
- o Exclusive licenses outside the US (Newsoara Collaboration Agreement established in 2021)

\* Believed to be the most-advanced, non-local delivery Oncolytic Virus clinical program.

Human Therapeutics	Therapeutic Indication	Design	Pre-clinical	Phase 1	Phase 2	Phase 3	Clinical Sites	Clinical Sponsor(s)	U.S. Revenue Projection
	<b>Regional Program</b>								(5-yr post-marketing approval)
Olvi-Vec <sup>1a</sup>	Ovarian Cancer <sup>2</sup> (resistant / refractory)	Olvi-Vec (i.pe.) +Chemotherapy		Active			US	⊡	1. Ovarian: \$250M
	Systemic Program							[•]	2. Total: \$1B+ <b>\$1B+</b>
	NSCLC <sup>3</sup> (recurrent)	Olvi-Vec (i.v.) +Chemotherapy	Planı	ned			US	NEWSOARA	
	NSCLC <sup>4</sup> (recurrent)	Olvi-Vec (i.v.) +Chemotherapy						6.	Additional Revenue
	SCLC <sup>4</sup> (recurrent)	Olvi-Vec (i.v.) +Chemotherapy	Regulator Submissio	ry on			China	NEWSOARA	<u>Opportunities</u> 1. Re-treatment
	Ovarian Cancer <sup>4</sup> (recurrent)	Olvi-Vec (i.v.) +Chemotherapy							2. Front-line cancer 3 Additional Indications
V2ACT Immunotherapy <sup>1b</sup>	Pancreatic Cancer <sup>5</sup> (newly diagnosed, surgically resectable)	Olvi-Vec (i.v) +Adoptive Cell Therapy	Regulatory Submission				US	THERAPEUTICS	
Animal Therapeutic	Therapeutic Indication	Design	Safety	Preliminary Efficacy	Pivotal E	fficacy	Clinical Sites	Clinical Sponsor	
V-VET1 <sup>1c</sup>	Hematologic & solid cancer(s) <sup>6</sup>	V-VET1 (i.v.) +/- standard of care	Active				US	ELIAS	

<sup>1</sup>Commercial Rights

<sup>1a</sup>Genelux: Worldwide (excluding Greater China); Newsoara (Greater China) <sup>1b</sup>V2ACT Immunotherapy: Worldwide (excluding Greater China)

<sup>1c</sup>ELIAS: Worldwide

<sup>2</sup> We have enrolled our first patient in our Phase 3 clinical trial.

<sup>3</sup> Based on the results of our previously completed Phase 1 clinical trials of Olvi-Vec administered intravenously to patients with solid tumors, we are planning to initiate a Phase 2 clinical trial of Olvi-Vec in recurrent NSCLC.

<sup>4</sup> Newsoara has submitted an IND and protocols to the Chinese National Medical Products Administration

<sup>5</sup> V2ACT has an active IND for this product candidate. The Phase 1b/2a clinical trial is not yet scheduled to be initiated.

<sup>6</sup> ELIAS is developing an efficacy trial.



# Near-Term Milestones

# Late-Stage Clinical Program

- Initiated Phase 3 registration trial in late-stage Ovarian cancer
- Initiate Phase 2 trial in recurrent Non-Small-Cell Lung cancer

# Strategic Partnerships

- Newsoara anticipates initiating 3 China-based Phase 1/2 clinical trials
- ELIAS anticipates initiating canine efficacy study(ies)

# In-house cGMP Manufacturing Facility

- Build-out of in-house production facility in San Diego, CA
- Produce additional GMP batches to meet supply requirements

# **Clinical Program & Science**



# **Our Lead Product**

\* Addressing significant unmet medical needs.



# A differentiated, and desirable immuno-oncology approach

• Physician-preferred methods of delivery locate and kill cancer cells to enhance antigen presentation and stimulate an anticancer immune response



## Signals of Differentiated Therapeutic Potential

• Immunostimulatory backbone, by turning the tumor "hot", for combination therapy with other therapies, including chemotherapies



# Oncolytic Vaccinia (Olvi-Vec) Primed Immunochemotherapy

• Patients who received Olvi-Vec-primed immunochemotherapy may respond to chemotherapy to which they previously were deemed resistant or refractory

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# **Clinical Trial Results**

Demonstrated anti-tumor activity as monotherapy and combination therapy

## Platinum-resistant / refractory Patients

- Heavily pre-treated with documented progressive disease at baseline
- No Standard of Care
   i.e., clinical trial or palliative care

## High & Condensed Dosing

- All patients received a single cycle of Olvi-Vec
- Bolus infusions (intraperitoneal delivery) on
   2 consecutive days, i.e., total dose: 6x10<sup>9</sup> pfu

## Phase 1b: Olvi-Vec Monotherapy (11 patients)

#### **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 tumor infiltration lymphocytes
- Favorable immune-related genetic signatures (via biomarkers)

## **Tolerability:**

- Toxicity:
  - No Dose Limiting Toxicity (DLT)
  - No Maximum Tolerated Dose (MTD)
- Most Common Adverse Events (AE):
  - o Transient, flu-like symptoms
  - Abdominal pain (Grades 1 & 2)
  - No Grade 4 AEs



## Ovarian Cancer Program: Platinum-resistant / refractory Ovarian Cancer

## Preestablished endpoints met

Phase 2: Olvi-Vec followed by chemotherapy<sup>1</sup> (Clinical Benefit<sup>2&3</sup>)

#### IGCS ANNUAL GLOBA

xDigital Annual Global Meeting of the International Gynecologic Cancer Society Oncolytic Vaccinia (Olvi-Vec) Primed Immunochemotherapy in Platinum-Resistant / Refractory Ovarian Cancer <u>Robert W. Holloway, et al</u>

### All PRROC (27 patients)

#### • 54% RECIST response

(vs.<15-20% historical to chemotherapy)

 11.0 mo. of median progression-free survival (PFS) (vs. ~5 mo. historical)

#### Platinum-refractory (13 patients)

#### • 54% RECIST response

(vs. <10% historical);

7% response to VIRO-15 patients' most recent prior platinum line

#### • 11.4 mo. of median progression-free survival (PFS)

#### (vs. ~3 mo. historical)

1Platinum doublet +/- Bevacizumab 2VIRO-15 patients had results in prior lines of therapy similar to historical data. 3RECIST readings based on pre-chemo baseline. Olvi-Vec Platinum-based doublet +/- Bev

> Olvi-Vec-Primed Immunochemotherapy

## Exemplary heavily pre-treated platinum-refractory

Patient who progressed while on last platinum, presented at time of enrollment with progressive disease and projected short life expectancy.

All achieved PFS exceeding any of their respective prior lines, and achieved objective partial *response*, *indicating meaningful* clinical benefit from Olvi-Vecprimed immunochemotherapy.

## 15B-01:

- 36 yrs old
- Stage IIIB, papillary serous
- ECOG: 0 .
- **BRCA** negative .
- MSI: stable

.

16.0

14.0

4.0

2.0 0.0

8 7

(sou 12.0 10.0 8.0

PFS 6.0

- # of mutations (load): 4 (low) .
- PD-L1 negative
- BOR: PR by CA-125 & CT scan
- Overall survival: 23.2 months

Failed 10 prior lines

10.9

12.0

Regimens

#### 15B-15:

- 67 yrs old
- Stage IIIB, high grade serous
- ECOG: 0

12

10

6

(mos) 8

PFS

8.1

15.5

- **BRCA** negative
- # of mutations (load): 0 (low) PD-L1 negative

#### BOR: PR by CA-125 & CT scan

Overall survival: 12.3 months

### 15B-17:

- 65 vrs old
- Stage IIIC, high grade serous
- ECOG: 1
- **BRCA** negative
- BOR: PR by CA-125 & CT scan
- Overall survival: 15.7 months







## Anti-tumor Activity: Tumor Shrinkage

\* Rapid, Common and Durable Responses

## Duration of Response

- All PRROC Patients: 7.6 months
- Platinum-refractory patients: 8.0 months

## <u>Tumor Shrinkage</u>

- All PRROC Patients: 86%
- Platinum-refractory patients: 91%



4 patients achieved 100% reduction of target lesions (even in a platinum-refractory patient with heavy tumor burden)



\* Demonstrated Survival Tail (~20%), a hallmark of Clinically Beneficial Immunotherapies



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## VIRO-15 Phase 2 Results: Comparison with Seminal Trials in Ovarian Cancer

## Driver of Market Penetration

- Currently 230,000+ ovarian cancer patients in the United States
- While clinical remissions are obtainable, a majority of patients will relapse (~80%)



#### **References**

- (1) Pujade-Lauraine *et al.*, J Clin Oncol 2014;32:1302-1308.
- (2) Ikeda *et al.*, Int J Gynecol Cancer 2013;23:355-360.
- (3) Matulonis *et al.*, ESMO 2018.
  (4) Arend *et al.*, Gynecol Oncol. 2020;157:578-584.
- (5) Konstantinopoulos *et al.*, J Clin Oncol 2018;36(S15)106.
- (6) Aghajanian *et al.*, Gynecol Oncol. 2015;139(1):10–16.

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

## Systemic Program: Dose-dependent survival benefit of Heavily Pre-treated Patients

## Demonstrated feasibility of multiple IV cycles





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

Groups lower vs higher TCD:

median Overall Survival at <u>4.6 months (95% CI: 1.3 – 11.0)</u> vs <u>16.8 months (95% CI: 5.9 – NA)</u>; p = 0.026; a statistically significant clinical benefit favoring the higher dose group.



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

#### Groups lowest vs highest TCD:

median Overall Survival at <u>4.6 months (95% CI: 2.7 – NA)</u> vs <u>20.9 months (95% CI: 16.8 – NA)</u>; p = 0.002; a statistically significant clinical benefit favoring the highest dose group.

Virus dose is in Total Cumulative Dose (TCD) received in all cycles in each patient

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## Systemic Program: Condensed Dosing followed by Chemotherapy

## Demonstrated Anti-tumor effect of IV immunochemotherapy



**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  $\geq$



- \* Chemotherapy after disease progression
  - >**Partial Response**
  - >**PFS: 70+ wks**
  - $\geq$ OS: 46.4 mos (ongoing)

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  $\geq$ **Objective Response per RECIST**, with PFS of 18 weeks



- $\dot{\cdot}$ Chemotherapy after disease progression  $\succ$ 83% drop of CA 19.9  $\geq$ 
  - Partial Response by RECIST  $\geq$ 
    - PFS: 31 wks

# **CHOICE<sup>™</sup>** Discovery Platform

Flexible, powerful and modular

# Comprehensive Approach

• Viral vectors selected based on multiple in vitro and in vivo selection criteria



# **Highly Productive**

• Extensive library of viral vectors with a variety of anti-tumor attributes



## **Broad Utility**

• Regression and elimination of a wide range (20+) of tumor types in pre-clinical models

## **\*** Generated an extensive library of engineered and selected viral strains

## **Unique Attributes of Vaccinia Virus**

- No genomic integration
- Highly modular, customizable
- Broad spectrum
- Robust lytic capabilities, high replication and proliferation
- Powerful immune activator (Th1-type immune response)

## Olvi-Vec



Engineered to selectively target and eliminate tumor cells while inducing a robust patient-specific immune response



# **Facilities and Operations**

## Facilities and Operations: Based in Southern California

## Integrated R&D and manufacturing capabilities



### Genelux has developed a large-scale cGMP manufacturing process to optimize production

- Established and equipped an independent, Company-controlled 7,500+ Sq. Ft manufacturing facility in San Diego to secure material for pivotal studies and potential commercial supply
- Genelux maintains agreements with raw material and equipment suppliers, as well as contract labs to provide supply chain redundancies and flexibility to offload certain services to CMOs / CROs
- Genelux maintains agreements with third-party companies for **labeling**, **packaging**, **distribution** of both clinical material as well as future potential commercial products
- Genelux plans to invest in and augment its internal development capabilities as well as continually improve its proprietary manufacturing processes



THANK YOU