



# Viral Vector Based Immunotherapies

Corporate Presentation

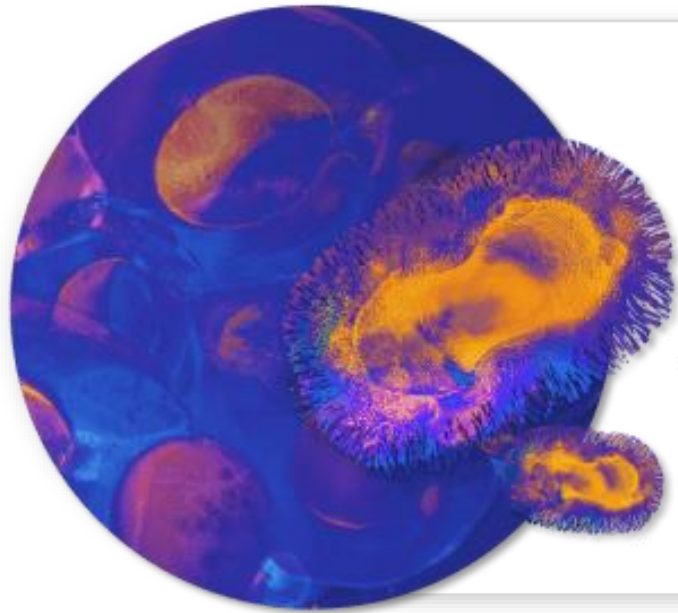
May 5, 2023



## Disclaimer

*This presentation contains forward-looking statements, which are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those anticipated. There can be no guarantee that (i) the results of pre-clinical work and prior clinical trials will be predictive of the results of the clinical trials currently under way, (ii) regulatory authorities will agree with the Company's further development plans for its therapies, or (iii) the Company will find development and commercialization partners for its therapies in a timely manner and on satisfactory terms and conditions, if at all. The occurrence of any of these risks could have a significant negative outcome for the Company's activities, perspectives, financial situation, results and development.*

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Leader in viral vector-based immunotherapies  
designed to transform  
the standard of care of solid tumors

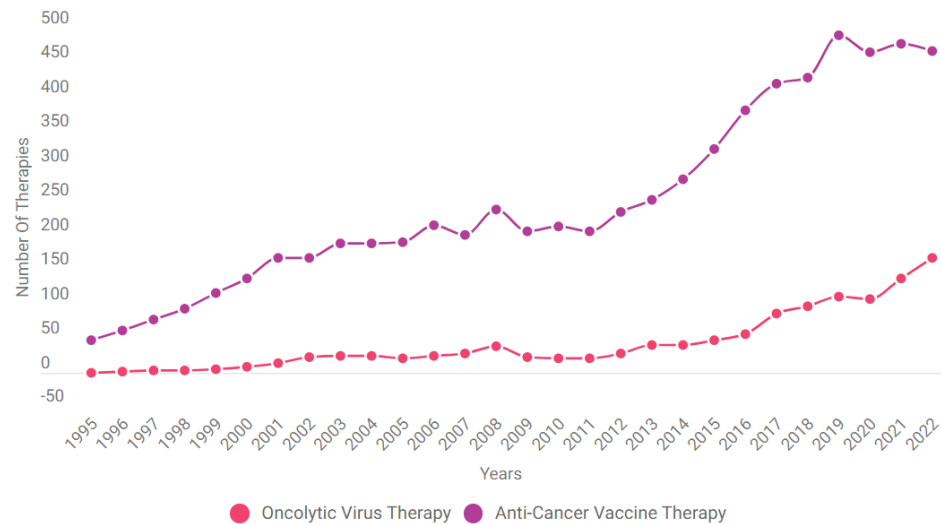
# Transgene is Focused on Two Exciting Areas of Immunotherapy

## Therapeutic Cancer Vaccines (TCVs) and Oncolytic Viruses (OVs) on the Rise

In Vivo  
Pharma Intelligence

### A Promising Future For Oncolytic Viruses As Cancer Immunotherapies

**Exhibit 1: Oncolytic Virus Therapy And Anti-Cancer Vaccine Therapy Trends, 1995–2022**



Note: annual snapshots are taken each May

The Washington Post  
*Democracy Dies in Darkness*

### Getting closer to a vaccine for cancer

**FIERCE**  
Biotech

**Oncolytic viruses show promise in cancer-killing combos**

**CANCER RESEARCH UK**

Hiding in plain sight: How we can use immune cells to deliver cancer-killing viruses to tumours

**GEN** Genetic Engineering & Biotechnology News

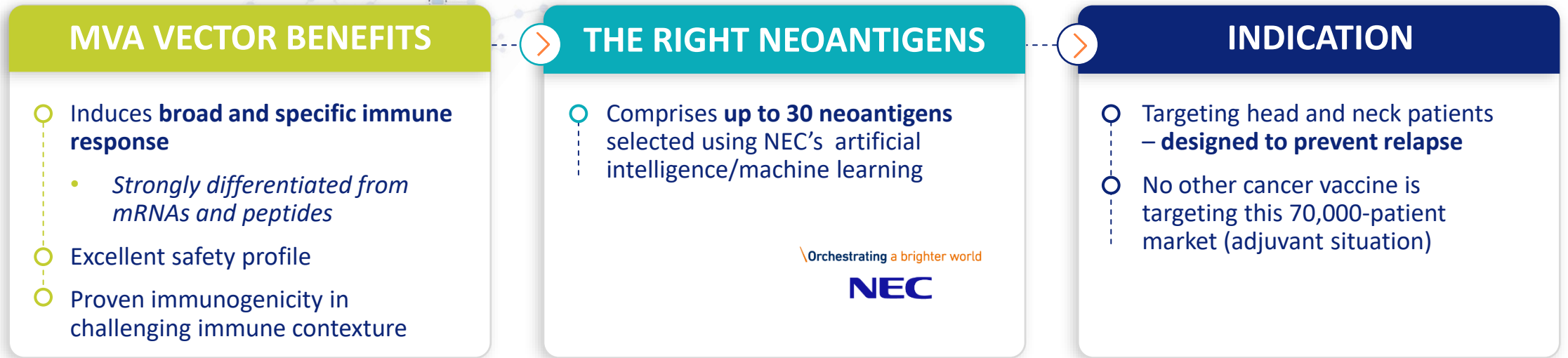
**Viral Vector Production Evolves to Meet Surging Demand**

# Transgene – a Global Player in Next Generation Cancer Immunotherapies



# Harnessing Innovation to Deliver Much Improved Cancer Vaccines

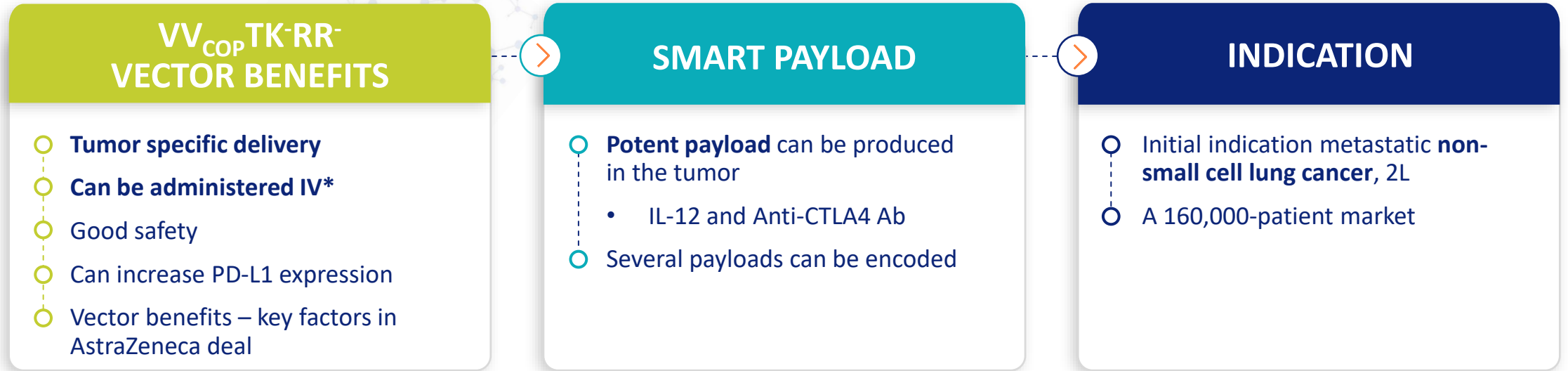
## TG4050 – a Novel Individualized Cancer Immunotherapy Designed for Success



**Immune responses linked to clinical benefits**  
**Potential registrational trial to begin H2 2023**

# Harnessing Innovation to Realize the Significant Potential of OV<sup>s</sup>

## TG6050 a Powerful Off-The-Shelf Cancer Immunotherapy Designed for Success








invirio

**Generated a multi armed IV OV  
that can potentially be an industry  
leading product for solid tumors**

\* IV: intravenous administration

# Advancing a Diversified Immunotherapy Portfolio

## From off-the-shelf treatments to patient tailored therapies

Product	Target/transgene	Indication	Collaboration	Preclinical	Phase I	Phase II
THERAPEUTIC CANCER VACCINE (TCVs) ➔ MVA						
TG4001	HPV16 E6 – E7	Anogenital HPV+ cancers		<div></div>	<div></div>	Potential registrational trial in preparation
	TG4050	30 neoantigens		<div></div>	<div></div>	Potential registrational trial to start in H2 2023
		Ovarian cancer		<div></div>	<div></div>	
ONCOLYTIC VIRUS (OVs) ➔ VV <sub>COP</sub> TK <sup>-</sup> RR <sup>-</sup>						
	TG6050	IL-12 + Anti-CTLA4		<div></div>	<div></div>	
	BT-001	Anti-CTLA4 + GM-CSF		<div></div>	<div></div>	
	TG6002	5-FU chemotherapy		Gastro-intestinal cancers (IV*)	<div></div>	<div></div>
Colorectal cancer (IHA*)			<div></div>	<div></div>		



# 2022 Achievements are Solid Basis for Multiple Readouts in Next 18 Months

The Viral Vector Experts In Immuno-Oncology

TG4050



- ✓ Promising data as single agent
  - ➔ H1 2023 | Start treatment of last patient in H&N Phase I
  - ➔ H2 2023 | Potential registrational Phase II trial expected to start

TG4001

- ✓ Positive Interim Analysis Results based on PFS
  - ➔ H1 2024 | Last patient randomized, 2024 | Phase II results
  - ➔ Intend to rapidly start registration-directed trial

invirio

- ✓ PoC of IV administration
  - ➔ Expand the potential of our technologies through existing and new partnerships, and proprietary development

TG6050 (IV)

- ✓ Positive data demonstrating IV feasibility of Invir.IO® backbone
  - ➔ H1 2023 | Enroll first patient

BT-001 (IT)

- ✓ Positive initial data as single agent (IT)
  - ➔ H1 2023 | Ph. I part A (single agent) data to be communicated
  - ➔ H2 2023 | Ph. I part B (combin. w. pembrolizumab) to start

# Transgene – 2028 Snapshot – Significant Value Created

Two approved products targeting sizeable market opportunities with clear clinical benefits

• **TG4001**

**Conditional approval for first indication targeting a ~\$1 bn market opportunity**

Limited competition

Ongoing trials in additional indications

• **TG4050**

**Conditional approval for first indication:**

Head and Neck cancer (maintenance)  
**~\$1+ bn market opportunity**

No other cancer vaccines targeting this indication

Potential registrational trial to start in H2 2023

• **TG6050**

**Delivered high value clinical data in initial indication when given IV**

**NSCLC 2L:  
\$1.5+ bn market opportunity**

Broader clinical development plan to be implemented



**Generated several additional new cancer vaccines and IV OV candidates** based on right vector, right payload, right indication approach

Further strengthened our viral vector and payload engineering technology platforms

Source: Company estimates



# Cancer Therapeutic Vaccines

Potent immunotherapies  
to induce specific antitumor immune responses  
and improve patient outcome



# Therapeutic Cancer Vaccines - Educate the Immune System to Destroy Cancer Cells

## MVA-based vaccines activate T cells through several mechanisms

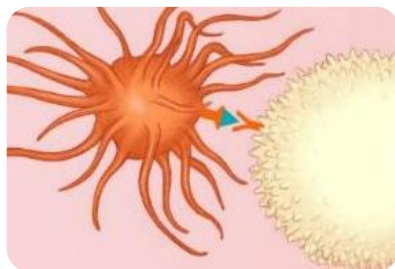
### SIGNAL ACTIVATION

Infected cells will **express vaccine antigens** that will be uptaken by APCs



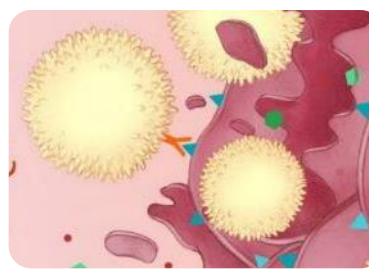
### IMMUNE AMPLIFICATION

APCs **boost specific antitumoral T cells**



### CANCER CELL KILLING

T cells **attack** tumor cells



*Strongly differentiated from mRNAs and peptide approaches*

**Induction of broad immune responses to induce antitumor activity**

- Priming of innate immunity
- Development of an active adaptive response – Increase of effector subgroups of CD4 and CD8 T-cells

Tumor-specific antigens and neoantigens can be used to target a broad range of solid tumors



### Compelling clinical evidence obtained

- Good safety profile
- Strong immune responses to antigen/neoantigen payloads
- Signs of clinical benefit for patients
  - As single agent in maintenance setting
  - In combination with ICI in advanced setting

# myvac® - TG4050 | Individualized Neoantigen Cancer Vaccine

Taking the Treatment of Each Patient's Tumor to a New Level

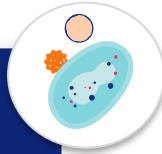
## MVA viral vector: a powerful platform for vaccine development

### Strongly immunogenic vector

- Demonstrated capability to express **complex antigen structures** and have them presented by APCs
- Ability to elicit **strong, durable and specific** immune response
- Established safety profile

### Optimal neoantigen display

- **VacDesignR™** for **optimal design of the recombinant cassettes**
- Selection of **best promoter sequences**



one patient • one genome  
• one vaccine



## Artificial Intelligence to identify up to 30 potent neoantigens

- NEC's machine learning environment based on multiple parameters **to classify most immunogenic neoantigens** from whole tumor genome analysis\*
  - **Takes in account multiple parameters**
- **NEC covers 50% of the development cost of TG4050**

**NEC**



**First clinical data has already shown remarkable induction of immune responses against chosen neoantigens and signs of patient benefit**



[Click here](#)

## ● TG4050 is already Showing the Potential To Manage Patients with High-Risk of Recurrence or Molecular Relapse



one patient • one genome  
• one vaccine

### Goal

to extend remission  
period in high-risk patients  
after initial cancer surgery

*\*TMB: tumor mutational burden*

To **induce specific T cell response**  
in patients in clinical remission but with high risk of relapse

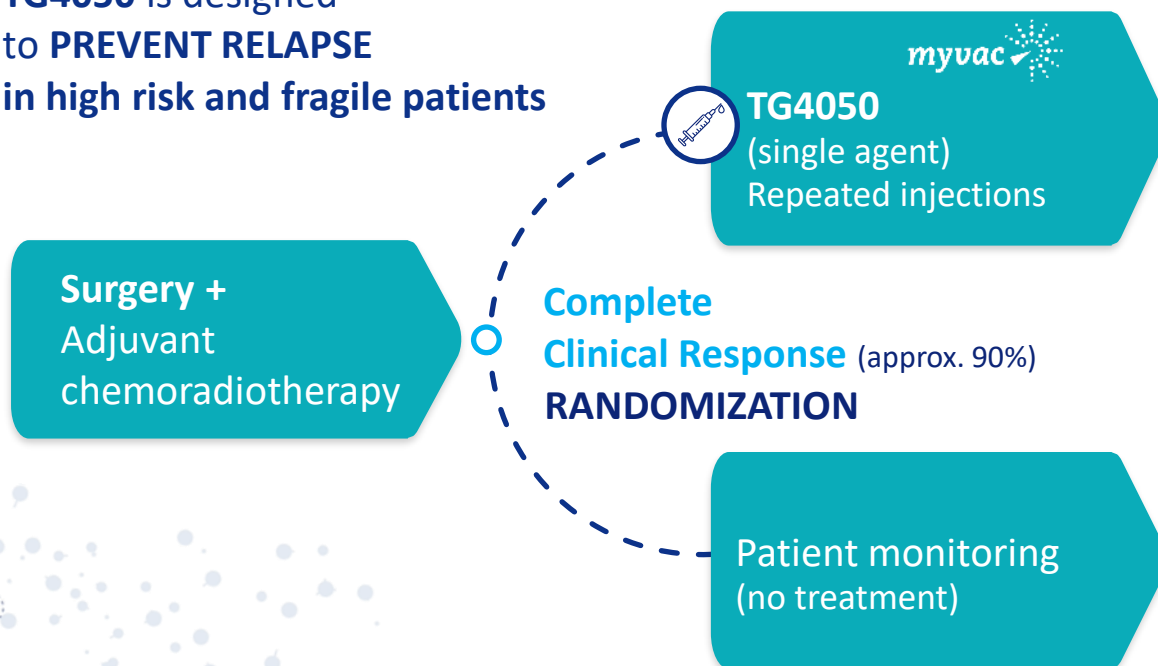
Two ongoing clinical trials – **Head & Neck and Ovarian cancers**  
TG4050 given **as single agent**

- **Positive initial data** (safety, immunogenicity, first signs of efficacy)
- Intend to **launch potential registrational Phase II trial in H2 2023**
- **Mid-term objective:** Establish TG4050 as the SOC in maintenance setting for patients with H&N cancers, a \$1+ bn market

**Potential to address numerous solid tumors after surgery**  
in **adjuvant/maintenance settings W or w/o ICIs**, such as H&N, ovarian, urothelial, breast, lung cancers, ie a multi billion market

# TG4050 | HPV-Negative Head and Neck Cancer - Trial after Surgery and Adjuvant Therapy

TG4050 is designed to **PREVENT RELAPSE** in high risk and fragile patients



## Recurrence

**12-month PFS is approx. 60% (w/o TG4050)\***

Clinical situation where checkpoint blockers have failed (ie. KN412)

## Randomized Phase I Trial

**30 Patients** (NCT04183166)

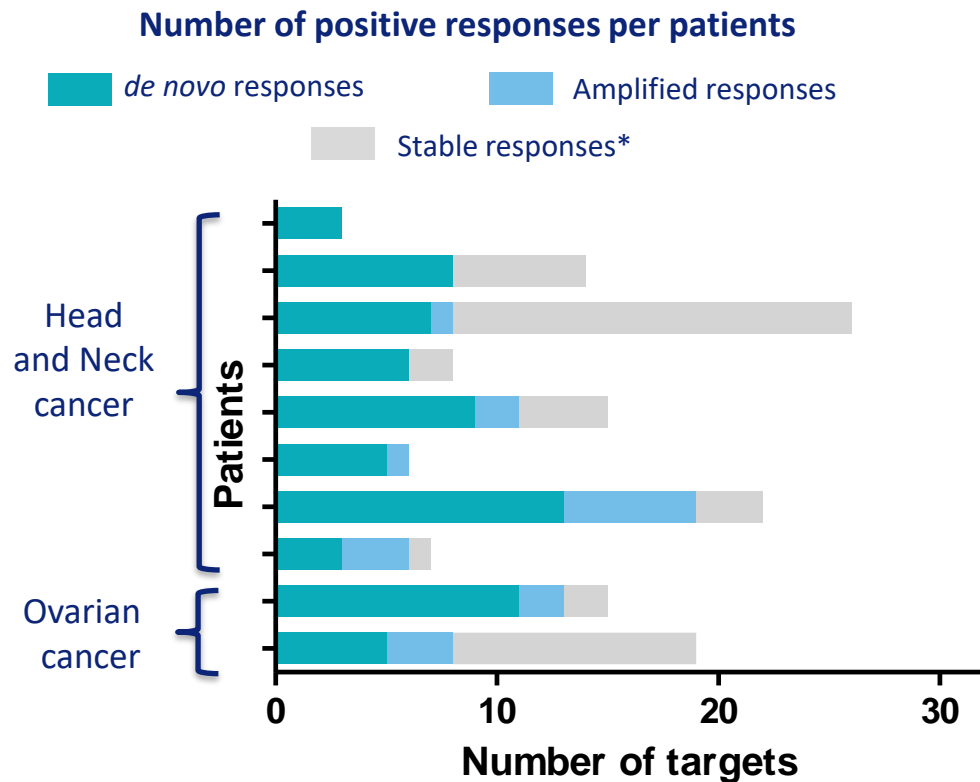
Last patient treatment expected in **H1 2023**



**LEAD INVESTIGATOR: Pr. Christian Ottensmeier,**  
Clatterbridge Cancer Care Center, Liverpool

# TG4050 – Generates an Unprecedented Rate of T Cell Response Against Tumor Specific Epitopes

## Induction of multiple T cell responses in all treated patients



Median of 9 positive responses per patient, out of 30

Responses were either **amplification of pre-existing responses** (20%) or **de novo responses** (80%) induced during vaccination

Profound remodeling of immune cells consistent with anti tumor response

\*Immunoreactive T-cells present at baseline but not amplified by vaccine.

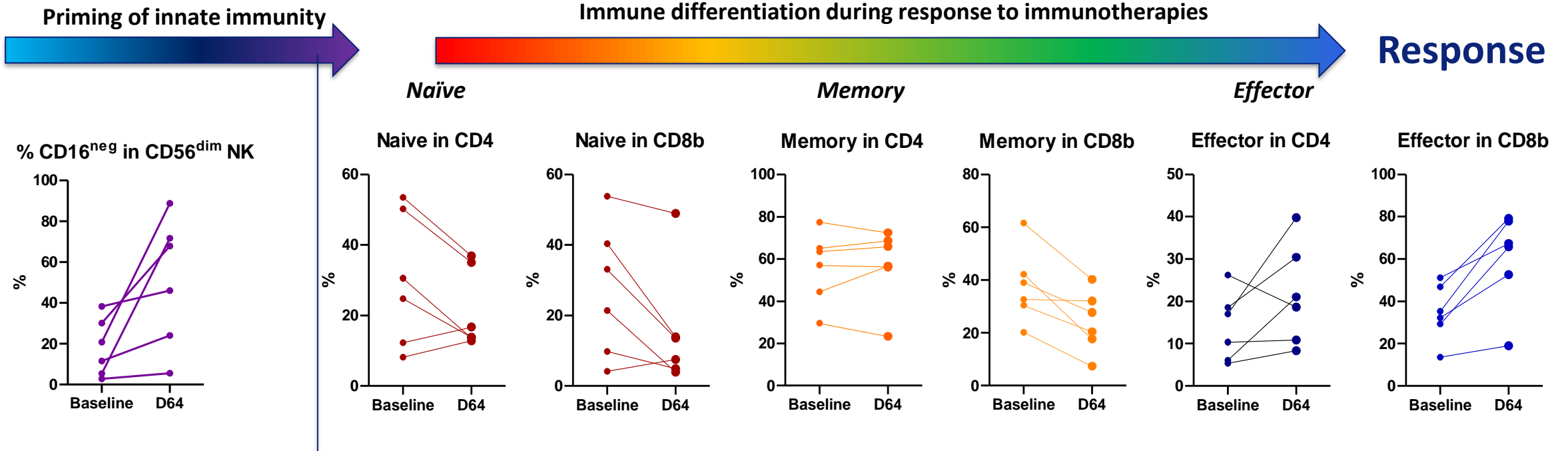


Source: Lalanne et al, "Phase 1 studies of personalized neoantigen vaccine TG4050 in ovarian carcinoma (OvC) and head and neck squamous cell carcinoma (HNSCC)" [AACR 2023](#), April 18, 2023, Poster presentation



# Profound Remodelling of Immune Cells consistent with Anti Tumor Response

Suggesting that the Vaccine Effectively Primes the Immune System



**AACR ANNUAL MEETING**  
American Association for Cancer Research  
2022 New Orleans

Source: Block et al, "Phase I trials of personalized cancer vaccine TG4050 in surgically treated high-risk head and neck squamous cell carcinoma (HNSCC) and relapsing ovarian cancer (OvC) patients" [AACR 2022](#), April 12, 2022, Poster presentation

- ✓ **Priming of innate immunity:** Loss of CD16 on CD56<sup>dim</sup> NK cells suggests **ongoing antitumor activity**
- ✓ **Maturation and differentiation of CD4 and CD8 into effector cells** – Consistent with the **development of an active adaptive response**
- **Effector subgroups of CD4 and CD8 T-cells are increased**
- Consistent with **decrease in naive and memory CD4 and CD8 T-cell** over treatment

# Extremely Promising First Signals of Clinical Activity

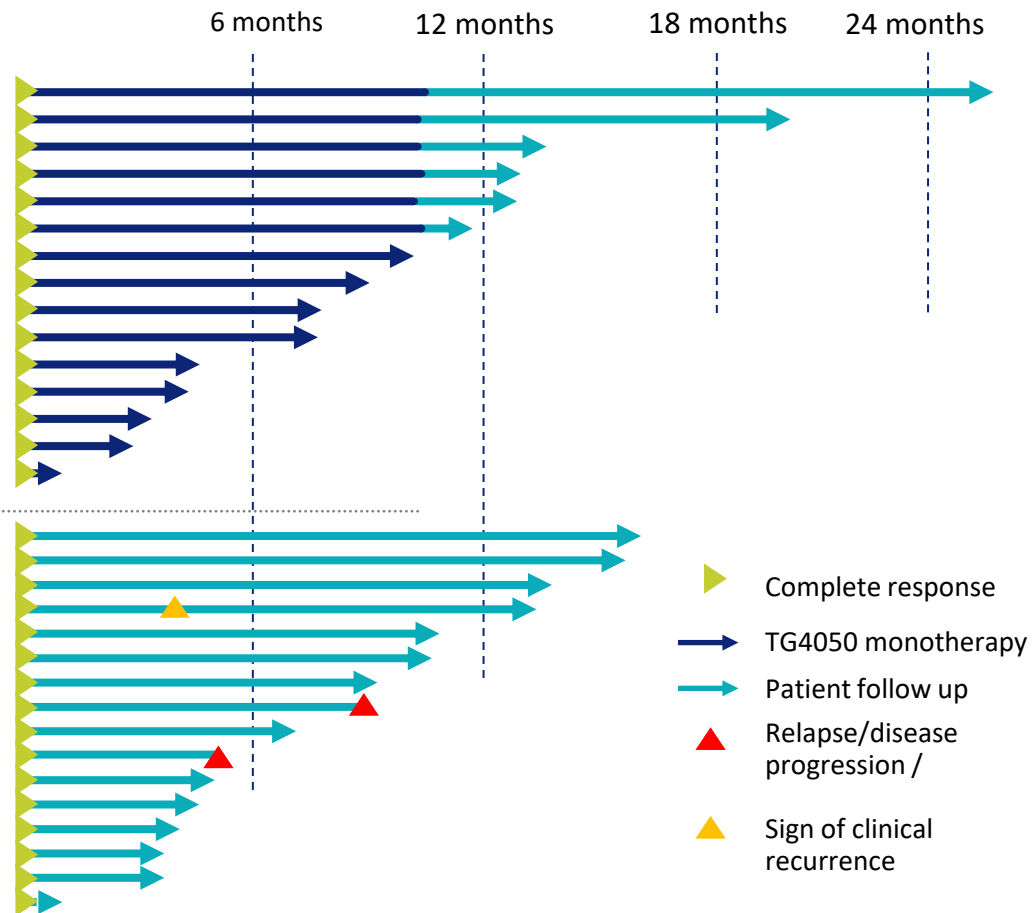
Repeated injections of single agent TG4050 in patients with minimal residual disease

## Head & Neck Cancer Trial

32 patients randomized – March 2023

**Arm A:**  
TG4050  
single agent

**Arm B:**  
Control arm



**No related SAEs**  
**Good safety profile**

**All 16 treated patients are stable**

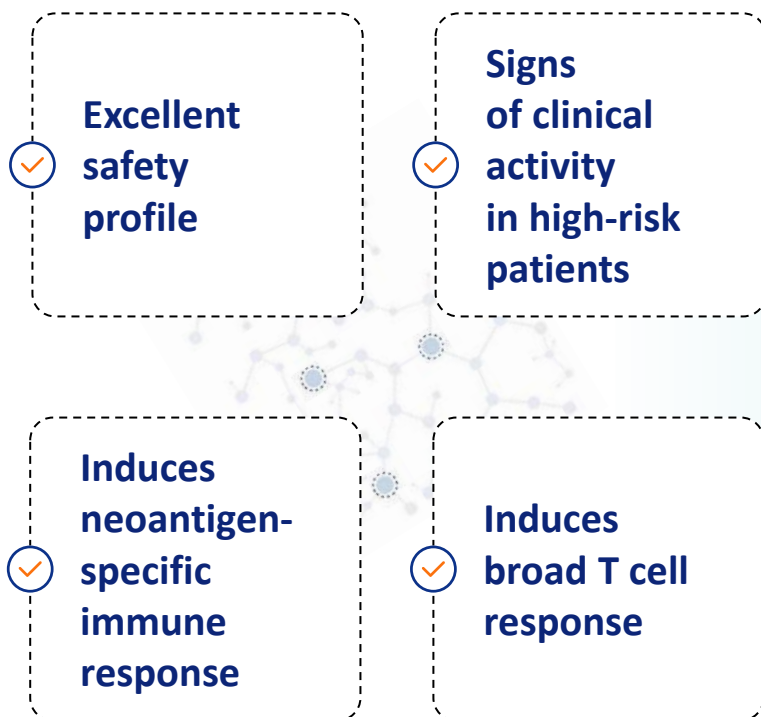
**Only patients  
in the control arm  
have relapsed**

**Trial fully enrolled**



Source: Lalanee et al, "Phase 1 studies of personalized neoantigen vaccine TG4050 in ovarian carcinoma (OvC) and head and neck squamous cell carcinoma (HNSCC)" [AACR 2023](#), April 18, 2023, Poster presentation

# TG4050 | Exciting First Data Justifies our Ambitious Development Plan



**New promising data** presented at **AACR 2023**



Intend to launch potential registrational **Phase II trial** in H2 2023



**Potential to extend remission period for high-risk patients and address a \$1+ bn market\***  
(head and neck cancer – adjuvant)



**Potential to address other solid tumors after surgery in **adjuvant/maintenance settings** w or w/o ICIs, such as ovarian, urothelial, breast, lung cancers, ie a multi billion market**

# ● TG4001 | Designed to Boost the Patient's Immune System against HPV-Positive Tumors



## INDUCES SPECIFIC AND DURABLE T CELL RESPONSES



**MVA virus - E6 and E7 HPV antigens + IL2**  
Designed to induce specific E6 and E7 T cell response

### Unsatisfactory treatment options for advanced HPV+ cancer patients

In 2L, ORR is around 10–15% , median PFS is around 2 months and median OS is less than 11 months with ICI single agent\*

○ Goal to double performance of SOC

A \$1 bn market opportunity (EU, UK, US, Japan)



### MoA and first signals of efficacy demonstrated in clinic in combination with ICI

- ✓ Clinically relevant anti-tumor activity - Induces strong and long lasting, specific responses against tumors
- ✓ Excellent safety profile - Good combination candidate
- ✓ In hard-to-treat HPV cancer patients, has induced
  - Increase of CD3, CD8 infiltrates
  - Increase of PD-L1 expression
  - Shifts cold tumours into hot tumors, in combination with ICIs

ORR: objective response rate (RECIST 1.1); m PFS: median progression-free survival; m OS: median overall survival; SOC: standard of care

\*Estimates based on the following trials: • Anal 2L: NCI9673 (Nivolumab, Phase II) <sup>[ref]</sup>; KN028 + KN158 <sup>[ref]</sup> (pooled analysis: Phase Ib KN028 and Phase II KN158); CARACAS (Phase II) <sup>[ref]</sup> • Cervical 2L: KN158 (Phase II) <sup>[ref]</sup> • Cervical, vaginal vulvar 2L: CM 358 (Phase II) <sup>[ref]</sup>

# TG4001 + Avelumab (Single Arm Ph. Ib/II) | Increased Benefit and Long-Lasting Responses

## Landmark Data Compare Favorably to ICIs in Monotherapy and Competitive Landscape

### Increased ORR and durable responses n=25

- **ORR: 32%**
- **mPFS: 5.6 months**
- **mOS: 13.3 months**
- **Good safety profile**

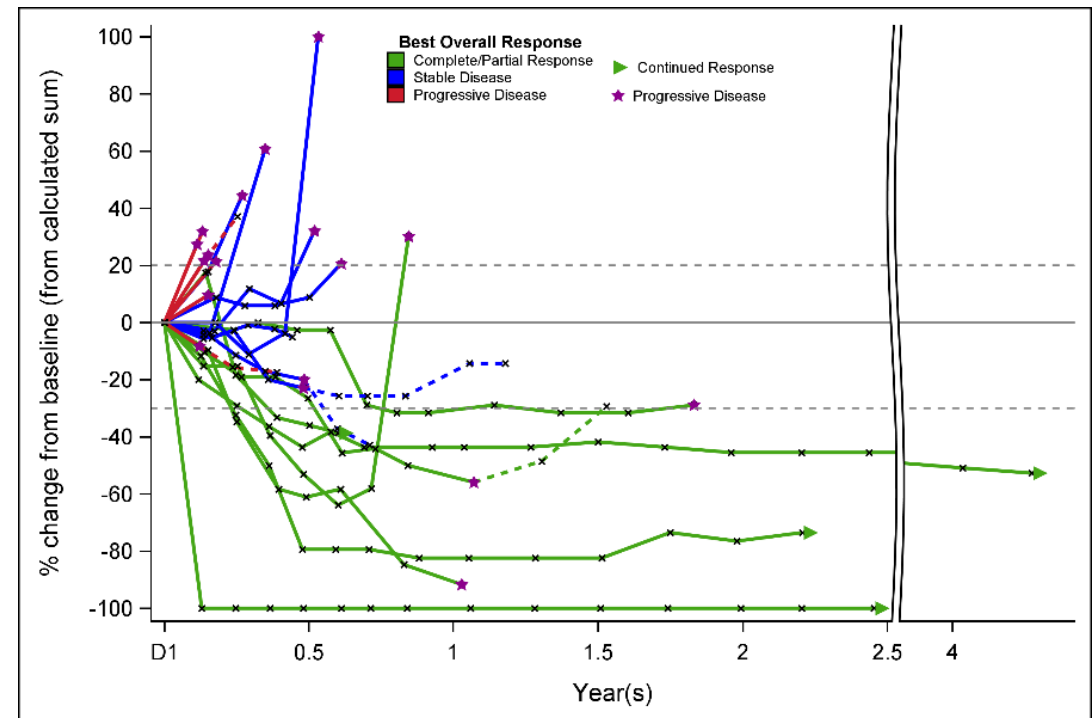
**1 COMPLETE RESPONSE**

*Patient with anal cancer and peritoneal extension that all disappeared – still followed in the trial*

**7 PARTIAL RESPONSES**

**9 STABLE DISEASES**

Long lasting responses in metastatic patients without liver metastases - Aug. 2022

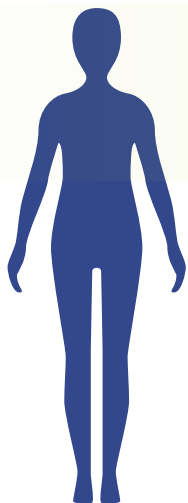


**Compares favorably to ICIs in monotherapy and competitive landscape**

Clinical collaboration  
for avelumab free supply



# TG4001 | Current Randomized Controlled Phase II Trial to Deliver Final Data in 2024



## Patients with HPV16-positive anogenital cancer *incl. cervical, vulvar, vaginal, penile and anal cancers*

- With recurrent/metastatic disease
- Treated in 1<sup>st</sup> line or in 2<sup>nd</sup> line (with a maximum of 1 prior systemic chemotherapy vs 2 allowed in Phase Ib/II trial)
- Without previous exposure to cancer immunotherapy
- Without liver metastasis at baseline
- Including all levels of PD-L1 expression

Patients with  
recurrent/metastatic disease

Randomized  
(1:1)

Arm A

TG4001 + avelumab

Arm B

Avelumab single agent

## POSITIVE INTERIM ANALYSIS RESULTS

(November 2022)

- ✓ First efficacy signals observed
- ✓ Good safety profile
- ✓ Trial to enroll up to 120 Patients (NCT03260023)

## PRIMARY ENDPOINT

- ✓ Progression-Free Survival  
(RECIST 1.1)



Clinical collaboration  
with  
for avelumab free supply



## Our Goal with TG4001: Boost Response to Immune Checkpoint Inhibitors in HPV+ Cancers

**TG4001 is the only HPV vaccine developed in comparison with ICI monotherapy that has shown a benefit from MOA\***

- ✓ Good safety profile
- ✓ Increased Response Rate and PFS in hard-to-treat patients
- ✓ Induces antigen-specific immune response
- ✓ Induces broad T cell response
- ✓ Long-lasting responses
- ✓ Active in PD-L1 positive and negative patients

**First Randomized Phase II trial of HPV vaccine + ICI expected to read out**

**Randomized Phase II data expected in 2024**

**Upcoming registration targeting trial in preparation, aiming for a \$1bn market opportunity**

TG4001 is owned 100% by Transgene



# Oncolytic Viruses

! Rapidly Generating Multiple Virus-Powered  
! Off-the-Shelf Drug Candidates Targeting Solid Tumors

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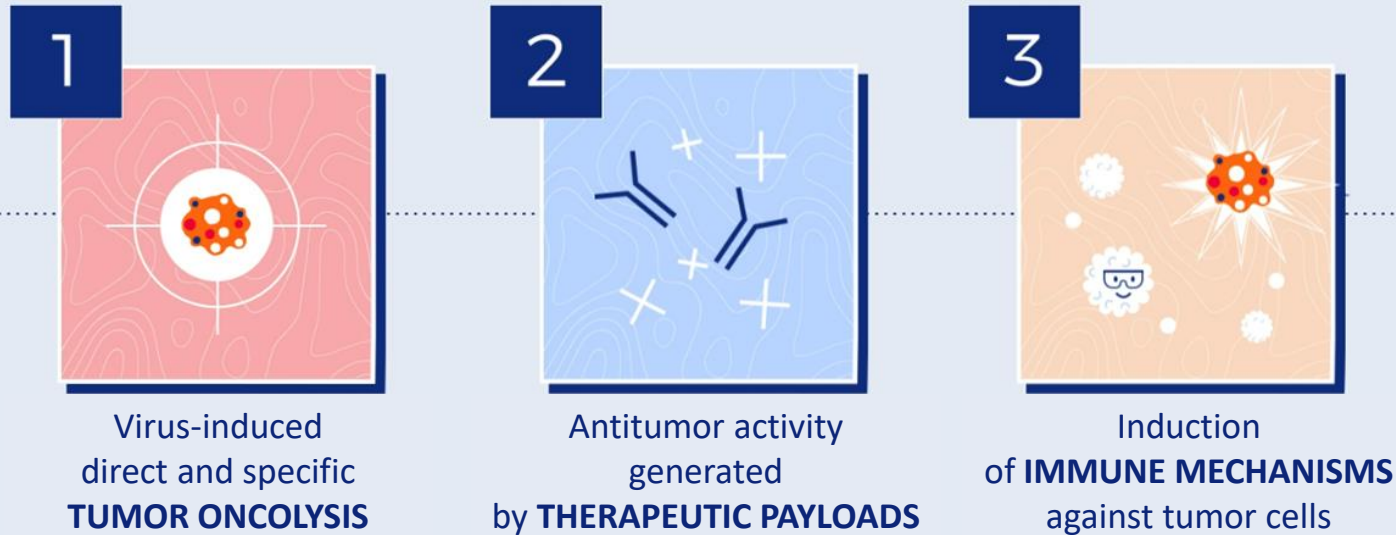




# Our Oncolytic Viruses (OV) – Combined Effects of Vector, Payload and Immune Stimulation

Competitive Advantage Enhanced by our Patented Backbone VV<sub>cop</sub>TK-RR<sup>-</sup> - basis of our Invir.IO® Platform

## Cancer cell death through multiple MOAs



## Proprietary vector with multiple competitive advantages

- Encode numerous and various **payloads**
- **Multiple routes of administration** (IV, IT, locoregional) and extend OV market beyond IT administration
- Potential to target multiorgan lesions and warm up TME
- Address broad range of solid tumors



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## Clinical evidence obtained

- Good safety profile
- Able to reach tumors, selectively replicate and express payload, incl. via **intravenous administration**

# Compelling Data Generated with TG6002 Support Intravenous (IV) Route of Administration



## Goal

to target multiorgan lesions and reverse tumor resistance



To turn cold tumors into hot tumors through multi-pronged MoA

### TG6002 demonstrated PoC of IV Route

- TG6002 replicates in tumor tissue without sign of widespread replication
- The payload is expressed in tumor tissue
- Long-lasting expression of the payload
- No impact of neutralizing antibodies on PK/PD data
- T cell activation, immune checkpoint receptor expression and priming of an adaptive response against tumor associated antigens\*

Potential to address numerous solid tumors via multiple routes of administration, in particular intravenous administration  
– strong differentiation versus other OV players

# BT-001 | Patented OV Armed with Anti-CTLA4 Ab + GM-CSF

Ongoing Phase I Trial Assessing IT\* Route of Administration

50/50 collaboration  
with BioInvent

## The right virus + payload

VV<sub>cop</sub> TK-RR<sup>-</sup> oncolytic armed with  
BioInvent's potent **anti-CTLA4 Ab + GM-CSF**

- Activates and increases T-effector cells
- Treg depleting activity
- Stimulates immune cells (incl. APC)

Winner of the **2022 JITC Best Oncolytic**  
and Local Immunotherapy Paper **Award**

Can be developed for  
**multiple cancer indications**  
lesions with high Treg infiltration



## Positive initial Phase I part A readout

- Single agent **well tolerated**
- **Replicates** and **persists** in tumor tissue
- **Anti-CTLA-4 expressed in the tumor**  
with **no detectable systemic exposure**
- **Tumor shrinkage** observed in one patient  
at the lowest dose level
- **Ph. I part A data** to be released in **H1 2023**

## Ongoing Phase I

monotherapy and combination with ICI

- **Ph. I part B** (combination with  
pembrolizumab) **to start in H2 2023**

**Objectives:** evaluate safety profile,  
determine Phase II dose and indications

Collaboration with MSD  
which provides pembrolizumab (KEYTRUDA®)



\*IT: intratumoral administration

# TG6050 administered IV | IL-12 and anti-CTLA4 Produced Directly in the Tumor

## Approved Phase I Trial to assess systemic route of administration

### Oncolytic armed with IL-12 and anti-CTLA4 Ab

- Triggers a powerful antitumor immune response
- Restores the immune defenses within the tumor

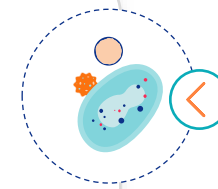
### The Invir.IO® objective

- Avoid toxicity / off target thanks to selective replication of viral vector
- Ensure sufficient production of IL-12 in the tumor
- **Outstanding preclinical data (strong antitumor activity)**

### Phase I trial - Indication: metastatic and PD1 failed tumors

- Advanced or metastatic NSCLC after failure with available treatment options, including anti-PD1/PD-L1 – **IV administration**
- CTA approved in France - First patient to be enrolled in H1 2023

### Potential to address a \$1.5 bn opportunity



## Initial goal

demonstrate potential of IV administration in “cold”, non-resectable metastatic tumors



\* IV: intravenous administration \*\*IHA: intrahepatic artery administration



Source: Marchand et al, TG6050, “An oncolytic vaccinia virus armed with interleukin 12 and anti-CTLA4 antibody induces TME remodeling and strong anti-tumoral responses” [AACR 2023](#), April 16, 2023, Poster presentation

# ● Invir.IO® Pipeline Will Allow us to Generate Significant Value



**Backbone with highly competitive properties and potential**

- Ability to safely be administered IV
- Express selectively its payload in the tumor



**Rapid progress from design to start of clinic development**

- Potential to generate **multiple novel oncolytics**



**Value provider and collaboration initiator**

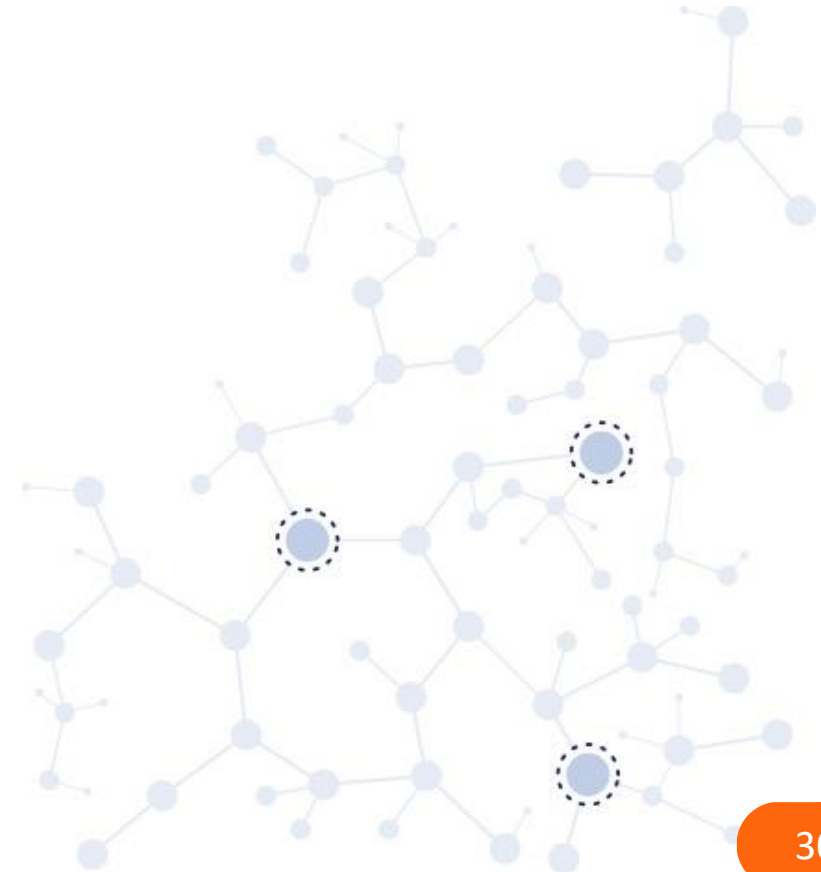
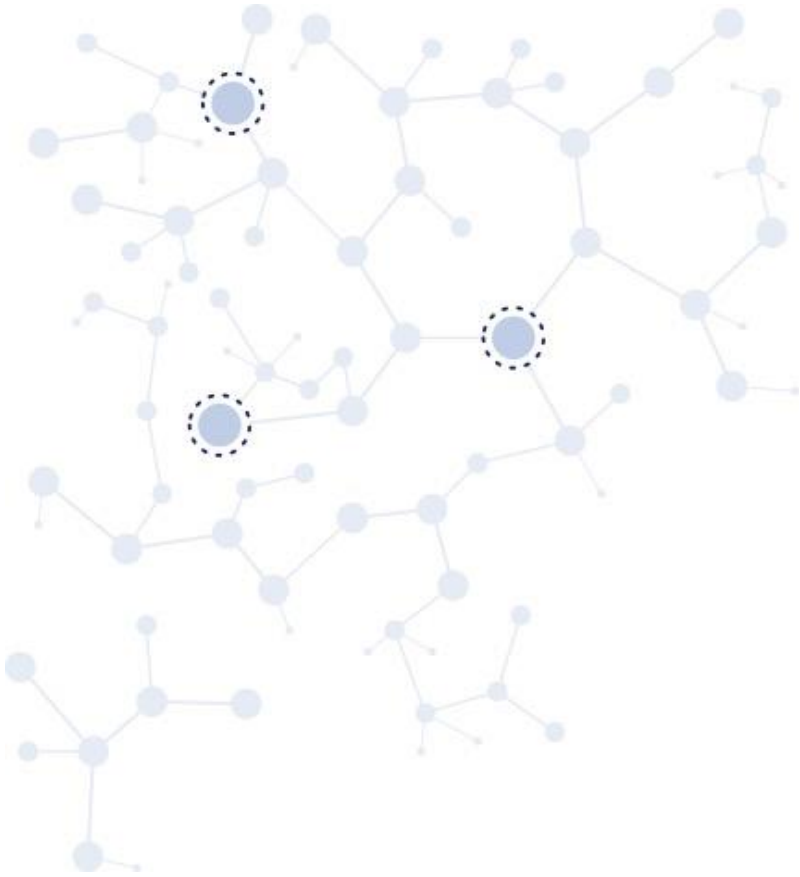
- **AstraZeneca collaboration:** development of new OV's
- **BioInvent collaboration:** clinical development of BT-001
- **PersonGen collaboration:** preclinical evaluation of CAR-T cell/OV combination
- **Potential other early out-licensing** of new unique OV's or new combinations

AstraZeneca 

BioInvent 

博生吉  
PersonGen 

# Outlook



## Company Funded to Deliver Multiple Value Generating Milestones

✓ **€26.8 million in cash and cash equivalents**  
as of December 31, 2022

- In addition: **Tasly BioPharmaceuticals shares** valued at **€14.3 million** at the end of Dec. 2022 – Sale of this stake expected to be completed in mid-2023

**FINANCIAL VISIBILITY until early 2024**

### Ownership

As of March 30, 2022



- Listed on Euronext Paris
- ISIN: FR0005175080 - Ticker: TNG

# 2022 Achievements are Solid Basis for Multiple Readouts in Next 18 Months

The Viral Vector Experts In Immuno-Oncology

## TG4050



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## TG4001

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## invirio

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# Transgene – Frontline Player in Virus-Based Immunotherapy Against Cancer

Versatile technology platforms to fit each patient need

Diversified **pipeline**  
(individualized and off the shelf)

**2 platforms**  
Therapeutic vaccines  
Oncolytic viruses

**Multiple clinical-stage immunotherapies**  
in Phase I and Phase II

**Dense news flow**  
in **2023-2024**

**Unique Technology** based on:

✓ Optimized viral vectors

✓ Strong clinical data

✓ Solid safety Track record

✓ Preclinical Proof of concept

✓ Robust IP portfolio

Integrated **GMP manufacturing**

Capacity for rapid delivery of pilot scale batches

Ongoing **collaborations**

**MERCK** **Pfizer**  
**MSD**  
Supply agreements

Orchestrating a brighter world  
**NEC**  
Technology and cost sharing agreement

**Biolnvent**  
Co-development

Strong **Shareholder Support**  
**and Financial visibility**

Financial visibility until early 2024  
Strong shareholder support

# Appendices

## An Experienced Management Team



**HEDI BEN BRAHIM**  
Chief Executive Officer

20 YEARS EXPERIENCE



**ÉRIC QUÉMÉNEUR, PHD**  
Executive VP  
Chief Scientific Officer

30+ YEARS EXPERIENCE



**ALESSANDRO RIVA**  
Chairman  
*Joined in May 2022*

30+ YEARS EXPERIENCE



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**MAUD BRANDELY, MD, PHD**  
VP Medical Affairs  
Chief Medical Officer

35+ YEARS EXPERIENCE



**STEVEN BLOOM**  
VP, Chief Business Officer



35+ YEARS EXPERIENCE



**JEAN-PHILIPPE DEL**  
VP, Chief Financial Officer

20 YEARS EXPERIENCE



## Board of Directors - as of May 5, 2023

**Hedi Ben Brahim**  
CEO & Director



**Alain Mérieux**  
Honorary Chairman



**Marie Landel**  
Independent Director



**Philippe Archinard**  
Director



**Carol Stuckley**  
Independent Director



**Alessandro Riva**  
Chairman



**Jean-Luc Bélingard**  
Director



**Maya Said**  
Independent Director



**Jean-Yves Blay**  
Independent Director

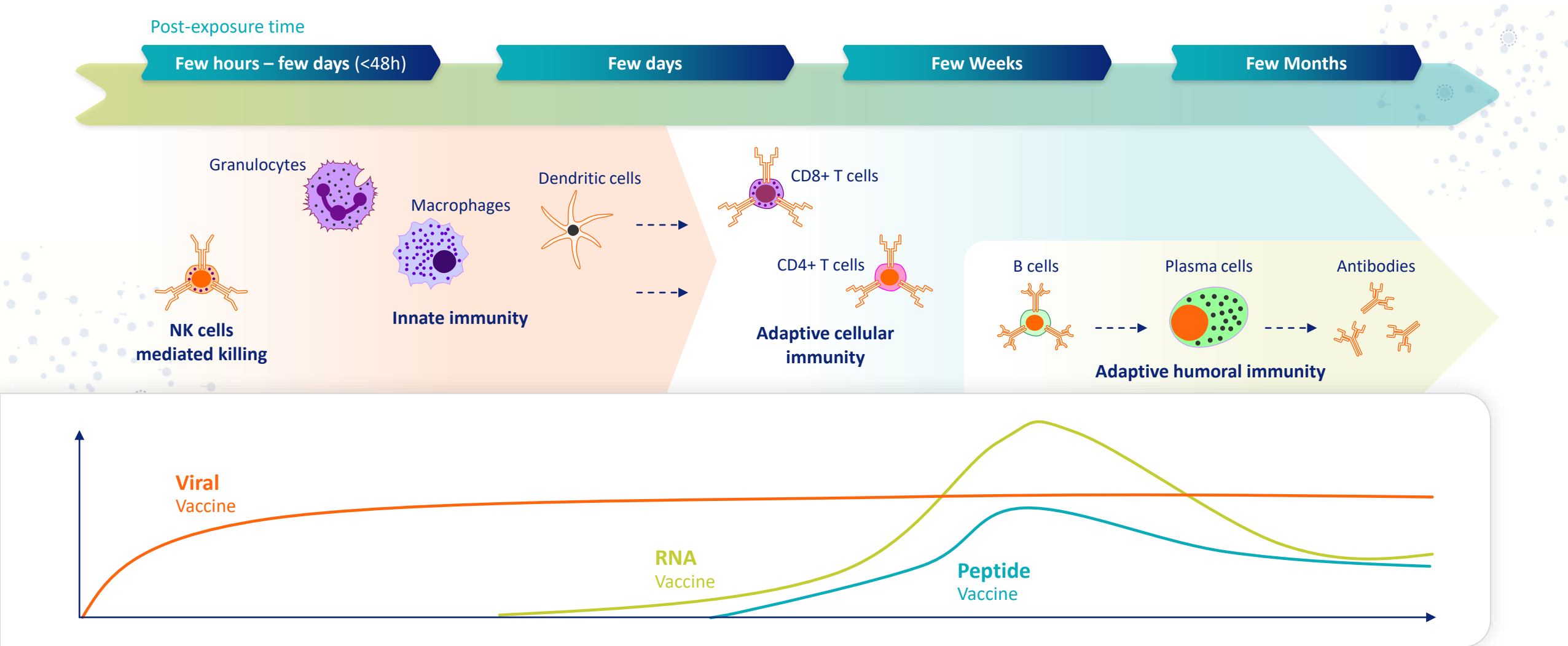


**Benoît Habert**  
Independent Director



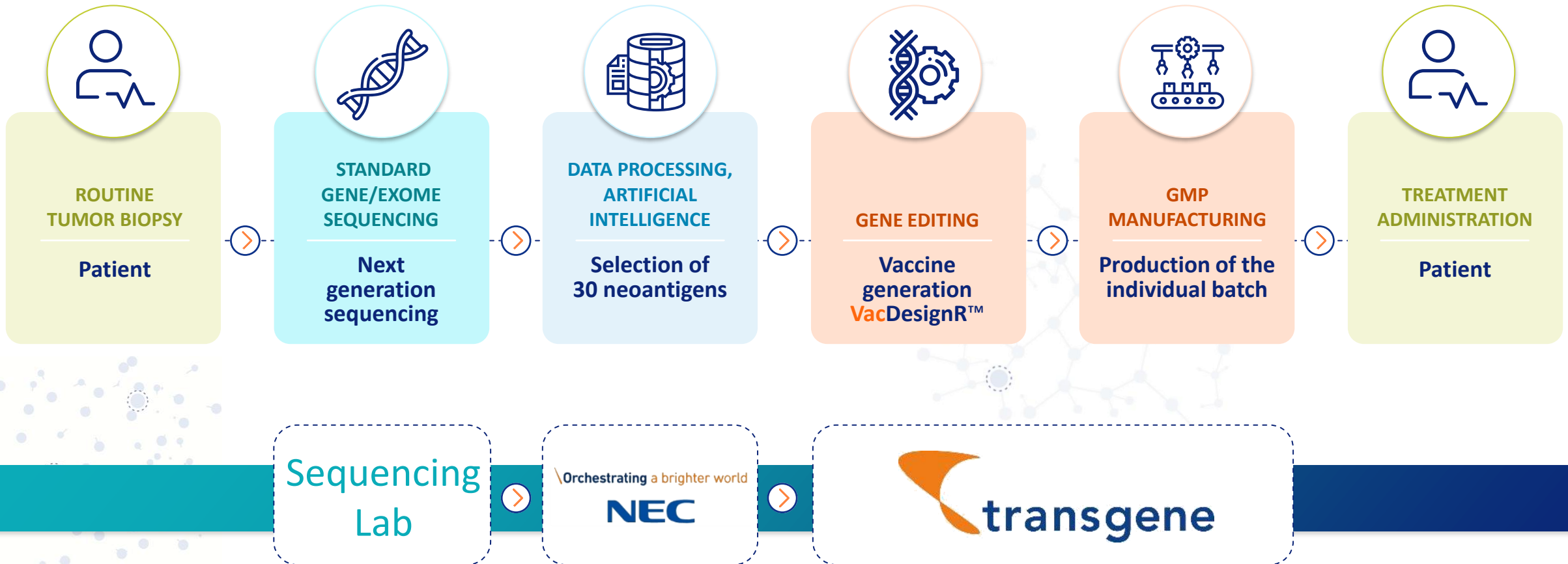
**Sandrine Flory**  
Director\*

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