



**NAYA**  
BIOSCIENCES  
*Science for Life*

February 2024

# Seeking Life-Transforming Patient Outcomes in Oncology, Regenerative Medicine, and Fertility



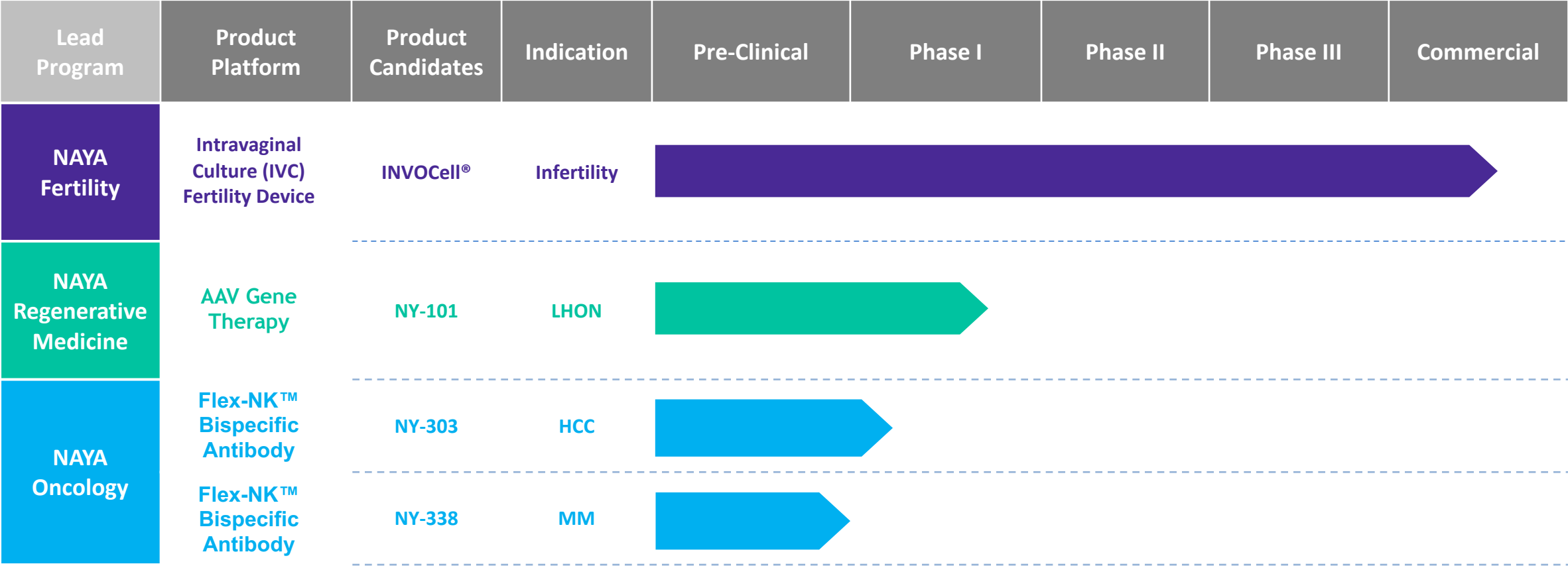
## A Promising Commercial & Clinical-Stage Portfolio with 2025 Milestones

- Oncology: First-in-class **GPC3 Flex-NK™ Cell Engager Antibodies** positioned as 2nd line therapy in HCC patients not responding to standard of care (TECENTRIQ® + Avastin®)
- Oncology: Best-in-class **CD38 Flex-NK™ Cell Engager Antibodies** with a differentiated profile to Darzalex® (Daratumumab), the leading Multiple Myeloma treatment
- Regenerative Med: Unique **AAV gene therapy** for Leber's Hereditary Optical Neuropathy (LHON) w/ 28-patient phase I data & curative potential through improved mitochondrial targeting
- Fertility: Accelerated commercial growth of **INVOCell® device**, leveraging recent FDA clearance for improved success rates, on par with IVF

## Independent Financing and Scaling Up of Signature Fertility Clinics

- Rapid expansion through **acquisition of independent fertility clinics**
- Establishment of a **signature clinic experience**, with focus on unified branding, best fertility practices, increased accessibility, and improved patient experience.
- Opportunity for **leadership position** in underserved, highly-profitable fertility clinic market

# A Promising Commercial & Clinical-Stage Portfolio with 2025 Milestones



LHON: Leber’s Hereditary Optic Neuropathy  
 HCC: Hepatocellular Carcinoma  
 MM: Multiple Myeloma

# Hub & Spoke / Portfolio Model Leverages Strategic Franchises to Fuel Accelerated Growth & Value-Creation



# Experienced, Entrepreneurial Leadership Team



**Daniel Teper, PharmD, MBA**



**Seline Miller, CPA**



**Peter Kash, MBA**



**Laurent Audoly, PhD**



**Lyn Falconio**



**Prakash Raman, PhD**



**Mark Rothera, MBA**



**Gilles Seydoux, PharmD**



**Patrick Tricoli, PharmD, MBA**



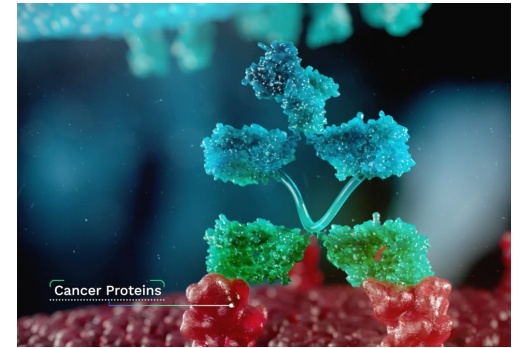
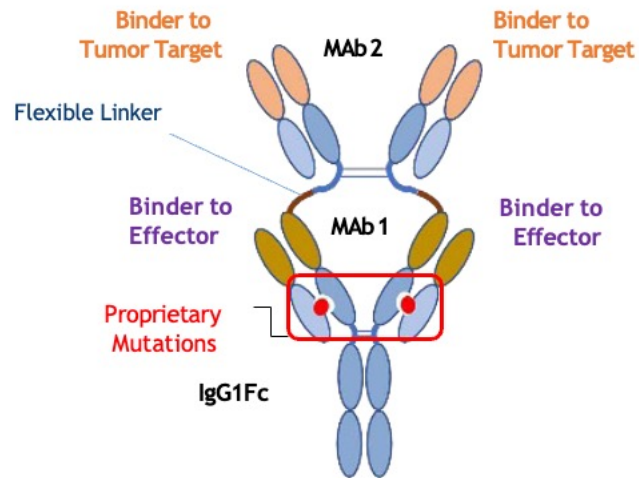


**NAYA**  
ONCOLOGY

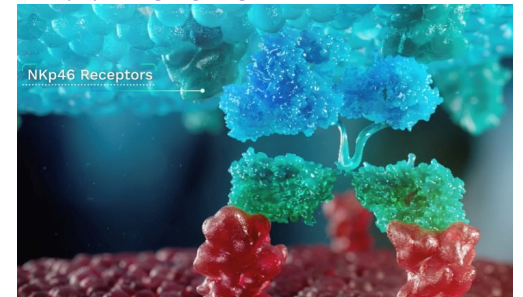
*Advancing Towards Breakthrough Outcomes for Cancer Patients*

# Enhanced Tumor Killing With Flex-NK™ Cell Engager Antibodies

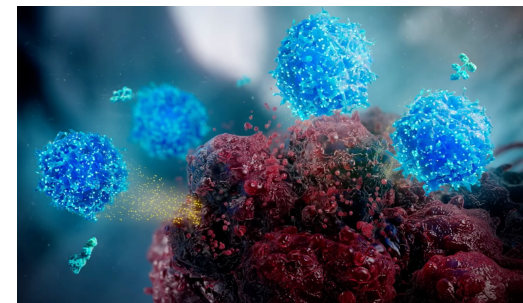
- Proprietary, differentiated design
- Validated manufacturability
- Simultaneous attachment to both Natural Killer (NK) cells & targeted cancer cells
- Improved and sustained engagement of NK cells in the tumor microenvironment through NKp46 activating receptors
- Demonstrated reversal of NK cell dysfunction
- Demonstrated synergy with both endogenous & allogeneic NK cells



(1) Engaging Cancer Cells



(2) Engaging NK Cells Through NKp46



(3) Destruction of Tumor

# Flex-NK™ Cell Engager Antibody Pipeline Validated at Major Oncology Meetings, Promising Data Supports Clinical Development



European Society for Medical Oncology



Society for Immunotherapy of Cancer



## NY-303

*Targets GPC3 for the treatment of Hepatocellular Carcinoma*



## NY-338

*Targets CD38 for the treatment of Multiple Myeloma*



# Top Key Opinion Leaders to Drive Clinical Development

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Michael Caligiuri,  
MD



Josep Lovett,  
MD, PhD



Ola Landgren,  
MD, PhD



Yaron Ilan,  
MD



# Suboptimal Therapies Driving Need For New Hepatocellular Carcinoma (HCC) Treatments

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**800,000**

Patients Worldwide  
With HCC (Most  
frequent Liver Cancer)

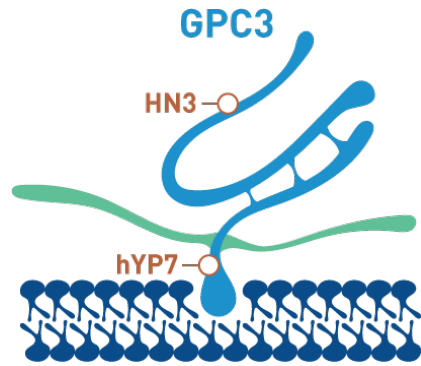
**28%**

Response Rate With Current  
Best Standard of Care  
TECENTRIQ® (atezolizumab)  
+ Avastin® (bevacizumab)

**\$10+ billion**

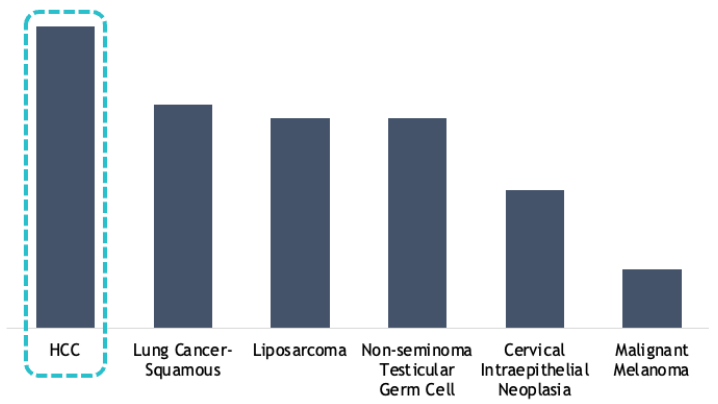
Expected Annual Value  
of HCC Market  
To be Reached in the  
Next Decade

# GPC3: A Promising Therapeutic Target For HCC & Other Solid Tumors

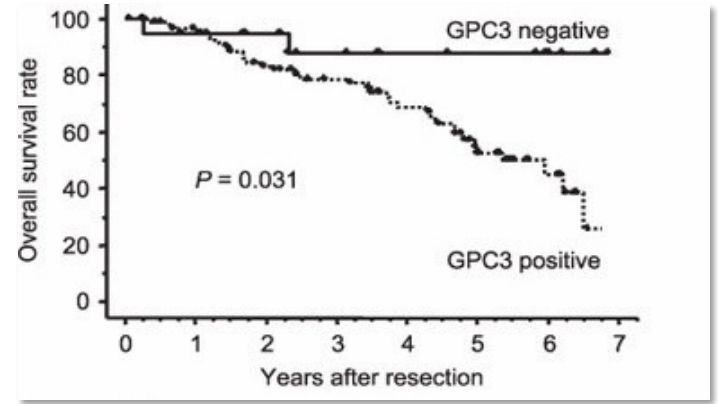


Glypican 3 (GPC3) is a protein expressed on the cell membrane of HCC & select other solid tumors, while predominantly absent in normal tissue.

GPC3 Relative Expression in Solid Tumors



GPC3 Blood Levels Correlate with Severity of Disease



Major pharma companies investing in GPC3 drugs in early clinical development include:



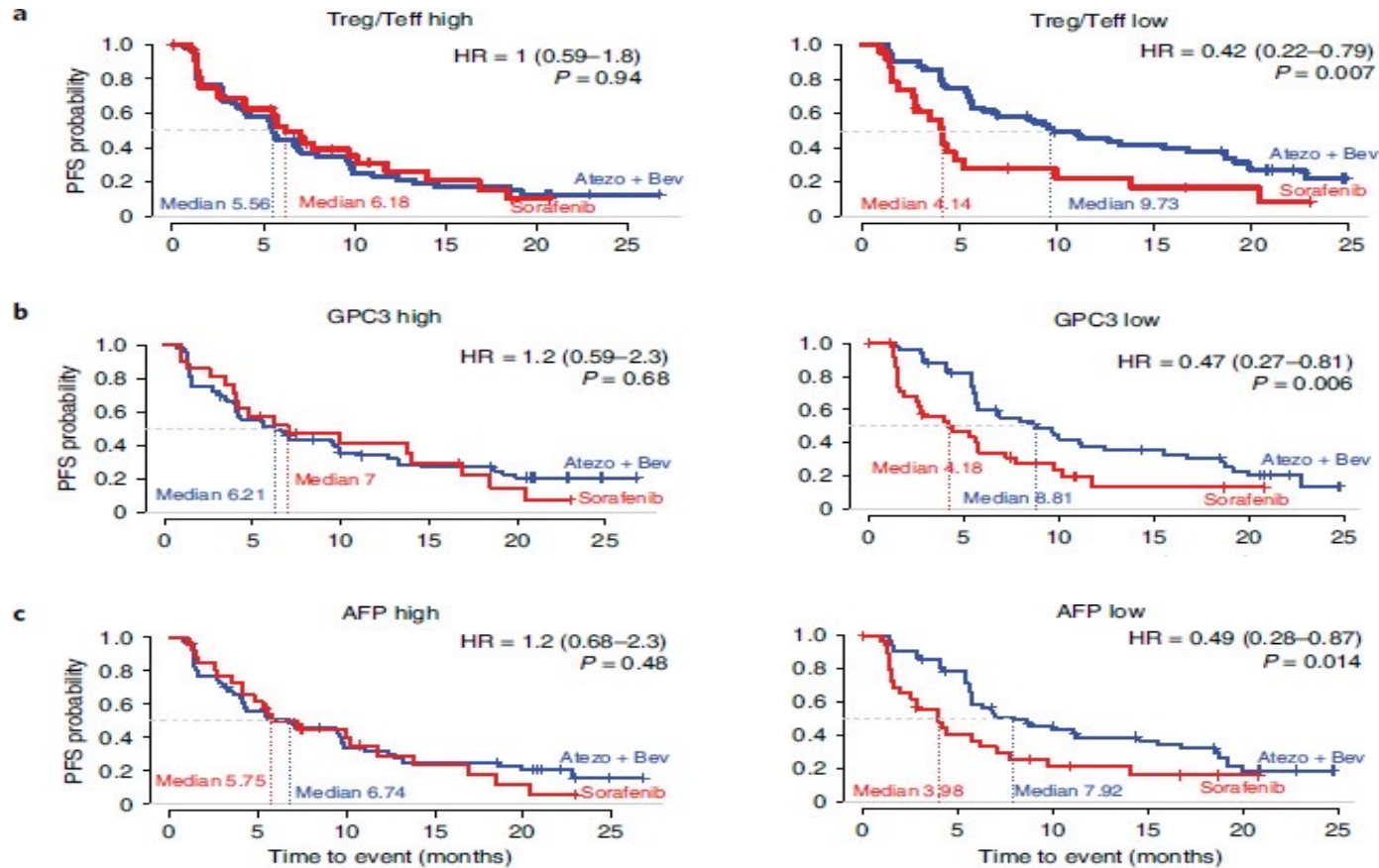
*Additional indications for GPC3-targeting therapies include Lung, Ovarian, and Pediatric Cancers.*

# Targeting GPC3 To Enable Response in Patients Refractory to 1<sup>st</sup> Line Immunotherapy HCC Treatment (TECENTRIQ® + Avastin®)

Since NY-303 can activate NK cells and reduce HCC tumor burden, high GPC3 & AFP levels can be converted to low GPC3 & AFP signatures that are responsive to first-line immunotherapy

## Tecentrig® + Avastin® Checkpoint Non-Responders

## TECENTRIQ® + Avastin® Checkpoint Responders



Nature Medicine  
 A Xu et al Nat Med 2022 and  
 GO30140 and IMbrave150

# Phase I/IIA To Evaluate NY-303 As Monotherapy in 2nd Line HCC Following TECENTRIQ<sup>®</sup> + Avastin<sup>®</sup> 1st Line Treatment

## Phase I: 15-20 patient dose escalation study in HCC Patients

- 4 dose levels, each with weekly administration over a 28 day cycle
- Key endpoints include safety, pharmacokinetics, activity markers, and preliminary clinical efficacy
- Initial hospital approval secured, targeting at least 5 academic centers
- 1st patient expected by mid-2024
- Initial clinical data in early 2025

## Phase IIA: 40 patient randomized to 2 dose levels, based on Phase I

- Key endpoints to include overall response and progression-free survival
- To be conducted in at least 10 academic centers in multiple regions (US, Europe, Israel, Asia)
- 1st patient expected in 2025

*Opportunity for accelerated registrational Phase II/III based on Phase I/IIA results*

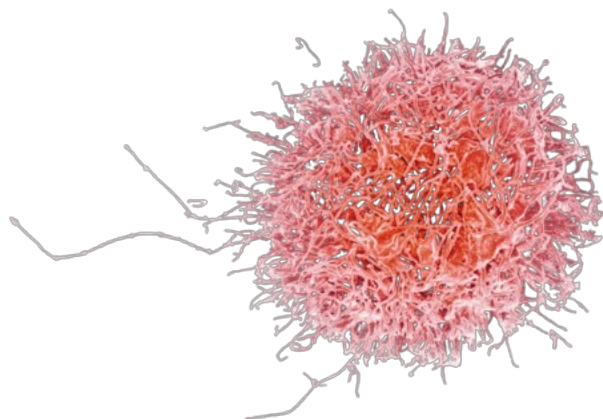
# Combining Our Antibodies with Optimally Engineered Off-the-Shelf NK Cells

*Combination therapy expected to improve efficacy and response rate in hepatocellular carcinoma (HCC)*



**ONKT105**

*Highly Functional,  
Gene-Edited  
Natural Killer Cell*



**NY-303**

*GPC3-Targeting  
Bispecific Antibody  
for the treatment of HCC*

# A Need for 2<sup>nd</sup> Generation Products in Multiple Myeloma Market

*Bispecific Antibodies Show Promise of Addressing Current Limitations & Expanding The Market*

**\$22 billion**

2021 Value of the Rapidly-Growing Multiple Myeloma Market

**\$8 billion**

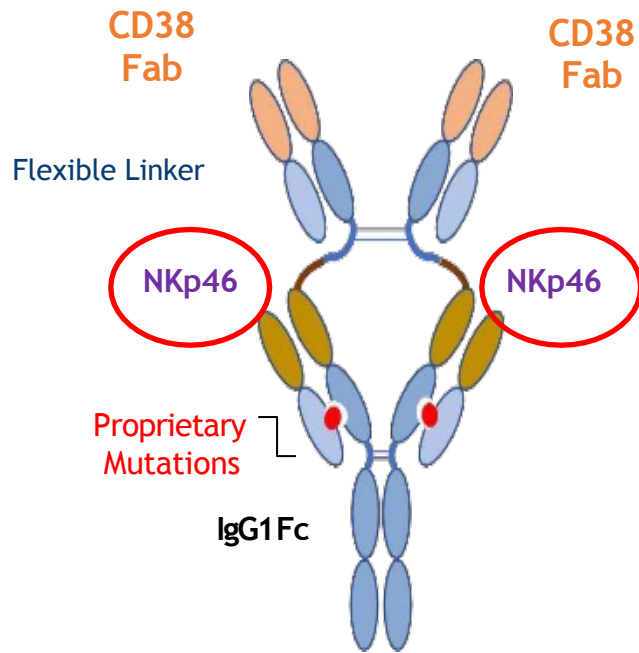
In Sales for J&J's Darzalex (Monoclonal Antibody) – Now Moved To 1<sup>st</sup> Line of Treatment

**3**

Bispecific Antibodies Approved For Multiple Myeloma In The Last Year

# NY-338 Differentiated from Daratumumab

*Data Monotherapy or Combination Therapy with NK Cells*



Attribute	NY-338	Daratumumab
MOA	CD38 cytotoxicity + NK cell redirected cytotoxicity (NKp46+ CD16)	ADCC
CD38 Binding	Different epitope 3 fold higher than Dara	Lower
NK and Macrophage cytotoxicity against MM	Higher	Lower
Fratricide	Minimal (unique MOA)	Significant
Immune subset depletion	Minimal (unique MOA)	Significant
Cytokine release	Minimal (unique MOA)	Significant



# NY-338: A Potential Best-In-Class Therapeutic for Multiple Myeloma

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*"The synergistic engagement of NK cells through NKp46 greatly enhances the immunotherapeutic effects of FLEX-NK™ bispecific antibodies, reducing NK cell fratricide, maintaining NK cell levels, and enhancing potency including reversal of NK cell dysfunction. The data supports initiation of clinical trials to evaluate this promising new therapy and makes it a potential best-in-class anti-CD38 therapeutic for multiple myeloma."*

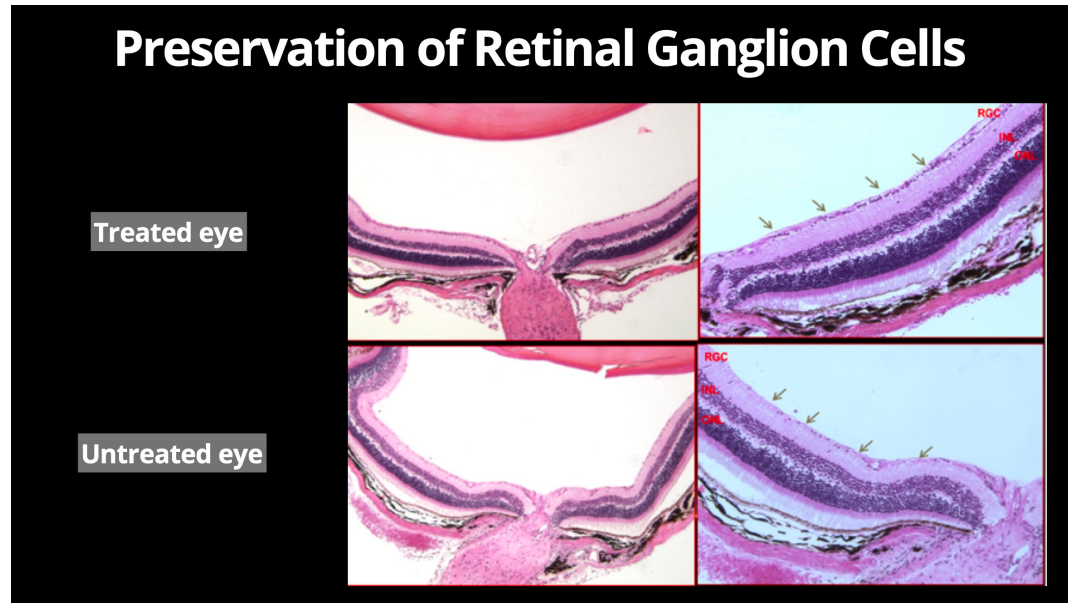


— Ola Landgren, MD, PhD  
Co-author of the Abstract,  
Chief of Myeloma, Sylvester Cancer Center



*Curing Ophthalmic Diseases Through Cell and Gene Therapy*

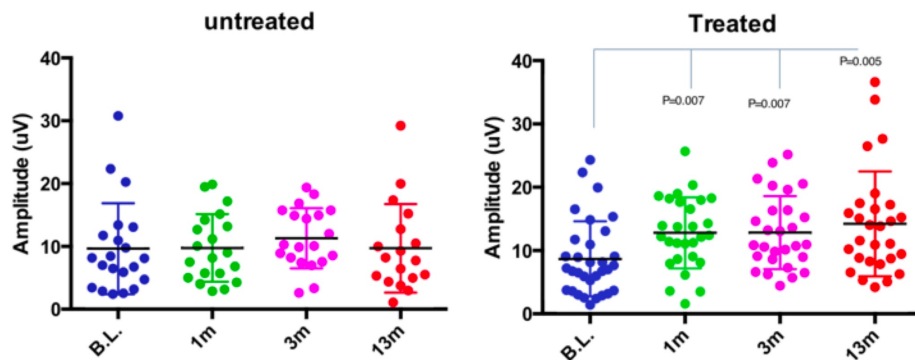
# 35,000 Young Adults At Risk of Blindness Without LHON Treatment Options



- Initial focus on **Leber's Hereditary Optic Neuropathy (LHON)**, a genetic disease that leads to progressive vision loss and blindness in young adults (15-35 years old)
- No currently approved therapeutic regimen for LHON, leaving patients permanently debilitated
- 7,000 US patients / 35,000 worldwide
- Comparable gene therapies priced at over \$750,000 per treatment

# A Potential Best-in-Class AAV Gene Therapy for Leber's Hereditary Optic Neuropathy (LHON)

## *Improved Mitochondrial Targeting & Preclinical Curative Data*



*Rescue of Retinal Function in LHON*

- Therapy's strong intellectual property focused on modification to traditional AAV gene therapy
- Sequence added to the capsid allows for direct mitochondrial targeting
- Preclinical data demonstrates curative results without serious adverse events

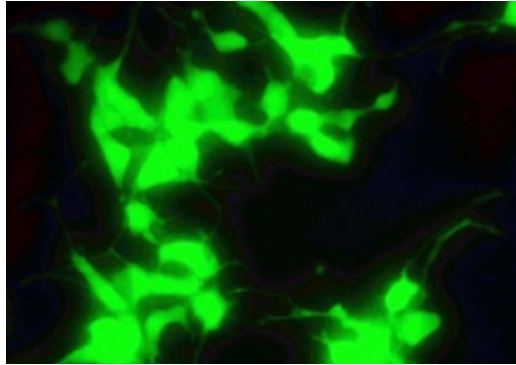
# World-Class AAV Gene-Therapy Manufacturing

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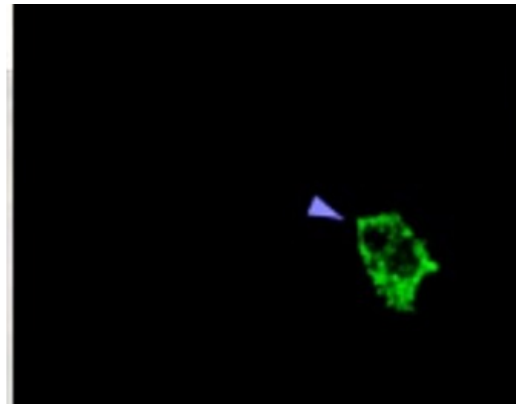


- Therapy originally developed & produced at the University of Florida's Ocular Gene Therapy Core Facility
- New option for manufacturing at ABL Europe, now part of Oxford Biomedica, a leading global gene therapy CDMO

# Accelerated Clinical Development Seeking Early Market Access & Commercialization by 2026-27



*Non-Targeting AAV  
(1st Gen.)*



*Direct Mitochondrial Targeting AAV  
(2nd Gen.)*

## 1st Generation Therapy

- Uses allotopic delivery system
- Demonstrated safety in 28-LHON-patient University of Miami Phase I trial
- Opportunity for additional clinical investigation and/or named patient use in '24

## 2nd Generation Therapy (Improved Mitochondrial Targeting)

- Uses mitochondrial targeting sequence with direct localization to the mitochondria
- Planning for 2025 IND

*Therapies qualify for RMAT designation & multiple priority review vouchers*



**NAYA**  
FERTILITY

*The Next Generation of Accessible Fertility Care*

# A Need For Solutions in Fast-Growing, Underserved Fertility Market

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**7-15%**

of women of reproductive age  
experiencing infertility worldwide

**Over 95%**

of infertile couples remain untreated

**2.5 million**

IVF cycles performed worldwide

## Key Demand Drivers Include:

Increasing Infertility Rates | Later-Age Pregancies | LGBTQ Family Building

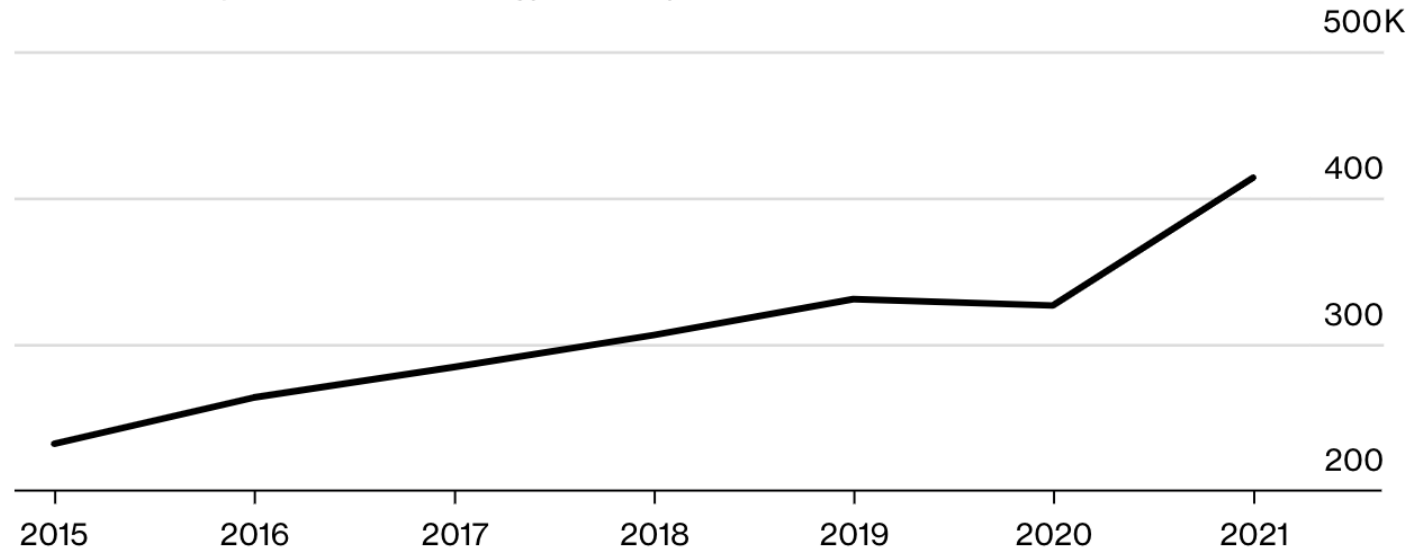


# IVF is Booming But Unable to Meet Demand

## IVF is Booming

The number of ART cycles, largely IVF, has jumped 78% since 2015

✍ Assisted reproductive technology (ART) cycles



Source: Centers for Disease Control and Prevention

Note: 2021 data is preliminary. Approximately 99% of ART procedures performed are in-vitro fertilization (IVF).

## Barriers to Access Include:

- Out-of-Pocket Cost
- Employer/Insurance Coverage
- Clinic Capacity
- Physical Proximity to Clinics
- Patient Experience

# INVOcell<sup>®</sup>: A New Path to Parenthood

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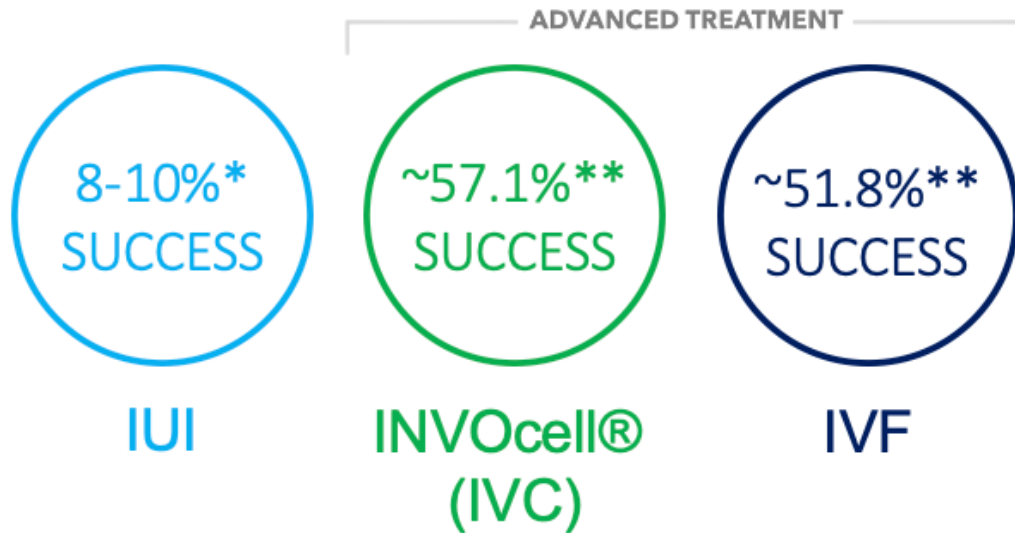
INVOcell<sup>®</sup> is our novel, FDA-cleared & CE-marked intravaginal culture (IVC) device.

It uses the female body for fertilization and incubation, keeping women at the center of the reproductive process.

This unique method allows us to reduce costs, increase accessibility, and improve the patient experience – addressing many of the limitations of current options like IUI and IVF.

# Exceptional Outcomes

INVOcell<sup>®</sup> is suitable for a majority of patients struggling with infertility and has demonstrated success rates on par with IVF and significantly higher than IUI.



## Patients Eligible for INVOcell

- < 38 years old (> 60% of market)
- < 38 BMI (> 90% of women)
- Adequate Ovarian Reserve (AMH > 1.5)

\*Fauque P, Lehert P, Lamotte M, et al. Clinical success of intrauterine insemination cycles is affected by the sperm preparation time. Fertil Steril. 2014;101(6):1618-1623.

\*\*Retrospective (real-world data) collected from four separate clinics (2017-2019). Not all conventional IVF was collected from the four clinics. See updated Indication for Use (IFU) for additional details.

To receive a copy of INVOcell's instructions for use, please send a request to [regulatory@invobio.com](mailto:regulatory@invobio.com).

# Unlocking Accessibility

\$4.5-7k\*  
per cycle

INVOcell®  
(IVC)

\$12-17k\*\*  
per cycle

IVF

- INVOcell® is significantly more affordable than a comparable IVF cycle. This means:
  - Increased likelihood of out-of-pocket affordability
  - Increased likelihood of insurance/employer coverage
- Cost has been identified as the number one barrier to utilization of IVF in United States.
  - Analysis indicates that a 50% reduction in the price of IVF services would translate into a 160% increase in utilization of such services.<sup>1</sup>

\*Fauque P, Leher P, Lamotte M, et al. Clinical success of intrauterine insemination cycles is affected by the sperm preparation time. Fertil Steril. 2014;101(6):1618-1623.

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# Accelerated Growth Strategy: Commercialization

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We plan to rapidly increase sales of our INVOcell<sup>®</sup> device toward \$50+ M annual revenues through:

- Fertility Clinics
- OBGYN Clinics
- Direct to Consumer Marketing
- Expansion of Employer Benefits & Insurance Coverage
- International Partnerships

# Building a Best-in-Class Network of Clinics



We plan to scale up our network of clinics in key regional centers, offering both IVF & IVC procedures.

By harnessing INVOcell's key benefits, our best-medical-practice expertise, and a commitment to innovation and patient care, we aim to offer:

- **Optimized Outcomes & Patient Experience**
- **Expanded Accessibility & Clinic Capacity**
- **Signature Branding & Design**

The closing of our upcoming merger will allow us to accelerate the expansion of our current network of clinics through a combination of access to public capital and dedicated equity & debt.



## Investment Considerations

## 2024-2025 Milestones

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- Complete merger, establishing expanded & well-capitalized public company
  - Integrate current assets into shared, agile platform with access to capital
  - Acquire additional undervalued clinical-stage assets
- 



- Achieve clinical milestones with oncology & regenerative medicine assets, advancing towards accelerated development & pharma partnerships
- 



- Secure dedicated funding to accelerate the acquisition of IVF Clinics
- Create brand & signature experience for clinics
- Scale up INVOcell<sup>®</sup> revenues through revamped & refocused commercialization strategy



# Contact Us

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