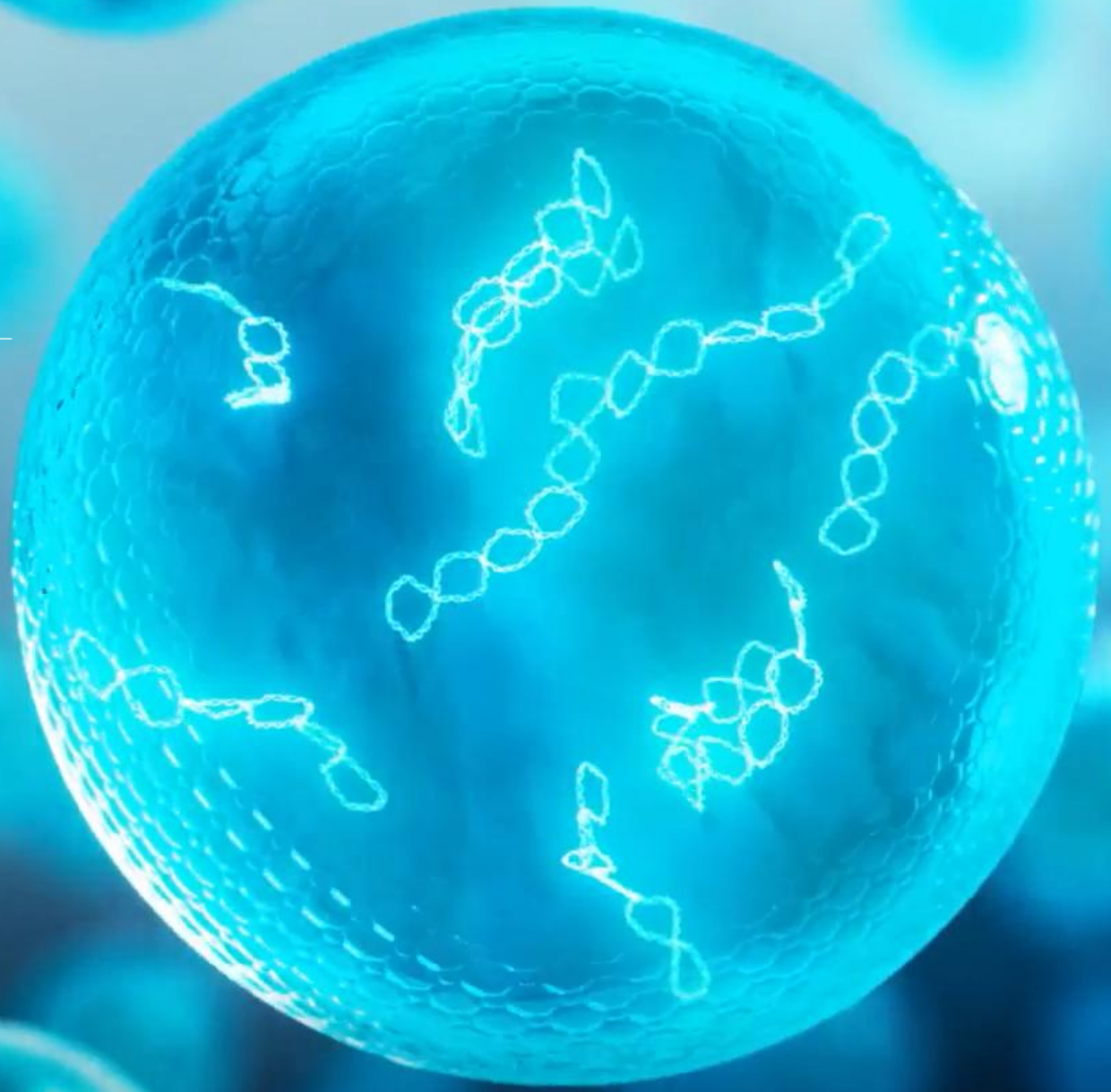
enGene

Non-Viral Genetic Medicine

Virtual KOL Event: Detalimogene voraplasmid with Surfactant

October 15, 2026



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Lead Program (detalimogene voraplasmid)

The lead program described herein is an investigational drug therapy that has not been subject to testing designed to demonstrate that the therapy is effective in humans or to provide a basis to predict in advance whether an adequate level of efficacy in humans will be demonstrated in further testing. Although the FDA has indicated that the Phase 2 portion of the current LEGEND study may potentially support BLA approval, that outcome will depend entirely on the final results of Phase 2 clinical testing and other factors.

Discussion Outline

01

Agenda & Opening Remarks

PRESENTER

Ron Cooper

Chief Executive Officer, enGene

02

Clinical Case Studies

Community Urology Key Opinion Leaders

PRESENTERS

Susan Merrill, MD, FACS

David Cahn, MD

Colorado Urology

03

Preclinical Deep Dive

Detalimogene with Surfactant

PRESENTER

Anthony Cheung, PhD

Co-Founder, enGene

04

Question & Answer Session

PRESENTERS

Ron Cooper

Anthony Cheung

Susan Merrill

David Cahn

Detalimogene: Investigational Next-Generation Therapy for NMIBC

Expanding NMIBC Opportunity

More treatment options may increase sequencing and expand the treatable population

Market growth creates room for multiple therapies

Scalable Non-Viral Platform

Simplified storage / handling designed for broad community adoption

Low-cost, readily available components support scalable manufacturing

CDRP supports BLA readiness

Compelling Clinical Profile*

54% CR at any time within the range observed for approved products

Potential best-in-class tolerability with low rates of TRAEs leading to treatment interruption or discontinuation

Surfactant Lifecyle Management Opportunity

Potential to improve CR and durability with a surfactant bladder rinse

Potential to reduce dwell time from 60 minutes to 30 minutes

$266M cash position**

Key 4Q 2026 Milestones:

Pivotal cohort 12-month data • FDA pre-BLA meeting • BLA filing

* Reflective of interim data presented as of April 21, 2026

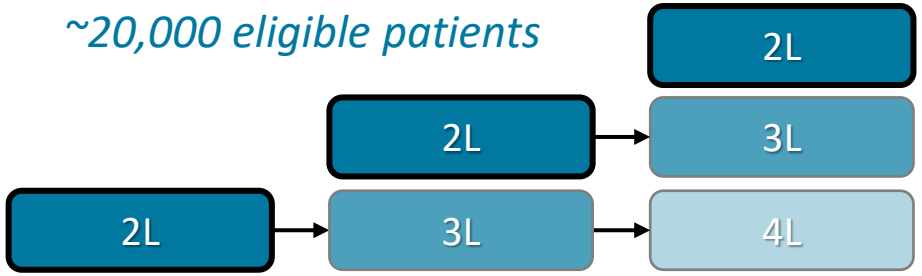
** Cash and cash equivalents and short-term marketable securities as of July 31, 2026

TRAEs = treatment-related adverse events; CR = complete response; NMIBC = non-muscle-invasive bladder cancer; BLA = biologics license application; PI = product information.

Key Takeaways: Eligible Patient Pool, Pricing, and Segmentation

Eligible Patients

- Eligible patient pool exceeds the annual BCG-Unresponsive incidence (i.e., 2L)
- Patients will sequence therapies creating a compounding effect on the eligible pool



New Price Point

- Recently launched therapies for High-Risk NMIBC BCG-Unresponsive exceed $500,000/yr
- NCCN guideline 2A dictates payer coverage at new price point

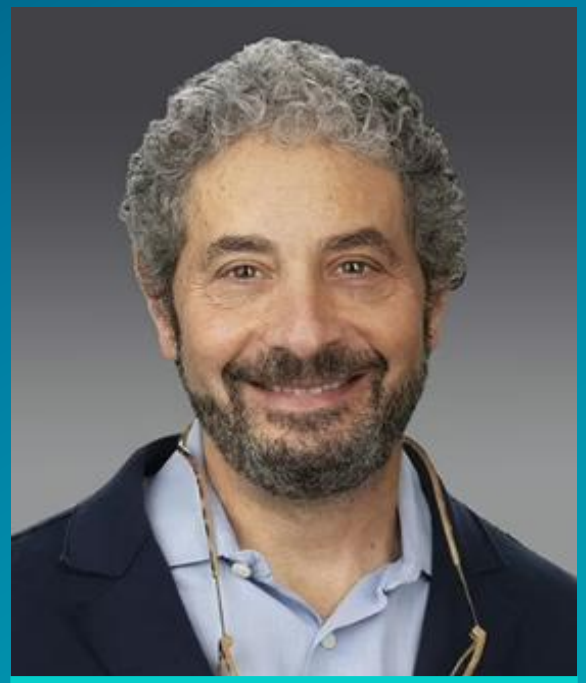


Urology Practice Segments

- ~40% of patients are in practices that consider the balance between efficacy, safety, available resources and practice economics



CLINICAL CASE STUDIES



David Cahn, MD

Colorado Urology
Director of Clinical Research



Suzanne Merrill, MD, FACS

Colorado Urology
Bladder Cancer Regional Leader

Colorado Urology

Practice Overview

COLORADO UROLOGY



Community scale + clinical sophistication

Denver metropolitan area and surrounding communities

30+
UROLOGISTS

18
LOCATIONS

~130K
PATIENTS SERVED

PART OF A LARGER NATIONAL GROUP

United Urology Group:
200+ physicians and 50+ advanced practice providers

CLINICAL RESEARCH CAPABILITIES

Dedicated clinical research access to novel bladder and kidney cancer trials.

Community-based investigators support evaluation of therapies in real-world practice.

REGIONAL EXPERTISE IN BLADDER CANCER

Patients have access to the most cutting-edge bladder and kidney cancer treatments and opportunities to engage in clinical trials that deliver highly anticipated novel therapies.

Case Study 1:

Patient Overview, Medical History, Current Symptoms, and Personal Circumstances

WALTER'S JOURNEY

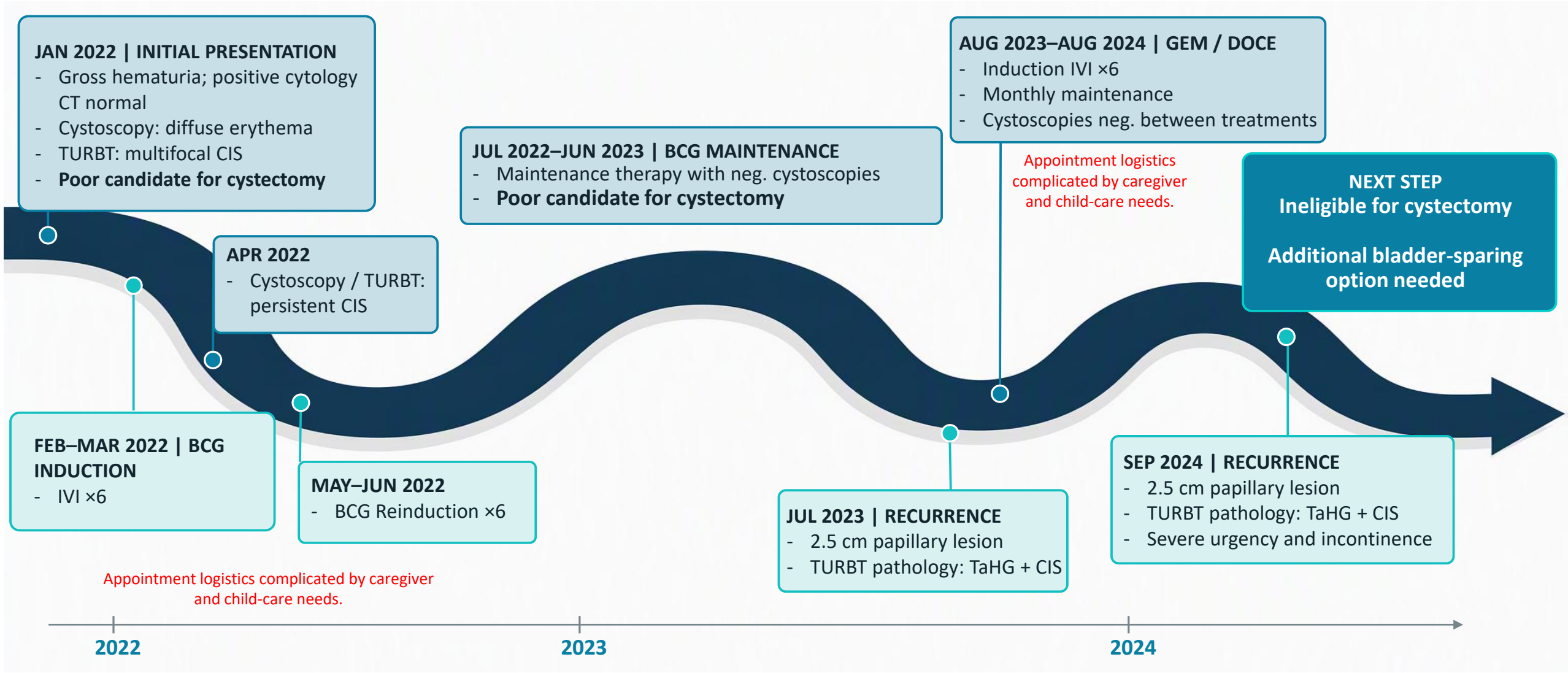


Suzanne Merrill, MD, FACS

- **82-year-old Walter is retired**
- **After his wife passed 2 years earlier, he moved into an apartment down the street from his daughter and 3 grandchildren**
- **80 pack-year history of smoking**
- **History of peripheral vascular disease, coronary artery disease, COPD, and atrial fibrillation**
- **Urinary frequency, urgency and urge incontinence, managed with Myrbetriq**
- **He is on Eliquis for cardiac symptom management**

Walter's Journey

Presentation, Treatment Considerations, Recurrence, Next Steps



Case Study 2:

Patient Overview, Medical History, Current Symptoms, and Personal Circumstances

ALBERT'S JOURNEY



David Cahn, MD

70-year-old newly diagnosed male

Retired business executive who travels frequently and maintains active lifestyle

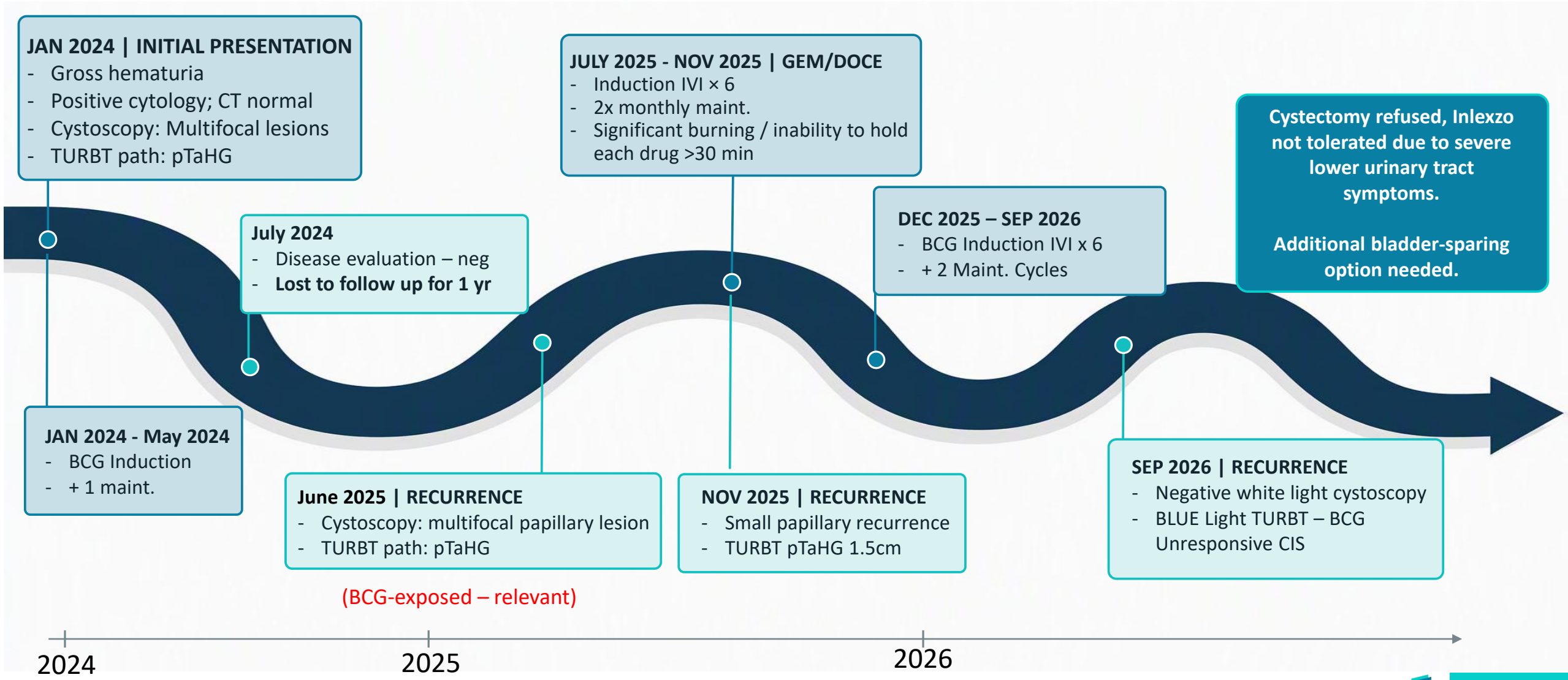
- **Advisory and board work**
- **Visits grandchildren on both coasts**
- **Plays golf and tennis weekly**

No significant medical co-morbidities

Lives with his wife of 35 years

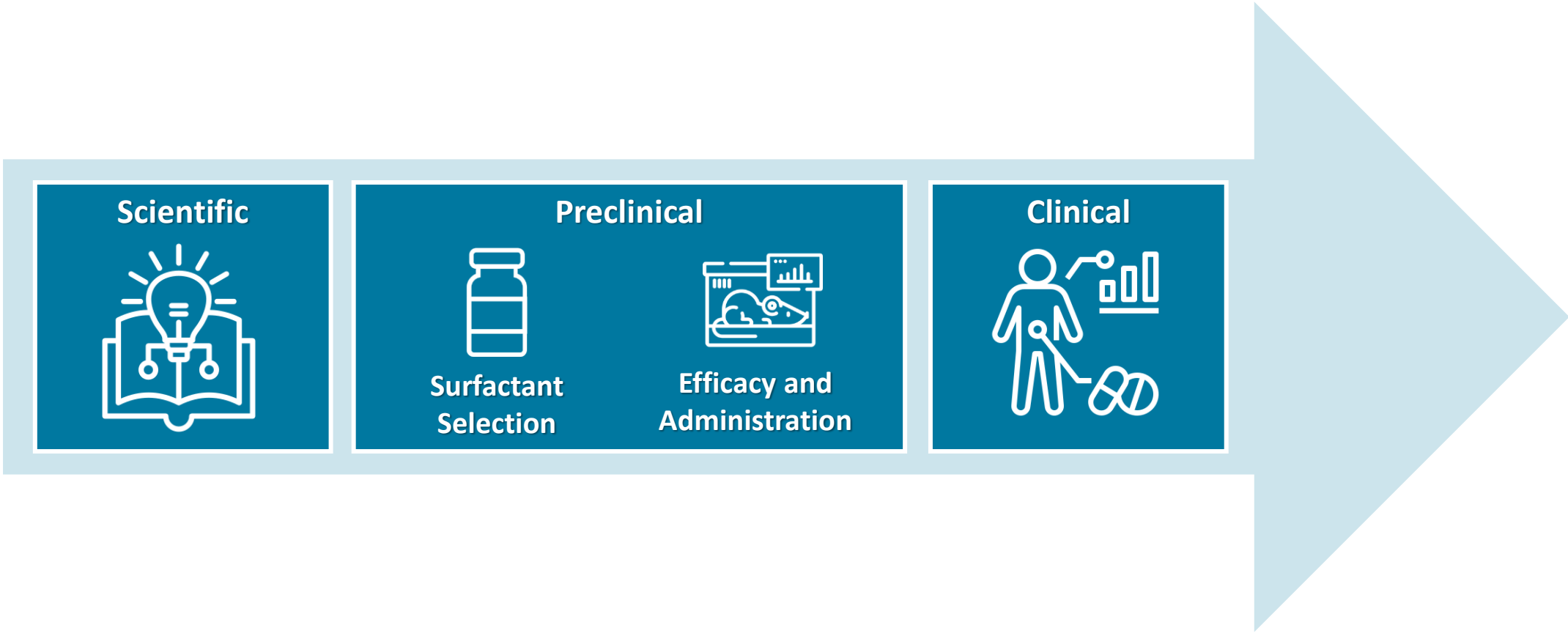
Albert's Journey

Presentation, Treatment Considerations, Recurrence, Next Steps



Rationale Behind Detalimogene with Surfactant

Insights: Rationale, Evidence, and Next Steps for Surfactant Cohort

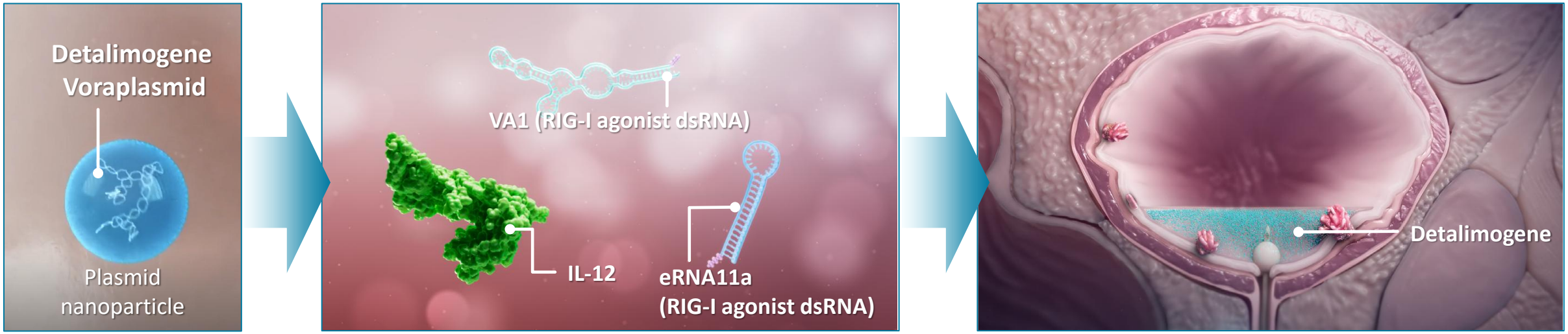


Scientific Rationale Supporting a Surfactant Bladder Rinse



Detalimogene: Designed for Bladder-Localized Immune Activation

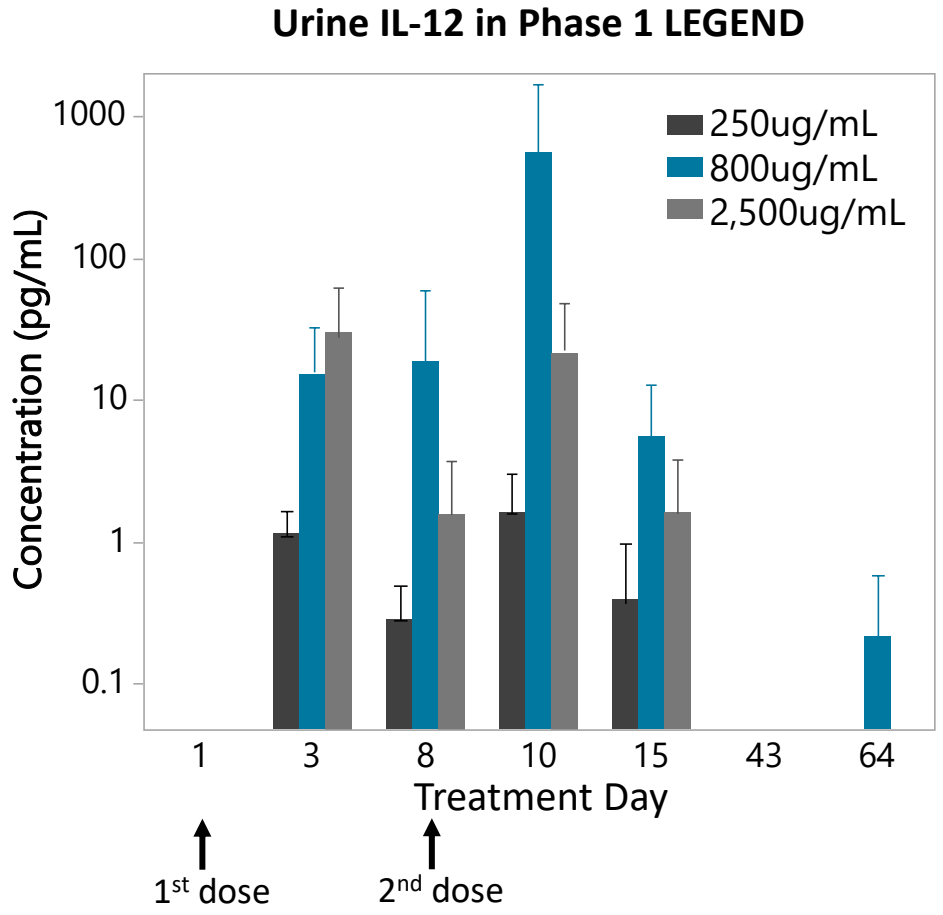
Synergistic Stimulation of Specific Innate and Adaptive Immune Responses



- Detalimogene **delivers plasmid DNA** encoding 3 genes that activate the RIG-I pathway and drive expression of IL-12
- RIG-I activation **triggers innate immune signaling** and recruitment of antitumor NK and T cells
- Localized IL-12 expression drives Th1 polarization of tumor-infiltrating –cells, antitumor cytokine production, and **immune memory formation**

1. Gao J, et al, inventors; enGene, Inc., assignee. US patent WO 2013/138930 A1. September 26, 2013. 2. Joshi S, et al. Presented at: 2025 ASCO GU Cancers Symposium; February 13-15, 2025; San Francisco, CA. Abstract TPS886. 3. Narayan VM, et al. Poster presented at: 2025 ASCO GU Cancers Symposium; February 13-15, 2025; San Francisco, CA. Abstract 826. 4. Taylor J, et al. Presented at: 2025 ASCO GU Cancers Symposium; February 13-15, 2025; San Francisco, CA. Abstract 802. 5. Steinberg JD, et al. Presented at: 2023 SUO; November 28-December 1, 2023; Washington, DC. Abstract 112

Beyond Dose Escalation: Breaking the Sigmoidal Dose-Response



Detalimogene shows a sigmoidal dose–response, consistent with other NMIBC gene therapies

Findings

- **Sigmoidal dose-response in humans:** Urine IL-12 jumps from dose 250 to 800 ug/mL, then plateaus at 2,500ug/mL dose
- **Pre-clinical animal models** had similar dose response profile

Conclusions

- Increasing detalimogene dose alone **will not** increase therapeutic gene expression

800ug/mL was selected as the RP2 dose and given at week 1, 2, 5, 6 every 3 months cycle; weeks 3 and 4 are skipped to minimize saturation of gene transcription mechanism

Surfactants Increase Transfection of Gene Therapies

Preclinical Evaluation Before and After Surfactant Incorporation

Cretostimogene[1]

Cretostimogene-like[2] virus: <5% transfection

Bladders

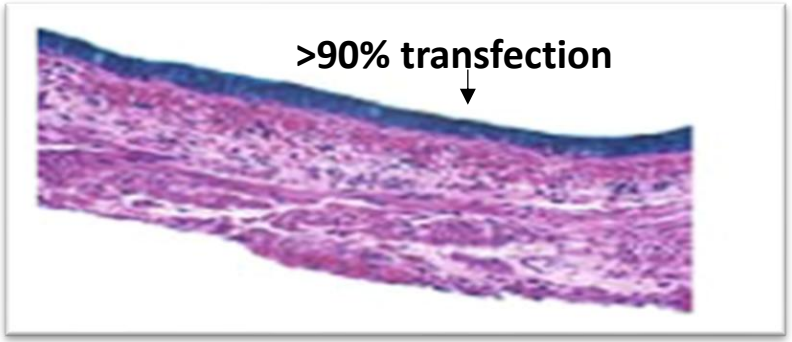


Harvested Bladder



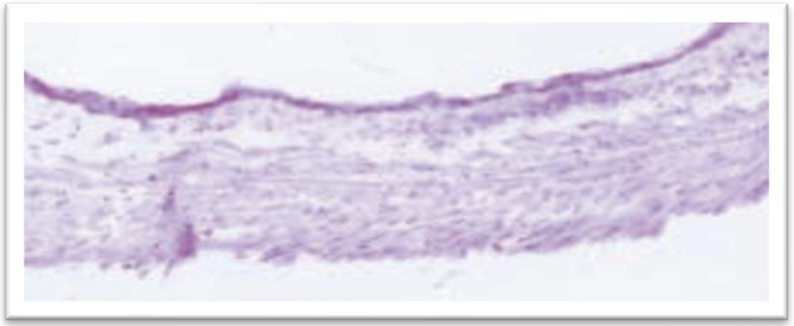
Surfactant (DDM) + Cretostimogene-like virus:



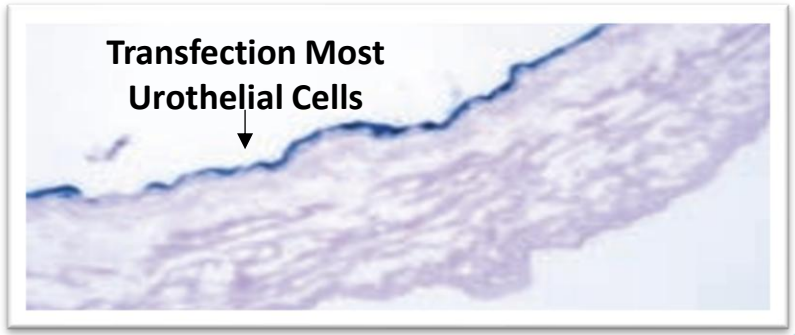


Adstiladrin[3]

Adstiladrin-like virus[4]: Negligible transfection



Surfactant (Syn3) + Adstiladrin-like virus:



1: Cretostimogene developed with a pre-wash surfactant, DDM, before administration of drug. 2: Ramesh et al. Molecular Therapy Vol. 10, No. 4, 2004. doi:10.1016/j.ymthe.2004.07.002, same serotype adenovirus as cretostimogene, different genetic payload; 3: Approved with a surfactant, Syn 3, mixed in with the viral vector. 4: Yamashita, et al. Cancer Gene Therapy (2002) 9, 687–691. doi:10.1038/sj.cgt.7700488, same serotype adenovirus as Adstiladrin, different genetic payload.

Selection of Polidocanol for Surfactant Bladder Rinse

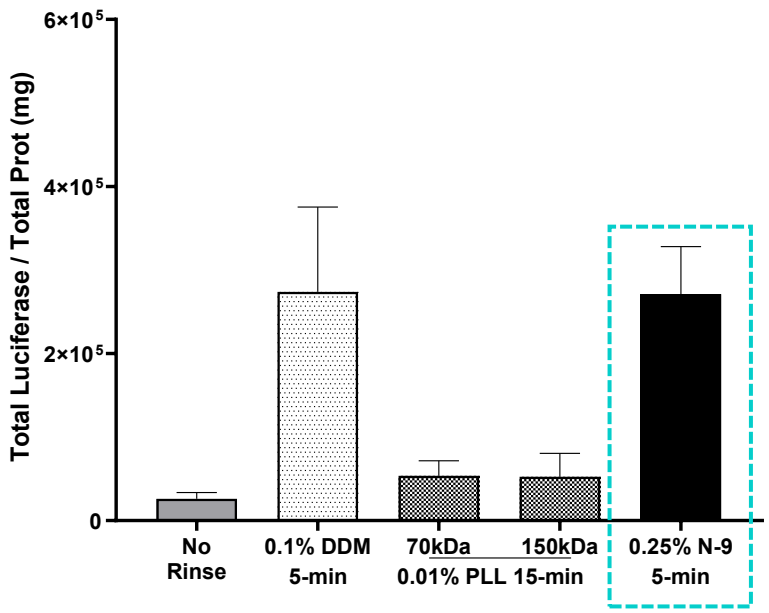


Selection Criteria: Commercial Availability and Extensive Safety Data

- **Commercially Available**: surfactant must already be commercially available to ensure immediate, uninterrupted supply
- **Global Access:** GMP-grade material must be manufactured at scale, at low cost of goods, and available in all regions where sites are located
- **Safety:** extensive safety data are required to ensure detalimogene's best-in-class tolerability is not compromised

Tested Multiple Agents Before Proceeding with Polidocanol

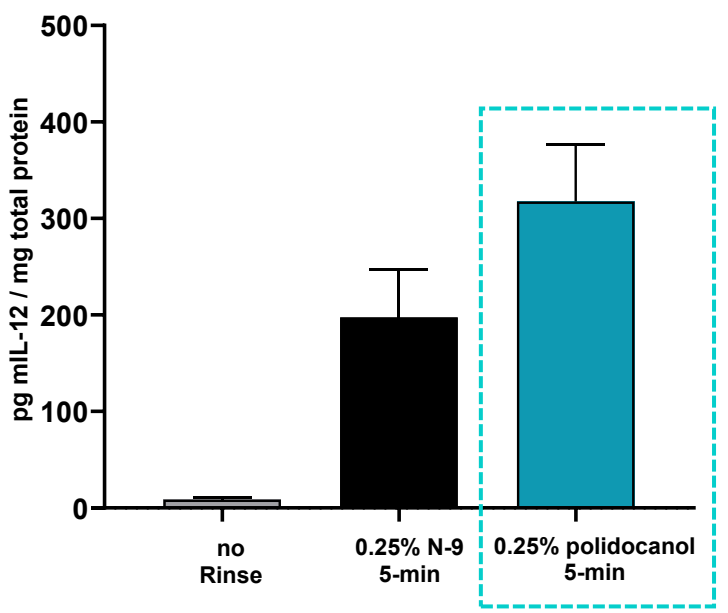
Part 1



N-9 matched gene transfer of benchmark comparator (DDM)

N-9 supply chain challenges

Part 2



Polidocanol offered greater increase in gene transfer and had broader regulatory access

Note: DDM = n-Dodecyl-β-D-maltoside, PLL = Poly-L-Lysine , N-9 = nonoxynol-9. Part 1 experiments used a reporter formulation identical to detalimogene but RIG-I and IL-12 sequences were replaced with luciferase

Polidocanol is Commercially Available with Extensive Safety Data

- **Commercially Available:** surfactant must already be commercially available to ensure immediate, uninterrupted supply
- **Global Access:** GMP-grade material must be manufactured at scale, at low cost of goods, and available in all regions where sites are located
- **Safety:** extensive safety data are required to ensure detalimogene's best-in-class tolerability is not compromised

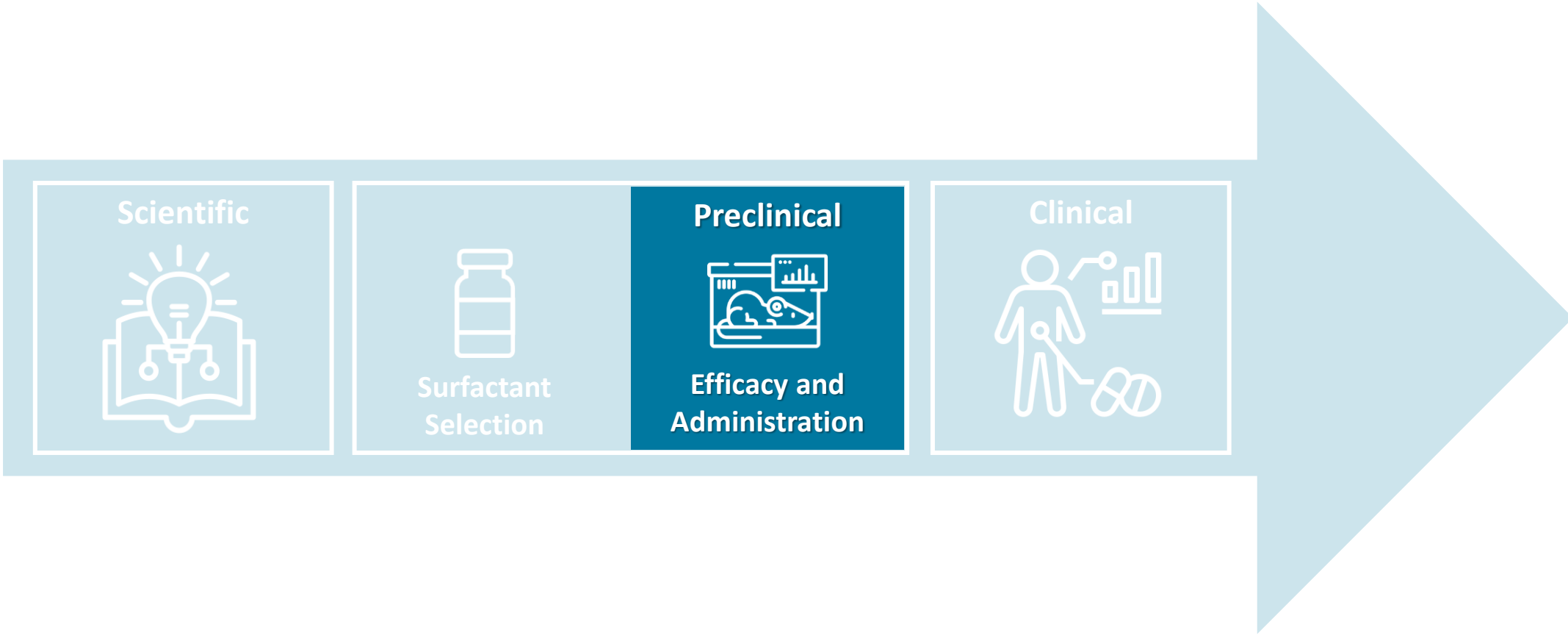
Concentration for Bladder Rinse Clinical Development : 0.25% polidocanol



Established Clinical and Safety Profile of Polidocanol:

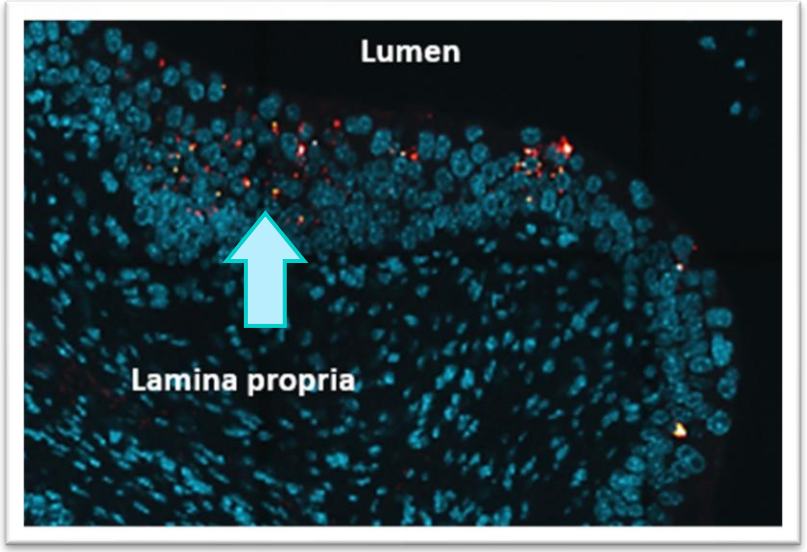
- **Clinical Use:** 1-4% IV sclerosing agent for varicose veins, telangiectasias and hemorrhoids
- **Consumer Use:** Used in shampoos and other products at 1%
- **Safety:** NOAEL 1 mg/kg/day (13-week IV rat study); ≤1% is non-irritating in rabbit eye

Efficacy, Safety, and Administration for Detalimogene with Surfactant

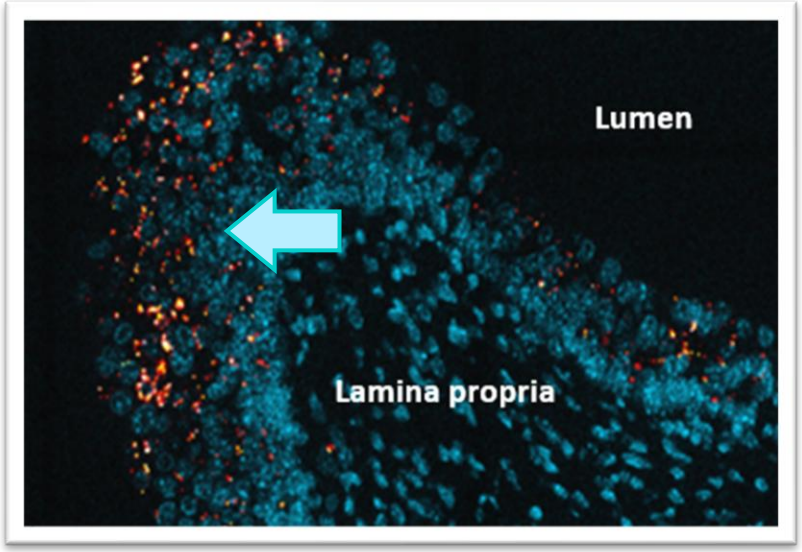


Surfactant Enables Detalimogene to Reach Deeper Urothelial Cells

Detalimogene Alone



Detalimogene with Surfactant



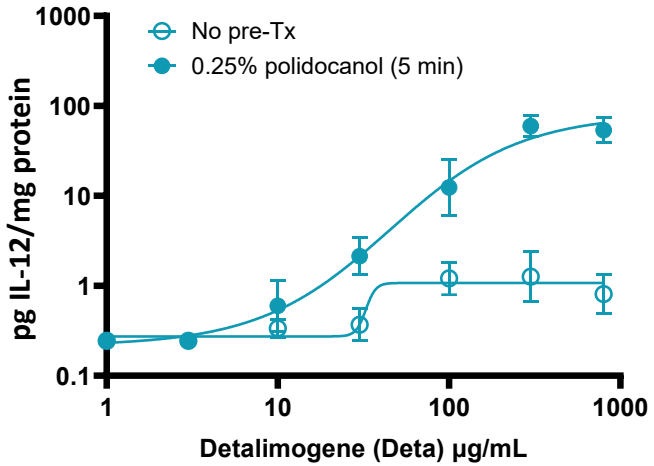
Deeper urothelial penetration lets nanoparticles reach intermediate and basal cells, which have significantly higher transfectability

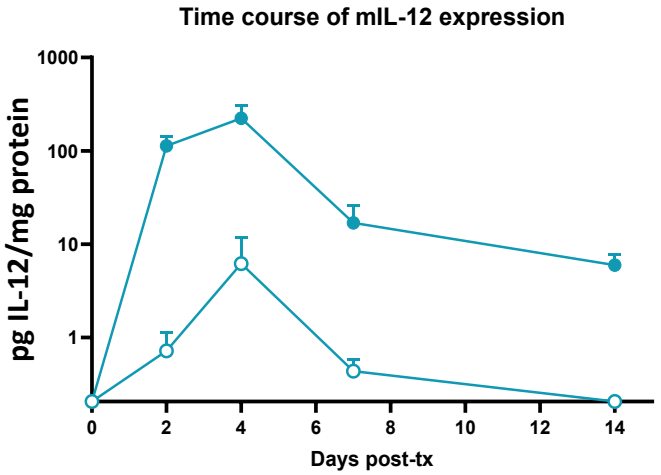
- Cells near the basal lamina are more metabolically and endocytically active
- This facilitates nuclear transport and transgene expression after vector entry
- Higher metabolic activity may enable greater and longer-lasting gene expression, with potential to improve efficacy and durability

Surfactant Rinse Increases Gene Expression 10X and Improves Efficacy

Preclinical Murine Models

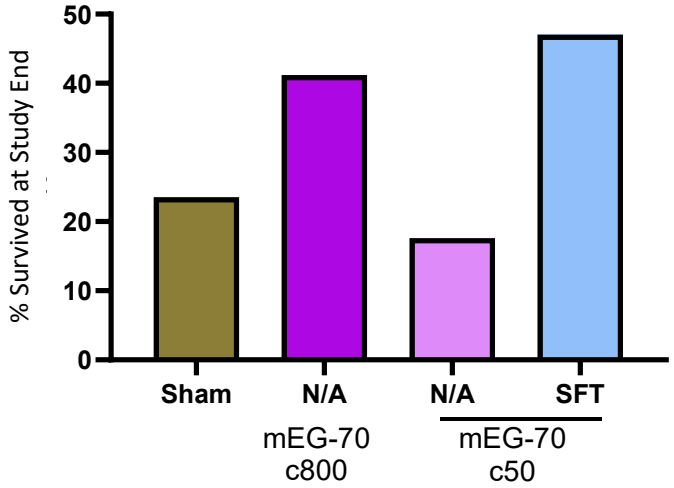
Increases Gene Expression





Murine: Surfactant leads to >10× increase in IL-12 expression for longer duration

Improves Efficacy



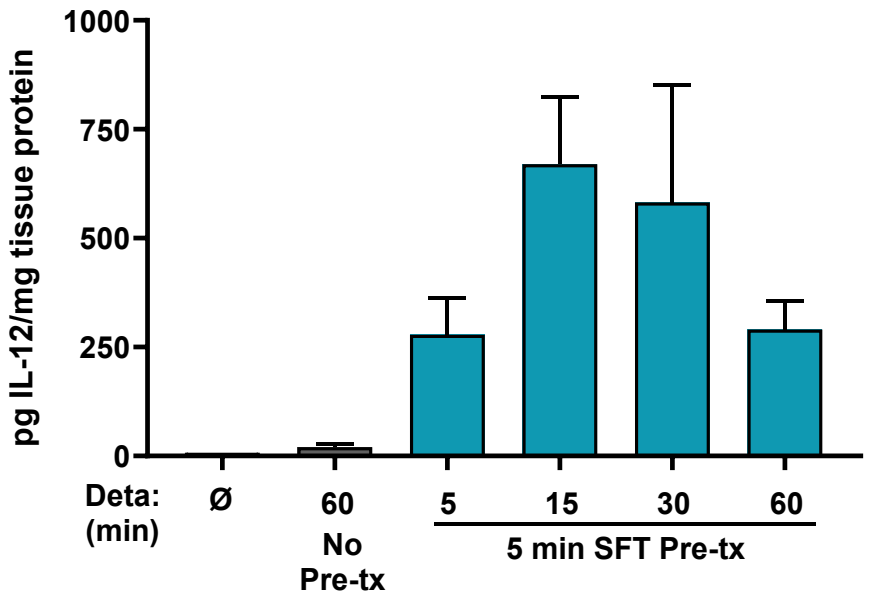
Murine*: A 5-min bladder rinse rescued the efficacy of a sub-optimal dose of deta

*Orthotopic mouse model was used.

Surfactant Rinse May Reduce Patient Burden by Reducing Dwell Time

Surfactant Bladder Rinse Improves Gene Expression at Shorter Dwell Times

Shortens Bladder Dwell Time



A 5-min bladder rinse reduced the detalimogene dwell time from 60 to 15 min.

Shorter Dwell Time

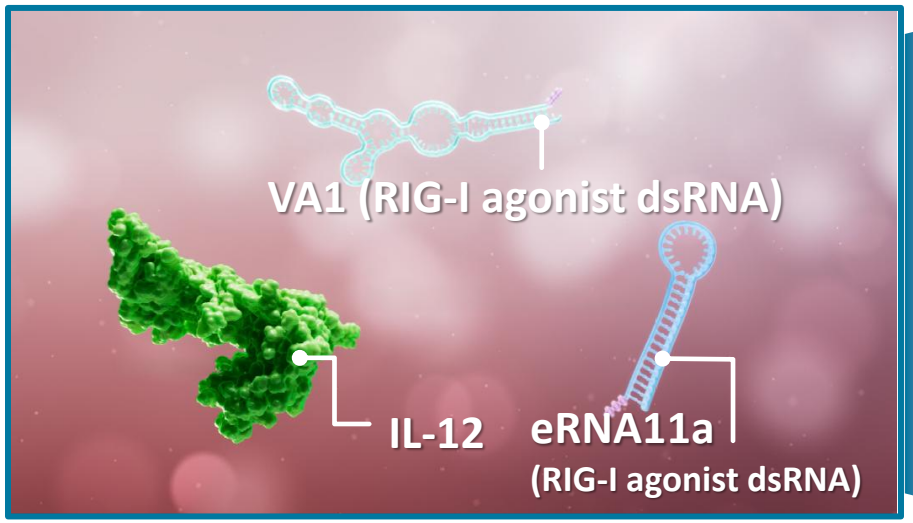


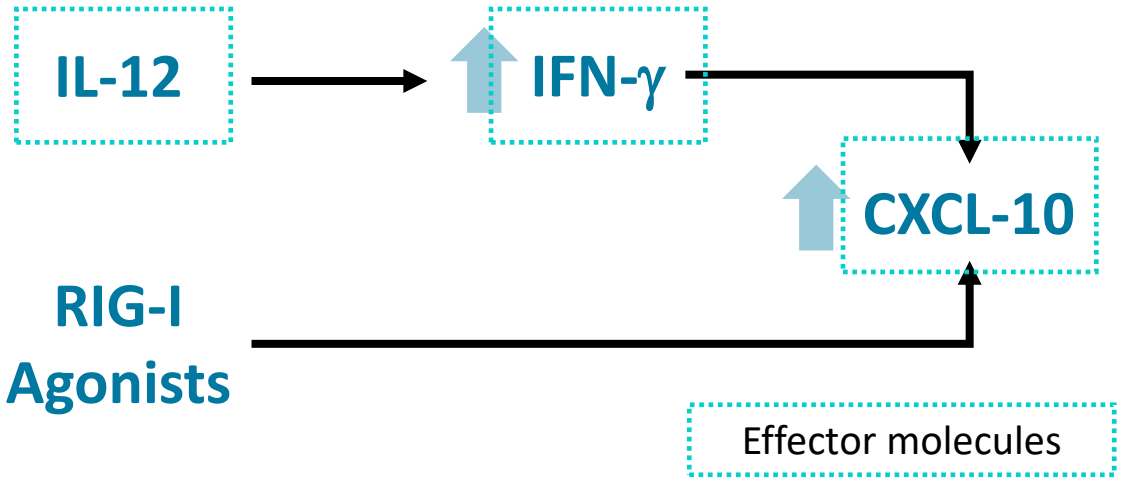
Patients: preferred in patients with irritated or overactive bladders



Practices: Frees up chair time, and increases patient throughput

Proven Anticancer Effect: Same Targets Upregulated by BCG





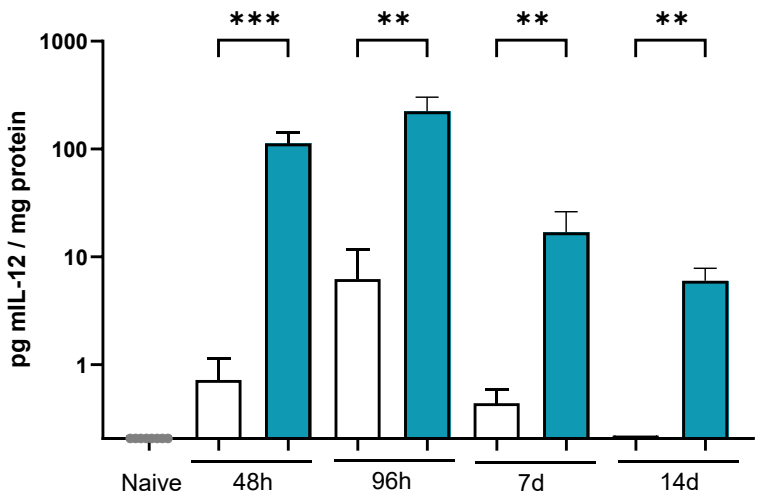
Established Effector Molecules

- **IL-12**, **IFN-γ** and **CXCL-10** drive anti-tumor immunity in the bladder, and are all upregulated by BCG
- BCG's clinical benefit is direct evidence that these targets drive anti-cancer activity

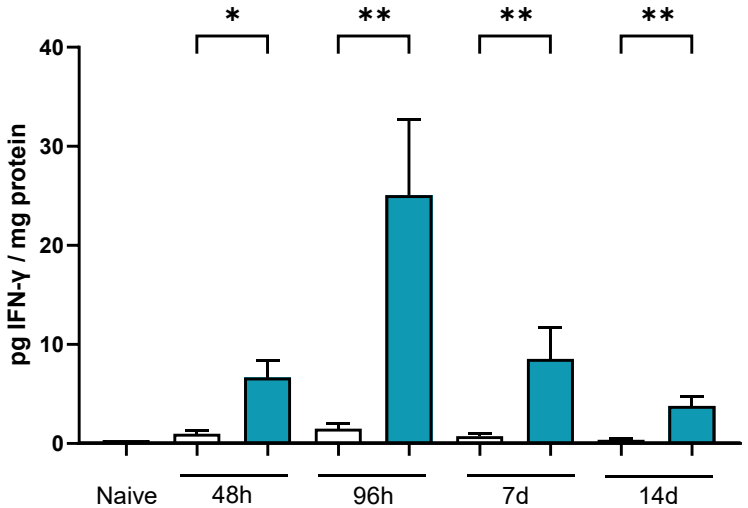
Source: Ashiru O, et al. Cancers (Basel). 2019 Jul 4;11(7):940. doi: 10.3390/cancers11070940; Dix P Poppas et al. Urology 1998 Vol 52 (2) 268-276. doi.org/10.1016/S0090-4295(98)00188-5; Riemensberger J, et al. Clin Exp Immunol. 2002 Jan;127(1):20-6. doi: 10.1046/j.1365-2249.2002.01734.x

Surfactant: Enhances IL-12 Expression & Downstream Target Engagement

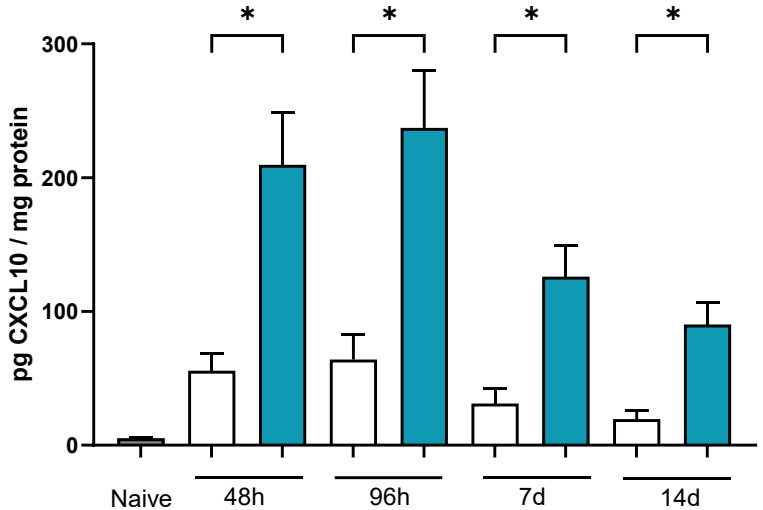
Increased and Prolonged IL-12 Expression in Bladder



Sustained Enhancement of IFN-γ Production



Sustained Enhancement of CXCL-10 Production



∗ $p<0.05$; ∗∗ $p<0.01$; ∗∗∗ $p<0.001$

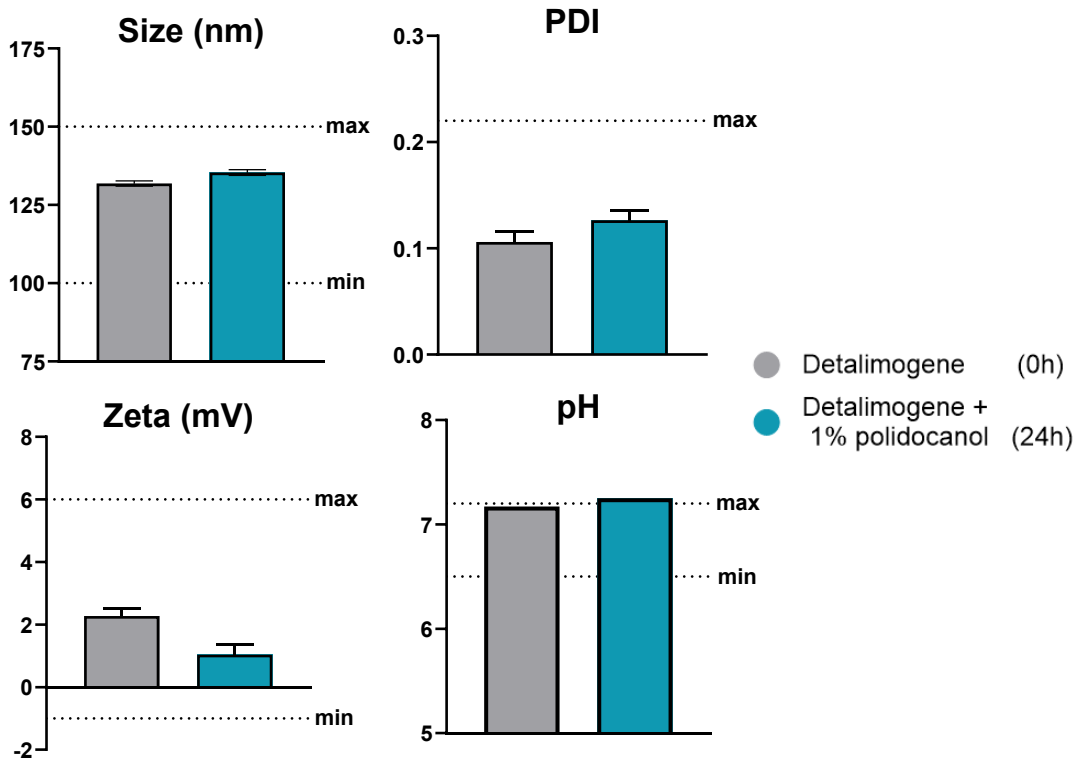
/w bladder rinse and 15min deta dwell

No bladder rinse and 60min deta dwell

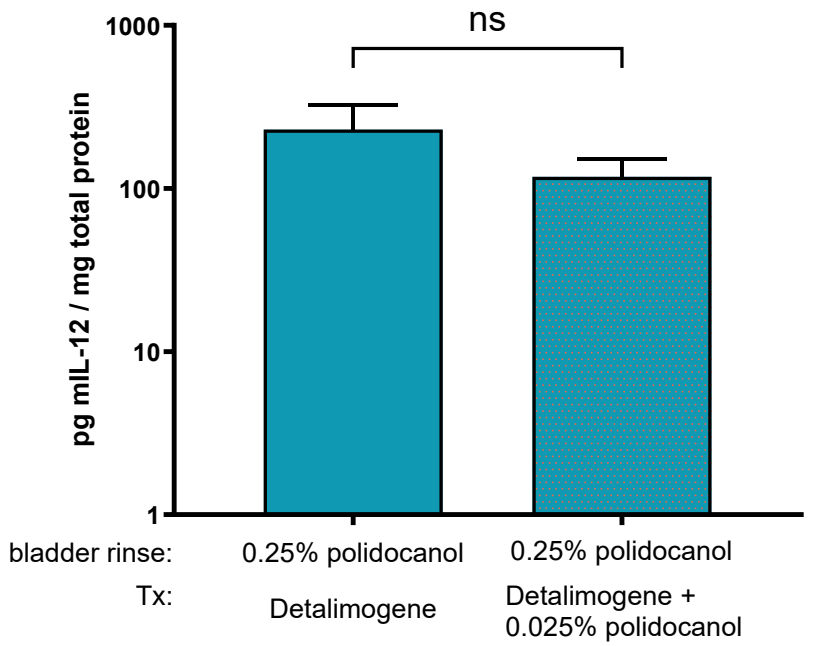
Maintain Detalimogene Simplicity by Not Requiring Multiple Rinses

No Bladder Washout with Saline is Needed Before Detalimogene Administration

No Impact to Detalimogene Stability



No Impact to Detalimogene Potency

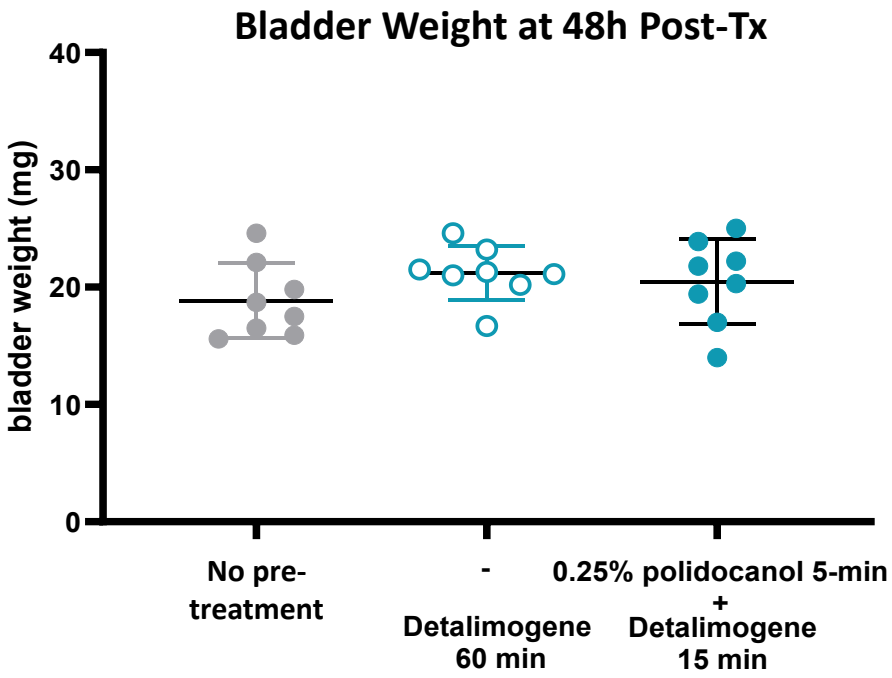


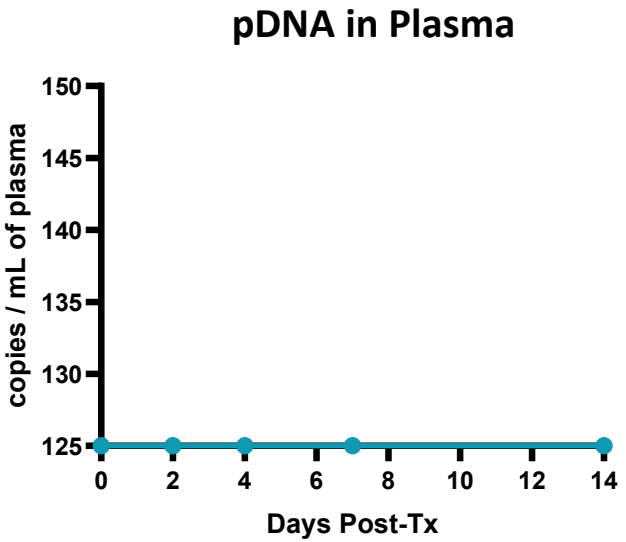
Possible residual volume of bladder rinse (up to 10%) in bladder/catheter has no impact on detalimogene (right hand graph)

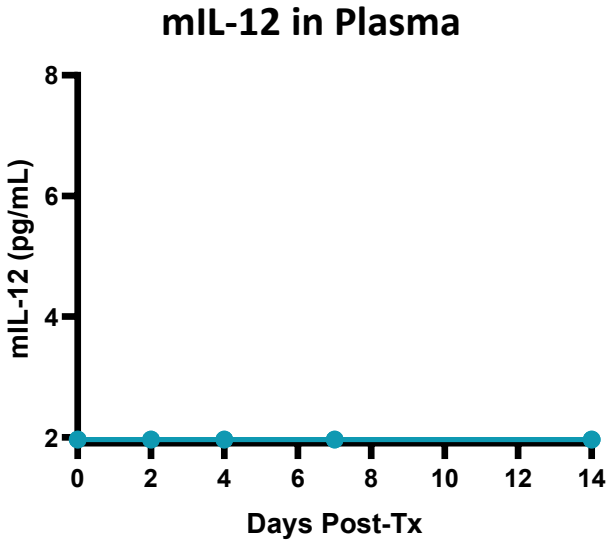
If surfactants disrupt the stability or potency of a drug then an extra wash step is required where saline is used to wash out the bladder, which can be disruptive to urologist workflow

Surfactant: No Observed Bladder Toxicity or Systemic Exposure

Preclinical Evaluation in Murine



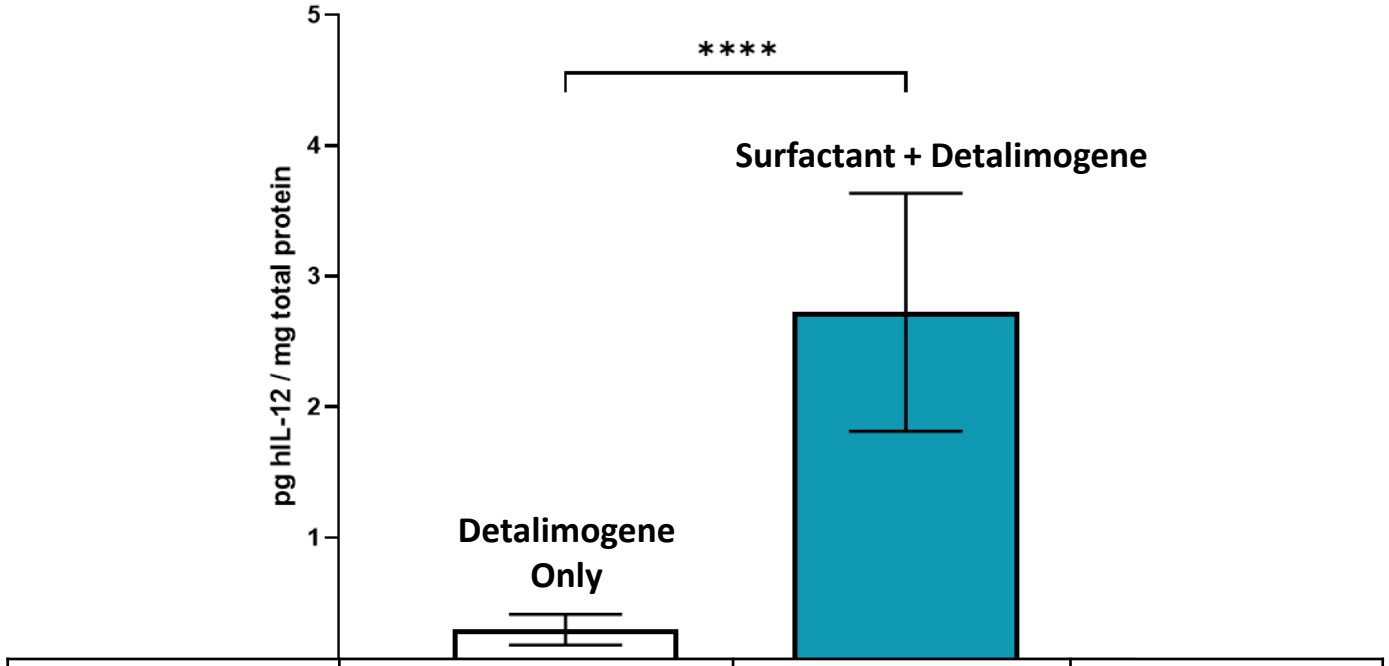




Bladder weight is a sensitive marker to track bladder toxicity
Bladder weight unchanged with polidocanol

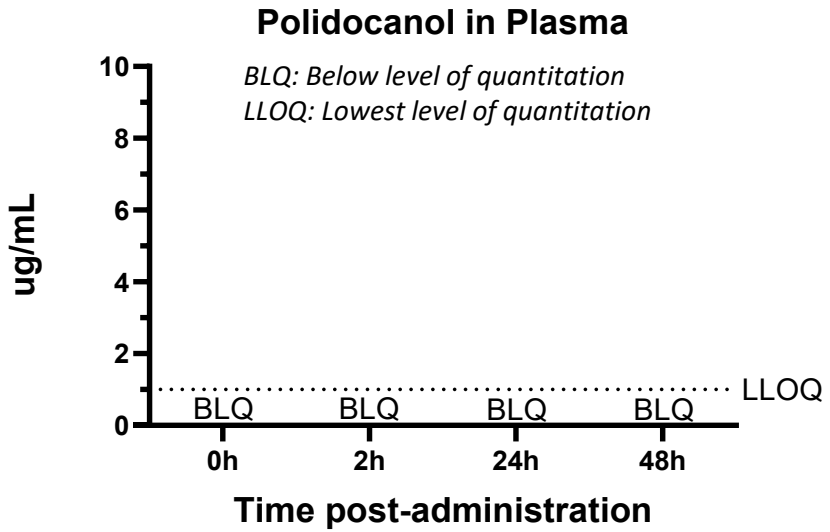
Non-Human Primates Model Validates Gene Expression and Safety Findings

Increases Gene Expression



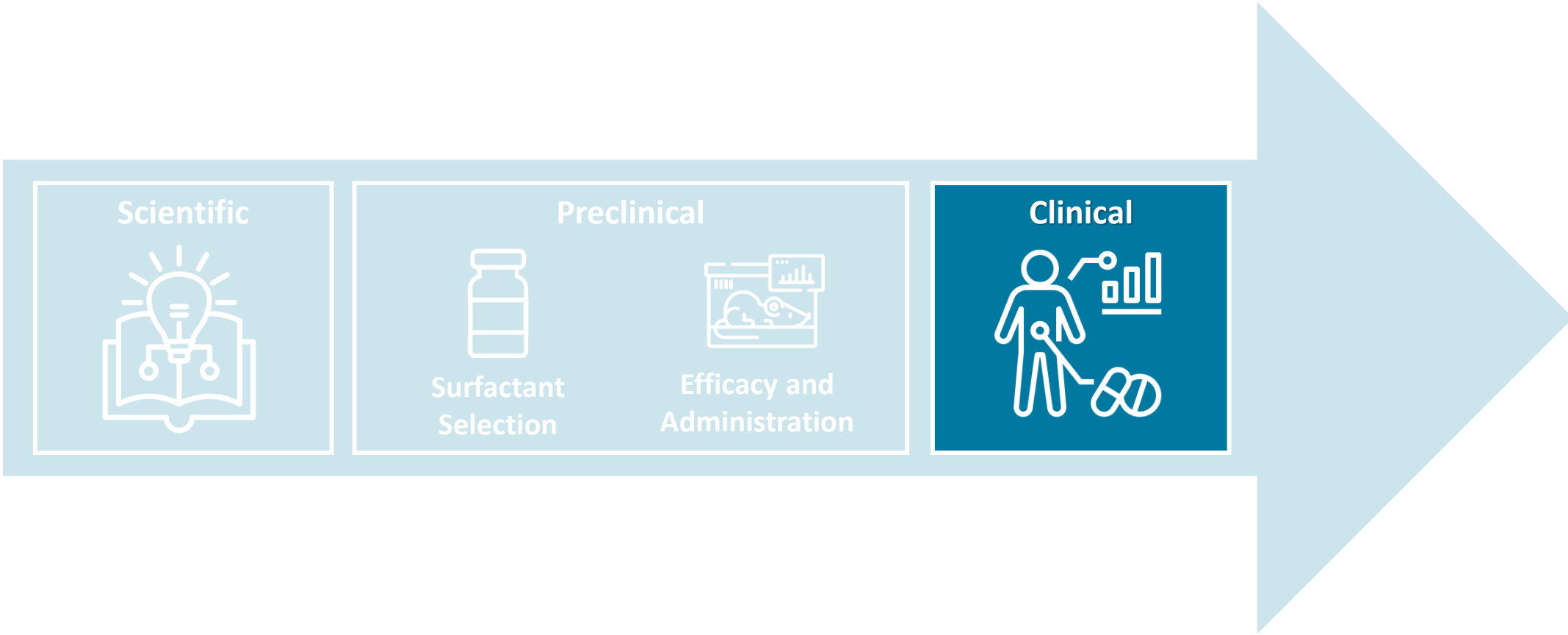
	No Pretreatment Detalimogene 60m	5-min Pretreatment Detalimogene 15m	Increase
Mean hIL-12 expression (pg/mg of total protein)	0.294	2.725	9X Magnitude
% of positive samples	29% (7/24)	81% (29/36)	+52% Distribution

No systemic distribution of polidocanol following administration*



*The bladder of NHPs (n=3) was rinsed with 0.25% polidocanol for 5-min and retrieved. The rinse was followed by an administration of detalimogene for 15-min.

Next Steps Studying Surfactant Bladder Rinse in a Clinical Trial



LEGEND Detalimogene + Polidocanol Surfactant Cohort

First Patients Enrolled and Past Safety Run-In

High-Risk NMIBC Study Design



- Single-catheterization **5 min bladder rinse** with 50 mL of 0.25% polidocanol prior to detalimogene administration
- Intravesical **dwell time for detalimogene reduced from 60 to 30 minutes**
- **~50 active enrolling sites** across North America, Europe, and APAC

Note: patients are illustrative and not reflective of exact patient numbers for the safety and efficacy run-in of the trial.

Detalimogene: Next Gen NMIBC Treatment Designed for Community Use



Large Total Addressable Market	NMIBC market forecasted to be >$20B
Differentiated Total Product Profile	Demonstrated Clinical Activity, Favorable Safety, and a Streamlined Patient and Practice Experience
Lifecycle Management	Surfactant Bladder Rinse has Potential to Improve Efficacy, Duration and Reduce Patient Burden
Near-Term Planned Catalysts	Pivotal 12-month Data, Pre-BLA Meeting & BLA Initiation: Q4 2026 Potential Approval Decision & Platform Designation: 2027 Surfactant Cohort 6-month Data: Mid-2027

$266M Cash* Expect to Provide Operating Flexibility through Potential BLA Filing and Approval

Sources: Transparency market research NMIBC Market Outlook 2034.

* Cash and cash equivalents and short-term marketable securities as of July 31, 2026.

Q&A

enGene

Thank You