enGene

Non-Viral Genetic Medicine

LEGEND Pivotal Cohort Interim Data Update

November 11, 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.

Agenda

01

Welcome

PRESENTER

Ron Cooper

Chief Executive Officer

02

New Interim Data Cohort 1:

Detalimogene Without Surfactant

PRESENTER

Ashish Kamat, MD

MD Anderson

03

NMIBC Market Insights

PRESENTER

Amy Pott

Chief Global Commercialization Officer

04

Q&A

ALL PRESENTERS

Introductory Remarks

Detalimogene: Only Non-Viral Gene Investigational Therapy for NMIBC

Compelling Clinical Profile*

- **56% CR at any time** (primary endpoint) within the range observed from approved products
- **Durability trending** towards range of approved products
- **Lowest rates of discontinuations** or dose interruptions due to treatment related adverse events**

Pre-BLA Meeting

- Successful **pre-BLA meeting**
- Alignment on definition of **efficacy evaluable**
- **CDRP supports BLA readiness**
- **Plan to initiate BLA filing** by end of year with potential approval in 2027

Unique Non-Viral Offering

- **More treatment options are** expected to increase sequencing which will **expand treatable population**
- Detalimogene non-viral approach provides **a unique MOA** for when doctors sequence therapies
- Low treatment burden for patients

Unlocking Community Practices

- **Simple storage and handling** designed to support broad community adoption
- Provides opportunity to **redefine community care**
- **75% of the patients** are in community practices

4Q 2026 Initiate BLA Filing; 2027 Potential BLA Approval; Detalimogene + Surfactant Data Mid 2027

*Reflective of data as available in the database as of 29 October 2026. Data Collection and Cleaning is ongoing and is subject to change.
** Compared to approved products USPI which references dose discontinuations and interruptions due to adverse reactions. Differences in compounds and trial designs require data comparisons to be interpreted with caution
TRAEs = treatment-related adverse events, CR = complete response, NMIBC = non-muscle-invasive bladder cancer, BLA = biologics license applications, PI = product information, CDRP = Chemistry, Manufacturing, and Controls Development and Readiness Pilot, DOR = duration of response.

LEGEND Principal Investigator



Ashish Kamat, MD

Dr. Kamat is an Endowed Professor of Urologic Oncology and Cancer Research at MD Anderson Cancer Center and founding President of the International Bladder Cancer Group. Dr. Kamat specializes in genitourinary cancers, with a particular focus on immunotherapy for urothelial cancers, he has authored over 610 publications and champions patient advocacy.

No “Winner Takes All”: HR BCG-UR NMIBC Patients Need Multiple Options

Unmet Need Persists as No Current Therapy Meets All Patient Needs

Bladder preservation

Multiple options after persistence/recurrence may delay cystectomy, an invasive surgery with substantial morbidity.

Treatment burden

Options with lower burden dosing schedule and fewer post-treatment precautions are needed to accommodate patient lifestyle.



Tolerability

Side effects disrupt care. More tolerable options remain an unmet need.

Community access

Storage and handling needs limit local availability and require referral.

Physicians need more options for shared decision-making with patients

HR, High Risk; BCG-UR, Bacillus Calmette-Guérin Unresponsive

November 2026: LEGEND Pivotal Cohort Interim Data Update

LEGEND: Multi-Cohort Study of Detalimogene In High-Risk NMIBC

PHASE 2: ONGOING

Pivotal Cohort

BCG-unresponsive NMIBC with CIS[1] (n=125)

- CIS ± HG Ta/T1 with persistent or recurrent disease within 12 months of adequate BCG

Key Eligibility Criteria

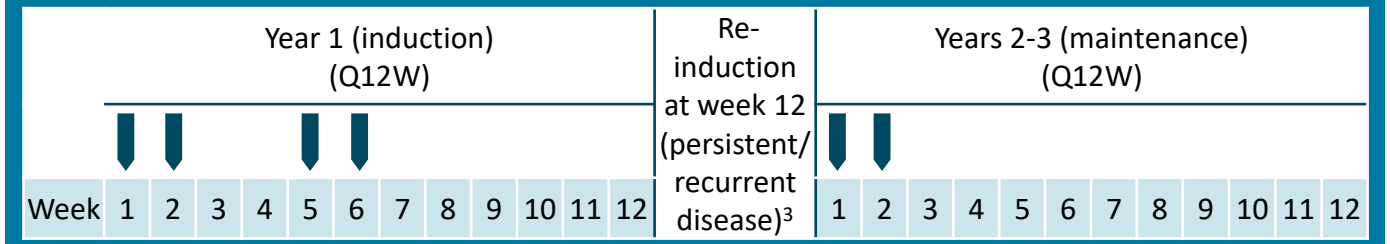
- Age ≥18 years
- ECOG PS of 0, 1, or 2
- Ineligible for or not electing cystectomy
- Adequate bladder function and can retain study drug for ≥60 minutes

Other Cohorts

- BCG-naïve NMIBC with CIS[1] (n=30)
- BCG-exposed NMIBC with CIS[1] (n=46)
- BCG-unresponsive HG Ta/T1 papillary disease without CIS[1] (n=47)
- BCG-unresponsive with CIS[1] utilizing a bladder rinse[4]

Treatment Schedule

Detalimogene 0.8 mg/mL (50 mL) IVI via catheter with 60-min dwell time[2]



Endpoints

Primary

- Complete response (CR) rate at any time

Key Secondary

- Duration of response (DOR) and DOR ≥ 12 months rate
- CR at landmark timepoints
- Safety
- PFS

[1]NMIBC with CIS with or without co-existing papillary (Ta/T1 tumors), protocol requires re-resection of T1 tumors prior to enrollment.
[2]Investigational intravesical therapy.
[3]Reinduction occurs may occur after the first 12-week cycle of the induction phase.
[4]Bladder rinse cohort dosing instructions Polidocanol 0.25% in 50 ml IVI via catheter, 5-minute bladder rinse, prior to detalimogene voraplasmid administration.
BCG, Bacillus Calmette-Guérin; CIS, carcinoma in situ; CR, complete response; ECOG PS, Eastern Cooperative Oncology Group performance status; HG, high grade; IVE, intravesical instillation; NMIBC, non-muscle invasive bladder cancer; PFS, progression-free survival; Q12W, every 12 weeks.

LEGEND Pivotal Cohort 1:

Baseline Demographics and Disease Characteristics

Characteristics	Pivotal Cohort 1 (N=125)
Age, years	
Median (Range)	71.0 (35.0-90.0)
Sex, n (%)	
Female	24 (19%)
Male	101 (81%)
Race n (%)	
White	114 (91%)
Asian	4 (3%)
Black or African American	2 (2%)
Not Reported	5 (4%)
ECOG PS, n (%)	
0	119 (95%)
1	6 (5%)

Characteristics	Pivotal Cohort 1 (N=125)
Tumor stage, n, %	
CIS with Ta/T1 disease	50 (40%)
CIS only	75 (60%)
Reason for no cystectomy, %	
Ineligible	9 (7%)
Declined	116 (93%)
Prior BCG doses, n	
Median (Range)	12 (6-50)
Patients with prior therapy other than BCG:	
Total	32 (26%)
Intravesical chemotherapy*	22 (18%)
Systemic immunotherapy	8 (6%)
Viral gene therapy	5 (4%)
Other	4 (3%)
Prior NMIBC recurrence(s)	
Median (Range)	2 (1-11)

Note: BCG, bacillus Calmette-Guérin; CIS, carcinoma in situ; ECOG PS, Eastern Cooperative Oncology Group Performance Score; NMIBC, non-muscle invasive bladder cancer.
*Single administration of cytotoxic agents (e.g. Mytomicin C, gemcitabine, doxorubicin or epirubicin) immediately following a TURBT are not included in this %
Data as of 29 October 2026. Data collection and cleaning is ongoing.

Cohort 1 Data:
Detalimogene Without Surfactant

FDA Aligned Efficacy Evaluable Population

Alignment on Critical Items in Proposed Statistical Analysis Plan (SAP)

125 – **5** = **120**

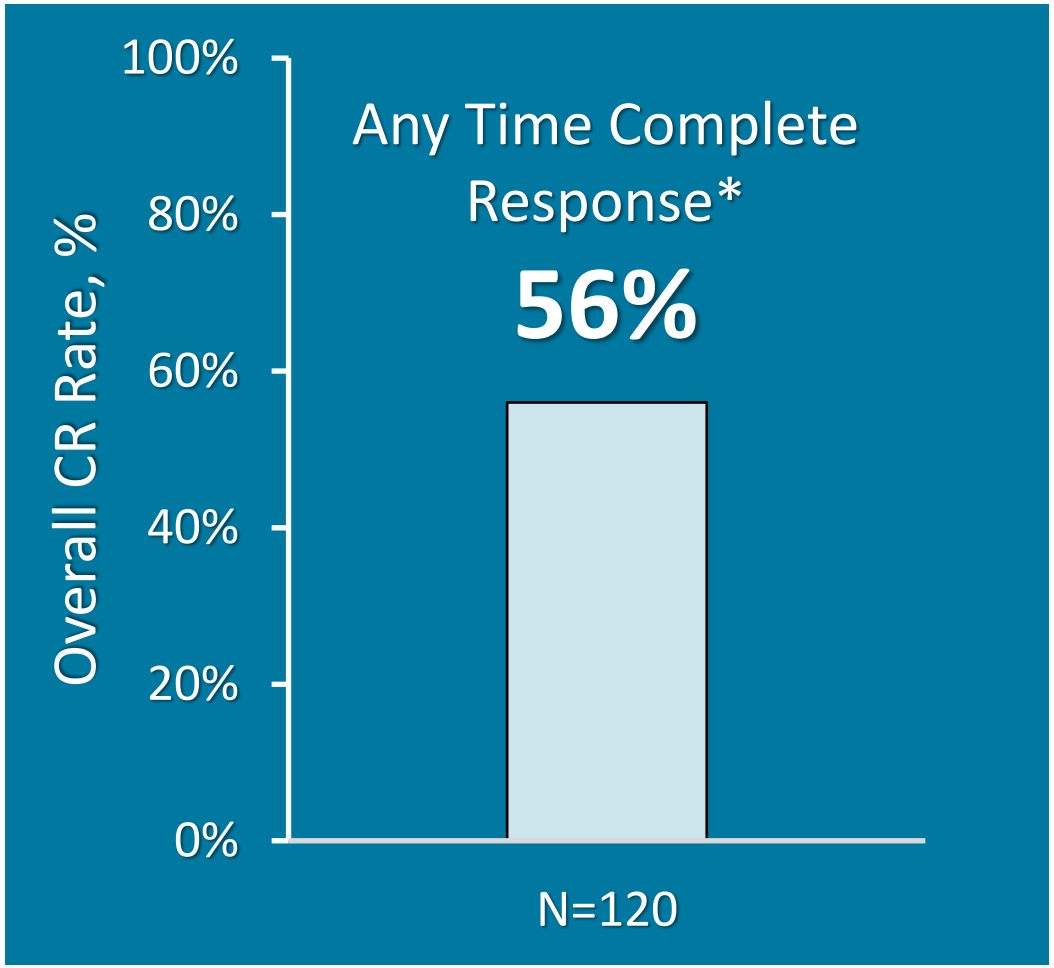
Trial patients | **Excluded from efficacy analysis** | **Efficacy evaluable (EE)**

Patient 1	Did not have a post baseline disease assessment
Patient 2	Did not have CIS within 1 year of receiving adequate BCG dosing
Patient 3	Did not have CIS within 1 year of receiving adequate BCG dosing
Patient 4	Did not receive adequate BCG dosing
Patient 5	Did not receive adequate BCG dosing and had a disallowed cancer (melanoma)

Data as of 29 October 2026. Data collection and cleaning is ongoing.

Detalimogene Without Surfactant Primary Endpoint: CR at Any Time

Primary Endpoint in Range of Approved Products



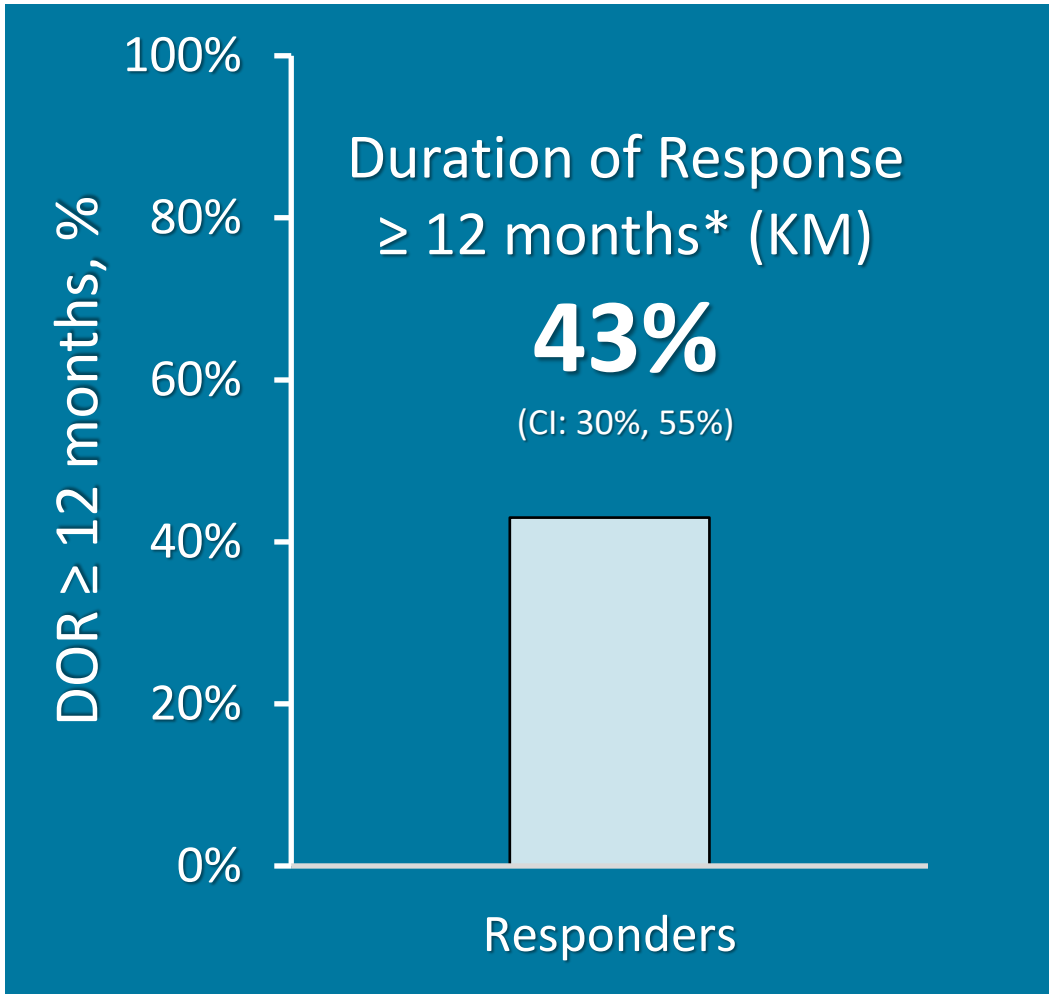
Endpoint	Data Analysis	CR Rate, % (95% CI)
Complete Response at Any Time	Oct 2026 (n=120)	56% (CI: 47%, 65%)
	Apr 2026 (n=124)	54% (CI: 45%, 63%)

- **91%** of CRs occurred at first assessment[&]
- **100%** of responders were free from progression to ≥T2 disease in the bladder
- **97%** of EE patients were free from progression to ≥T2 disease^
- **96%** of responders remain free from cystectomy
- **86%** of EE patients remain free from cystectomy

Median follow-up of all EE Population patients was 7.5 months (range, 1.9-33.8 months). Median follow-up of responders was 12.0 months (range, 3.7-33.8 months).
*Patients who discontinued without any disease evaluation or who discontinued after a CR are excluded from subsequent landmark response analysis.
[&]One patient was censored for Cycle 1, therefore N=66
^One additional progression was noted but not documented in the database as of the datacut date.
CR=complete response defined as negative cystoscopy and negative urine cytology, or positive cystoscopy/cytology with negative bladder biopsy. CI: 95% Confidence Interval; KM = Kaplan-Meier, EE = efficacy evaluable.
Data as of 29 October 2026. Data collection and cleaning is ongoing.

Key Secondary Endpoint: Kaplan-Meier Estimated Duration of Response

Durability Trending Toward Approved Products, Assessments Ongoing



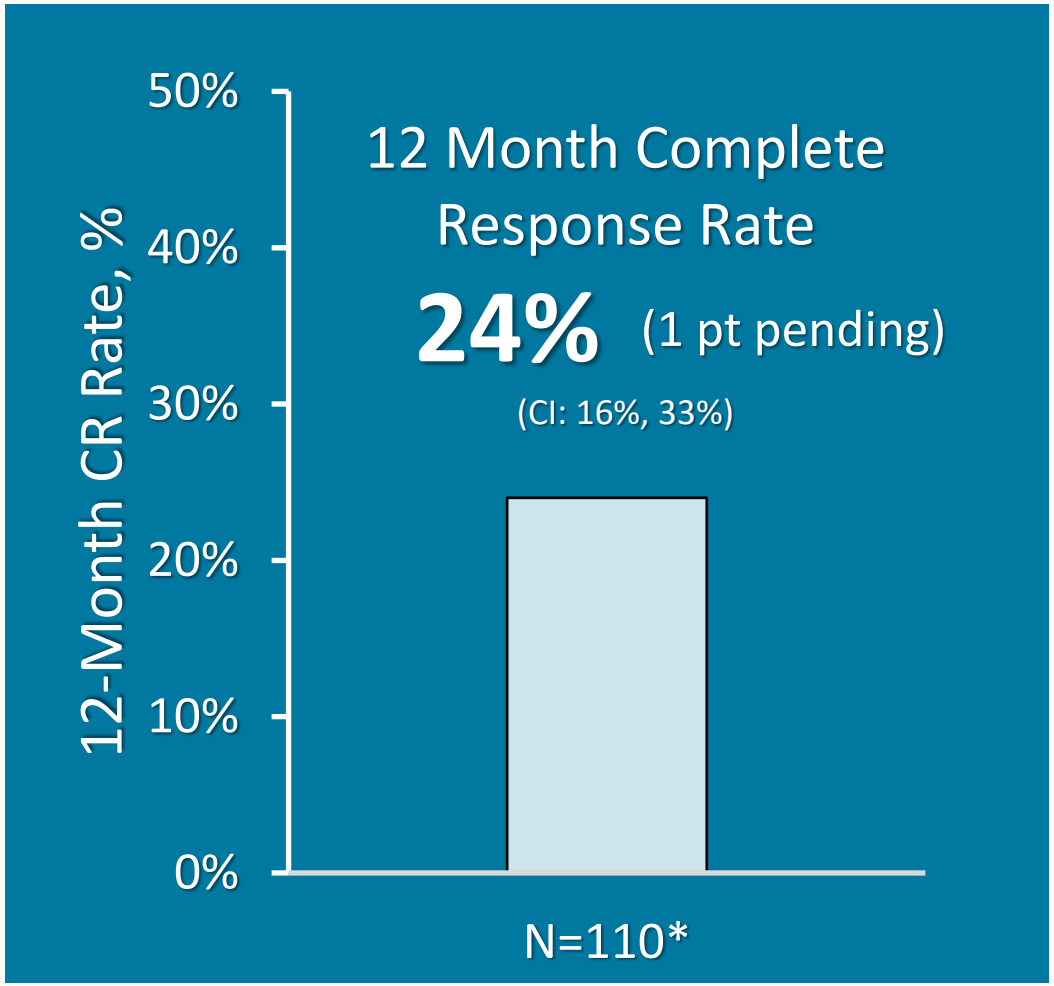
Data Analysis	DOR ≥ 12 months	Median Duration
Oct 2026	43% (KM est)	10.1 months (7.5 to NE)
Apr 2026	25% (KM est)	8.6 months

- **100%** of patients who entered maintenance and have been assessed for durability have recorded durable responses*
- **9 patients** are pending the DOR ≥ 12 months assessment
  - 8 were in CR at 48-week with 1 pending 48-week
- Maximum potential DOR ≥ 12 months is 40% (CI: 28%, 53%)

*For durability assessments, 1 year is defined as 358 to 365+ days. Nine patients are pending their response assessment. Patients are censored if have not yet had an assessment within 7 days of day 365 or beyond, or at the start of new anticancer therapy, Patients censored at start of new treatment will never be able to reach durability which leads to an overestimate in the KM model.
Deta = detalimogene; CR=complete response defined as negative cystoscopy and negative urine cytology, or positive cystoscopy/cytology with negative bladder biopsy. CI: 95% Confidence Interval; KM = Kaplan-Meier, NE = not estimatable.
Data is presented as available in the database as of 29October2026. Data Collection and Cleaning is ongoing and is subject to change.

Additional Supportive Data: CR Landmark 12 months

Endpoint Not Included in Approved Product Labels



Endpoint	Oct 2026	Apr 2026
Complete Response at 12 months, % (95% CI)	24% CI: 16%, 33% (n=110)	13% CI: 7%, 22% (n=98)
Median Follow Up of Responders (Months)	12.0 (range: 3.7, 33.8)	9.2 (range: 3.7, 25.8)

Median follow-up of all EE Population patients was 7.5 months (range, 1.9-33.8 months). Median follow-up of responders was 12.0 months (range, 3.7-33.8 months).
*Patients are censored if they have not yet had a disease assessment, for cycles in which they had suboptimal dosing; and from subsequent analysis if they withdrew from treatment while censored or in CR.
Deta = detalimogene; CR=complete response defined as negative cystoscopy and negative urine cytology, or positive cystoscopy/cytology with negative bladder biopsy. CI: 95% Confidence Interval; KM = Kaplan-Meier.
Data is presented as available in the database as of 29October2026. Data Collection and Cleaning is ongoing and is subject to change.

Detalimogene Demonstrated Favorable Safety and Tolerability Profile

TRAEs were Generally Mild and Reversible, Consistent with Catheterization

Participants with events n, (%)	Pivotal Cohort 1 (N=125)
≥ 1 Treatment-related adverse event	59%
Most frequent TRAEs (≥10%)	
Fatigue	21%
Dysuria	16%
Pollakiuria	16%
Bladder spasm	13%
Micturition urgency	13%
Urinary tract infection	10%
Most TRAEs were localized, brief, low grade events	
Of those with TRAEs, percent that were Grade 1-2	93%
Patients with Grade 3 TRAEs*	4%
Patients with Serious TRAEs	2%
Median Time for TRAE Resolution	6 days

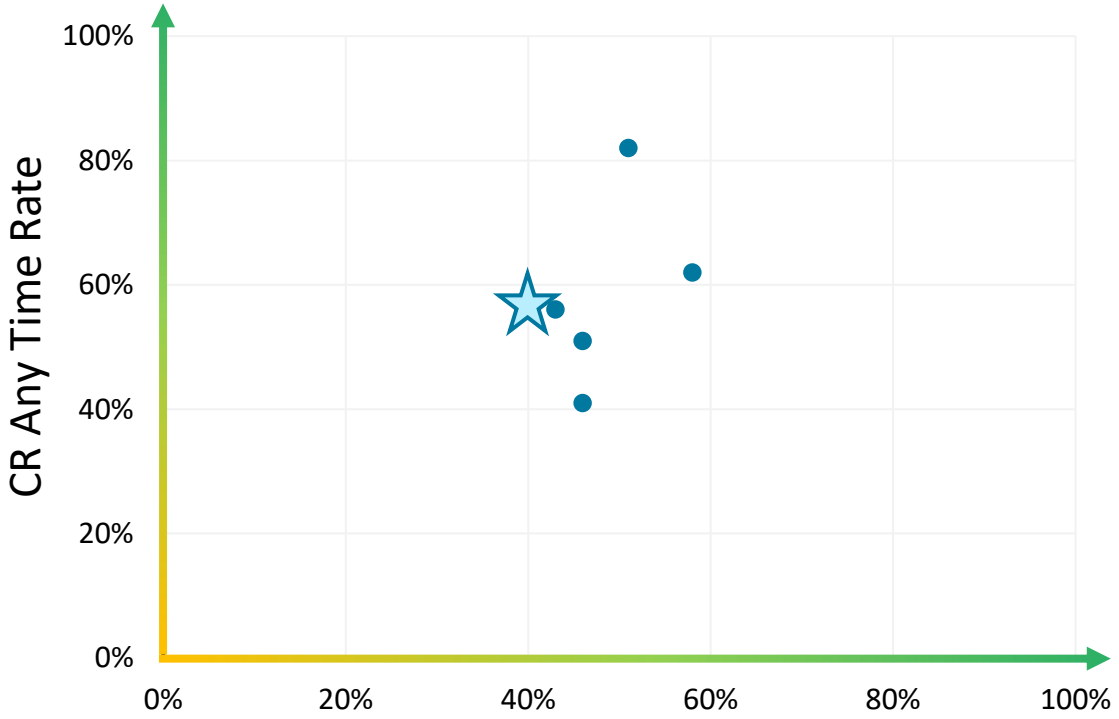
TRAEs leading to dose interruption or discontinuation were rare

4% dose interruptions (n=5)
1% discontinuation (n=1)

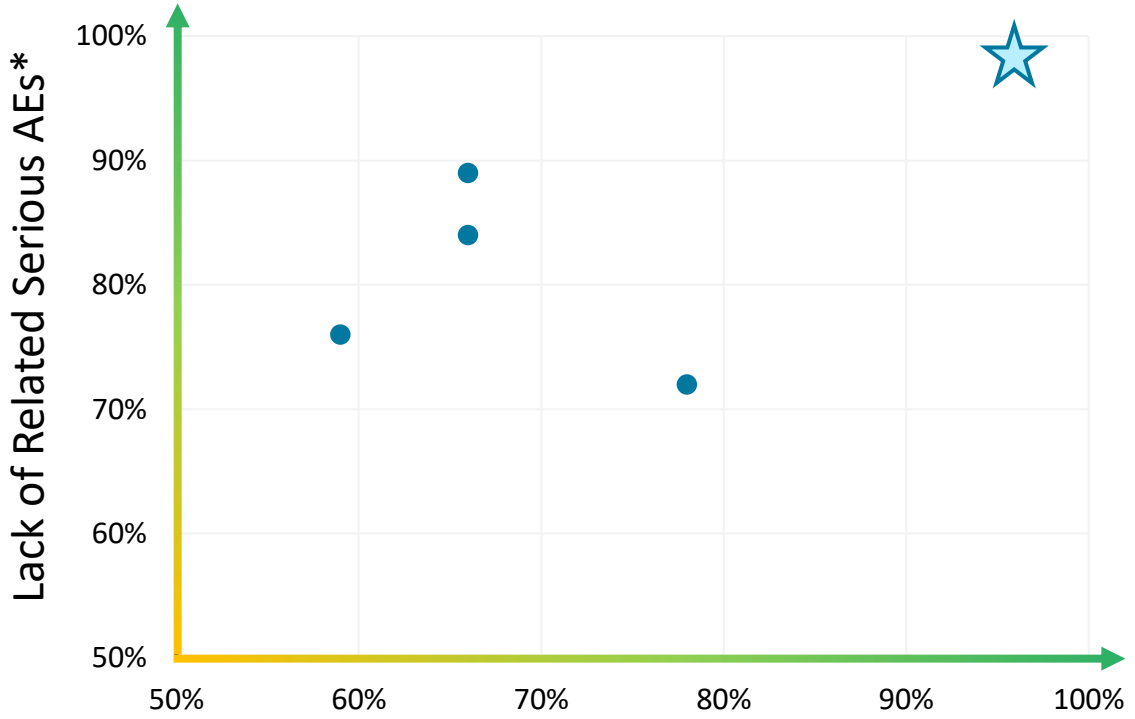
TRAE= treatment-related adverse event.
*One patient had a Grade 3 treatment-related pyelonephritis that led to a dose interruption. No grade 3 TRAEs led to discontinuation. There were no Grade 4/5 TRAEs.
Data as of 29 October 2026. Data collection and cleaning is ongoing.

Detalimogene Compelling Efficacy and Tolerability Profile

Efficacy of Detalimogene vs. Approved Drugs



Tolerability of Detalimogene vs. Approved Drugs



Detalimogene Approved Drugs

* Detalimogene dose interruptions associated with treatment related adverse events. Approved drugs interruptions associated with adverse drug reactions.
^For durability assessments, 1 year is defined as 358 to 365+ days. Nine patients are pending their response assessment. Patients are censored if have not yet had an assessment within 7 days of day 365 or beyond, or at the start of new anticancer therapy.
Deta = detalimogene; CR=complete response defined as negative cystoscopy and negative urine cytology, or positive cystoscopy/cytology with negative bladder biopsy. CI: 95% Confidence Interval; KM = Kaplan-Meier.
Data as of 29 October 2026. Data collection and cleaning is ongoing.

Detalimogene Efficacy Profile has Meaningfully Improved

Detalimogene is a next-generation non-viral gene therapy in development for HR NMIBC, designed to:

- **Reduce patient burden***: fewer visits, procedures, pre- or post-treatment precautions
- **Simplify urologist workflow**: administration, storage, handling

Detalimogene showed encouraging activity in heavily pre-treated participants with BCG-unresponsive NMIBC

- CR rate of 56% at any time
- CR rate of 24% at 12 months
- KM DOR ≥12 months est. 43%
- 100% of responders were free from progression to ≥T2 disease in the bladder
- 96% of responders remain free from cystectomy

Detalimogene was safe and very well tolerated

- Most TRAEs were brief, low-grade, lower urinary tract symptoms
- Serious TRAEs (2%) and grade 3 TRAEs (4%) were highly infrequent
- TRAEs leading to dose interruption (4%) or discontinuation (1%) were rare

Detalimogene has the potential to be a valuable treatment option for all patients

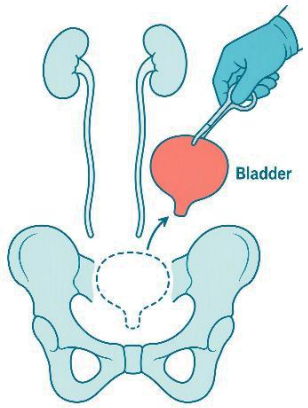
*Fewer visits and pre- post-treatment precautions compared to BCG.
Data is presented as available in the database as of 29October2026. Data Collection and Cleaning is ongoing and is subject to change.

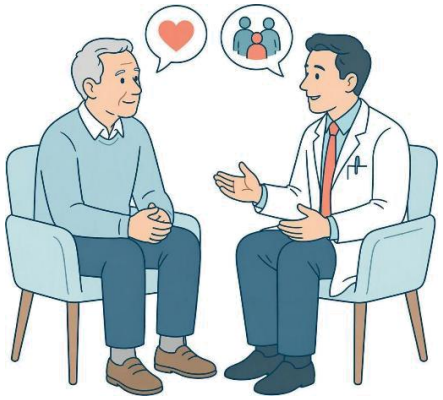
Commercial Opportunity

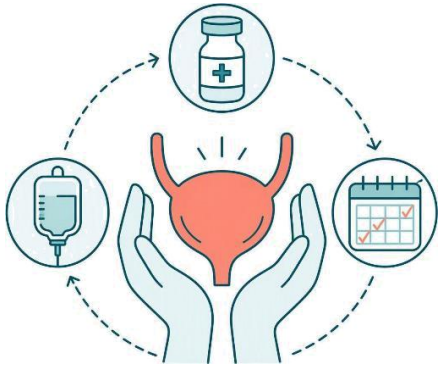
Grounded in Where Care Happens & How Decisions are Made

Detalimogene Go-to-Market Strategy











Settings of Care	Avoiding Cystectomy	Shared Decision Making	Treatment Options	Redefining Care Pathway
75% of HR BCG-UR NMIBC patients are seen in community settings	HR NMIBC is often “chronic” and highly recurrent - patients will do anything to avoid cystectomy	Urologists understand patients' priorities and select treatment together	Community urology practices do not have access to as many treatments as academic centers	No winner-takes-all. Recurrence will drive sequencing through multiple bladder-sparing therapies.

HR BCG-UR = High Risk BCG-Unresponsive.
Source: enGene market research, New Faces of Bladder Cancer Report 2025 (BCAN).

November 2026: LEGEND Pivotal Cohort Interim Data Update

Vision: Detalimogene to Redefine Care in Community Practices

01

Clinical value

A meaningful and tolerable bladder-sparing option for all patients, supported by a differentiated **non-viral MOA** profile.

02

Practice value

Office-ready workflow, requires no new infrastructure and lower post-treatment burden.

Designed to meet real world community treatment challenges.

03

Patient value

Alignment with future sequencing and the desire to keep appropriate patients in **community care**.

04

Economic value

Potential for **favorable net cost recovery** with manufacturer support and flexible terms to support practices facing increasing financial and capacity pressures.

Designed for real-world community practice, enabling more patients to remain on a bladder-sparing path.

Clinical value references data presented as available in the database as of 29October2026. Data Collection and Cleaning is ongoing and is subject to change.

Detalimogene Value Could Be Demonstrated Across All Segments

Safe Handling, Standard Storage and Simple Logistics May Promote Adoption

1. Settings of Care | 2. Avoiding Cystectomy | 3. Share Decision Making | 4. Treatment Options | 5. Redefining Care Pathway

	Urology Segment	NMIBC Patients
Private Practices	**Resource-Limited Practices** Acquisition cost and logistical burden are gating	19% (~3,800)
Private Practices	**Workflow-Constrained Practices** Logistical burden is gating	11% (~2,200)
Private Practices	**Economics-Focused Practices** Net cost recovery drives treatment selection	11% (~2,200)
Private Practices	**Clinical Excellence Practices** Prioritize efficacy and safety	6% (~1,200)
	Health System / Hospital Prioritize efficacy and safety	29% (~5,800)
	Academic Medical Center Prioritize efficacy and safety	24% (~4,800)

75% of High-Risk BCG-Unresponsive NMIBC Patients are Treated in Community Urology Practices

Note: Assumes ~20,000 addressable NMIBC BCG-unresponsive patients. Resource-Limited, Workflow-Constrained, Economics-Focused, and Clinical-Excellence all represent urology private practice.
Source: enGene market research (third party claims analysis of real-world data of >2,000 patient claims).

Shared Decision Making with Patients Occurs Across All Practice Settings

	Urology Segment	NMIBC Patients	
Private Practices	**Resource-Limited Practices** Acquisition cost and logistical burden are gating	19% (~3,800)	**Shared Decision Making**
Private Practices	**Workflow-Constrained Practices** Logistical burden is gating	11% (~2,200)	
Private Practices	**Economics-Focused Practices** Net cost recovery drives treatment selection	11% (~2,200)	
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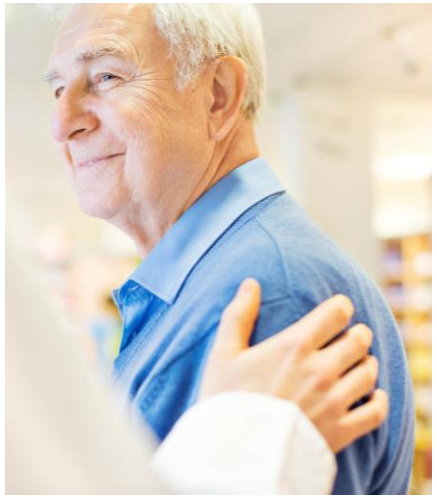
Source: enGene market research (third party claims analysis of real-world data of >2,000 patient claims).

High Risk NMIBC is a Long Journey

Trusted Urologist-Patient Relationship Built Over Time to Maintain Treatment Goals

1. Settings of Care | **2. Avoiding Cystectomy** | 3. Share Decision Making | 4. Treatment Options | 5. Redefining Care Pathway



Patients to seek effective **bladder-sparing options** that allows them to maintain their lifestyle

JAN 2024 | INITIAL PRESENTATION

JAN 2024 - May 2024
- BCG Induction
- + 1 maint.

(BCG-exposed – relevant)

July 2024
- **Lost to follow up for 1 yr**

June 2025 | RECURRENCE

JULY 2025 - NOV 2025
- Gem/doce induction IVI × 6
- 2x monthly maint.

NOV 2025 | RECURRENCE

DEC 2025 – SEP 2026
- BCG Induction IVI x 6
- + 2 Maint. Cycles

SEP 2026 | RECURRENCE
- **BCG Unresponsive CIS**

Treatment Selection Guided by Patient Priorities and Practice Capabilities

No Winner Takes All – Patients and Urologists Consider Many Factors

1. Settings of Care | 2. Avoiding Cystectomy | 3. Share Decision Making | 4. Treatment Options | 5. Redefining Care Pathway

First, understand the patient and the practice, then, discuss all options



Treatment Burden

Weigh visit frequency, doses, and duration against the patient's daily life and the practice's capacity to deliver



Efficacy

Compare bladder-preserving options in the context of long-term disease management and sequencing



Safety & Tolerability

Consider tolerability in an already-irritated bladder, and what monitoring the practice can support



Care Setting

Compare community care with referral to an academic center, considering continuity of care, convenience, and access



Insurance Coverage

Confirm which treatments the patient’s insurance will cover

Detalimogene's Profile To Date Aligns with Key Treatment Considerations

1. Settings of Care | 2. Avoiding Cystectomy | 3. Share Decision Making | 4. Treatment Options | 5. Redefining Care Pathway

	DETALIMOGENE OFFERING
Treatment Burden	**Shorter treatment time** (1hr vs. 2hr dwell) and **fewer doses** (4 vs. 6) in 12-week cycle than required for BCG
Efficacy	Unique MOA with complete response rate at any time and duration of response **similar to approved options**
Safety & Tolerability	**Potentially best in class tolerability** with the lowest reported rates of treatment related serious AEs, dose interruptions, and dose discontinuations
Care Setting	One of the few therapies that could be offered across all settings of care due to **favorable handling & logistics**
Coverage / Access	Coverage and NCCN guideline unknown, but **insurance coverage parity expected** across options assuming NCCN 2A status

Data is presented as available in the database as of 29October2026. Data Collection and Cleaning is ongoing and is subject to change.

Detalimogene is a Potential Low Burden & Convenient Option for Patients

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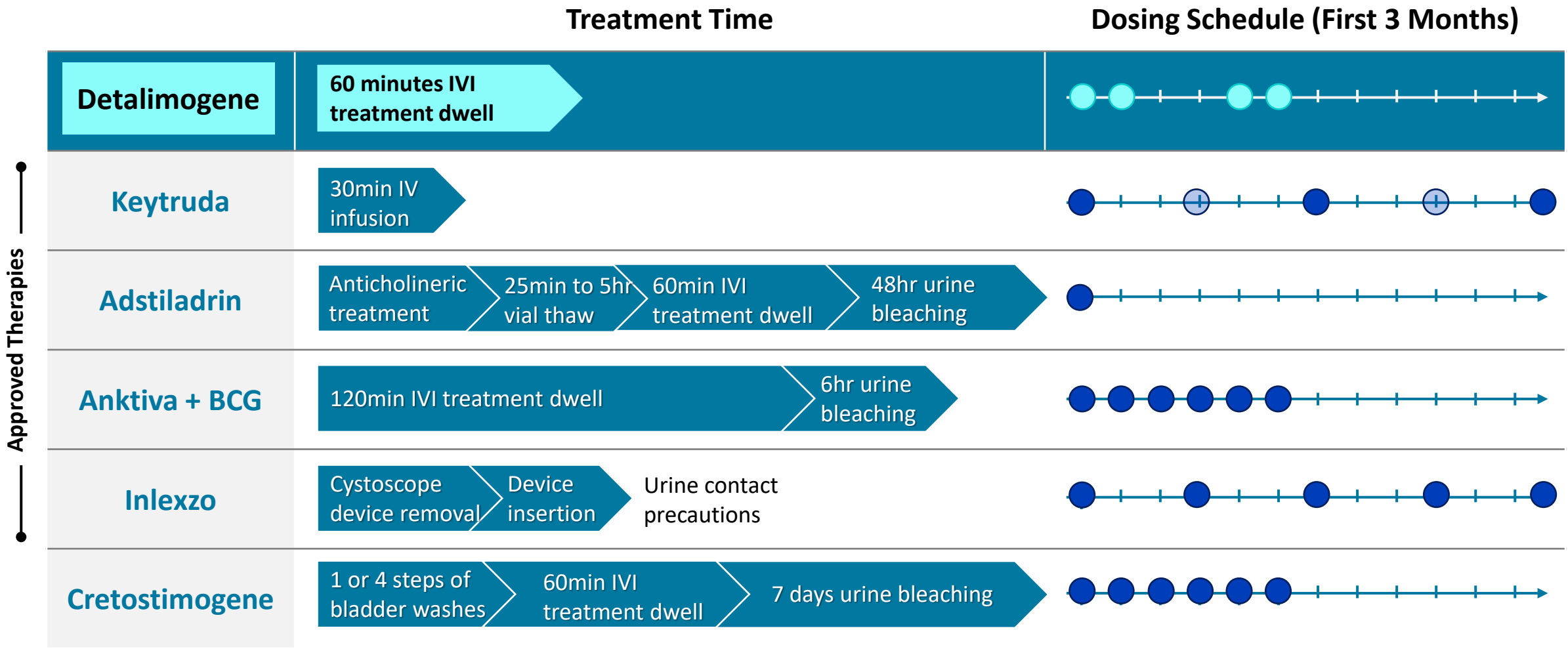

Source: Derived from product SOPIs and clinical trial publications. Not based on head-to-head or comparator studies, Cretostimogene Grenadenorepvec in Urology Practice Workflows (SUNA Urology Alliance, accessed Oct 27, 2026)
IVI = Intravesical.

November 2026: LEGEND Pivotal Cohort Interim Data Update

A Future Where Recurrent NMIBC Patients Can Keep Their Bladders Longer

Patients will Sequence Therapies Resulting in Enhanced Long-Term Care

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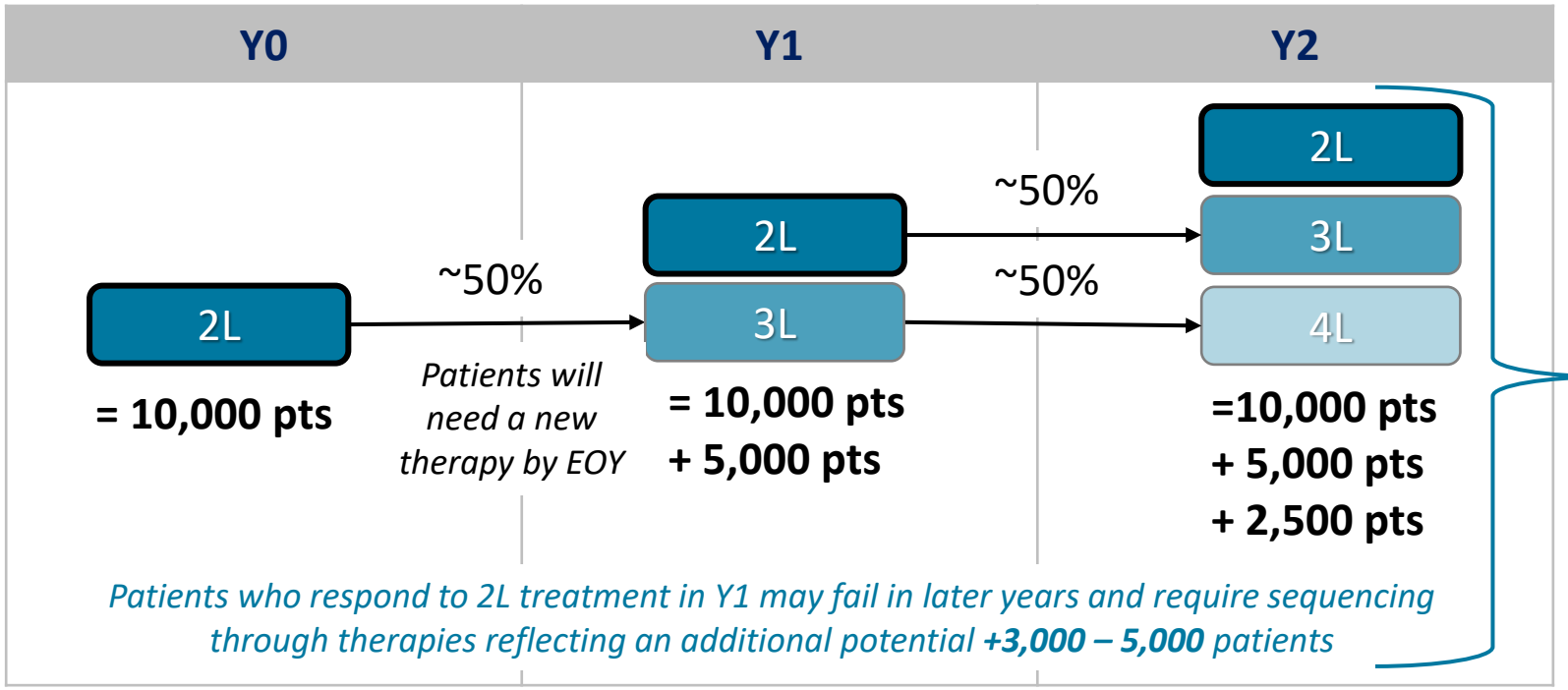
All interviewed urologists will sequence patients through 3-4L of therapy before radical cystectomy

89% patients would try anything to **avoid radical cystectomy**

Illustration of High-Risk BCG-Unresponsive Patient Sequencing



Note: Interviews n=22 urologists. The rate of patients requiring a 3L/4L therapy could be anywhere from 75% - 35% depending on which therapy they receive and rate of radical cystectomy.
Source: enGene market research (interviews, surveys, and claims data), other NMIBC company estimates, Harris Poll NMIBC Patient Preference Survey (November 2025, n=200 patients).

Sequencing & Shared Decision Making Creates a New Care Pathway

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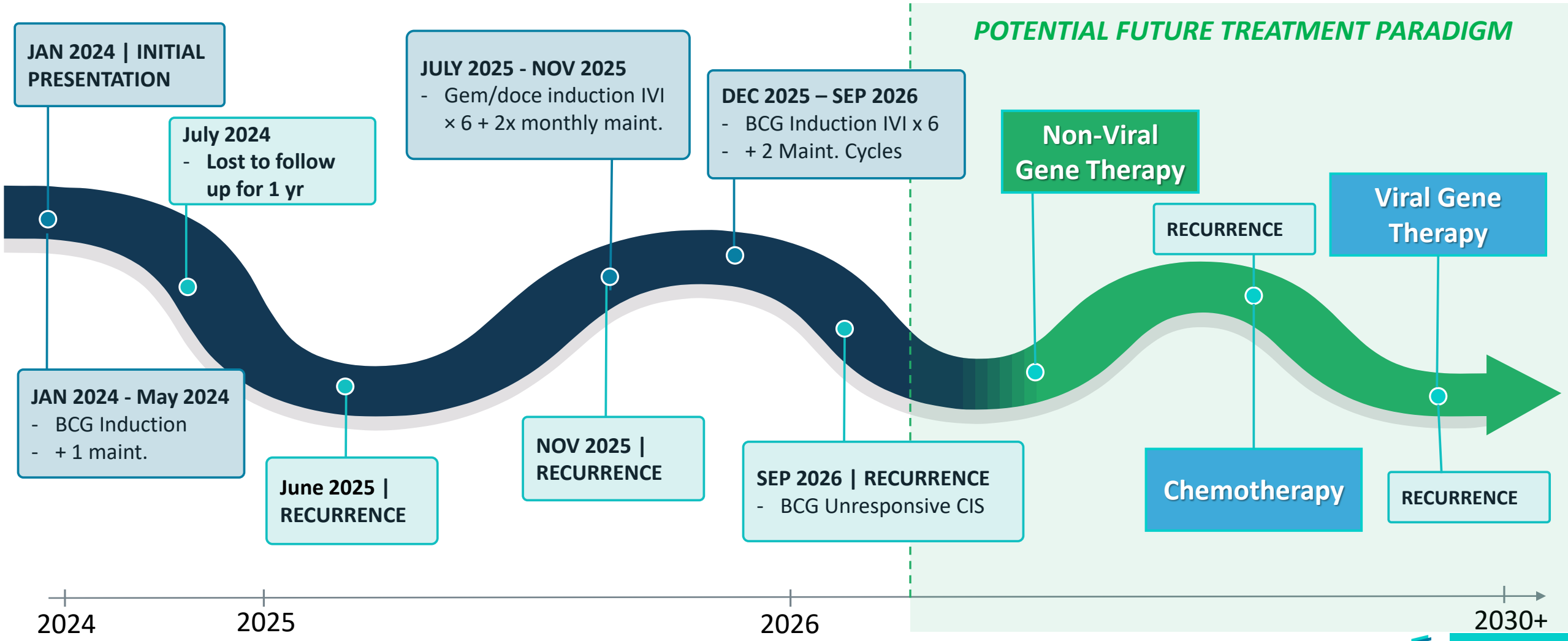

NCCN Guideline 2A Dictates Payer Coverage at New Price Point

Interviewed Payers Cover Therapies at Parity at New Price Point Assuming Category 2A

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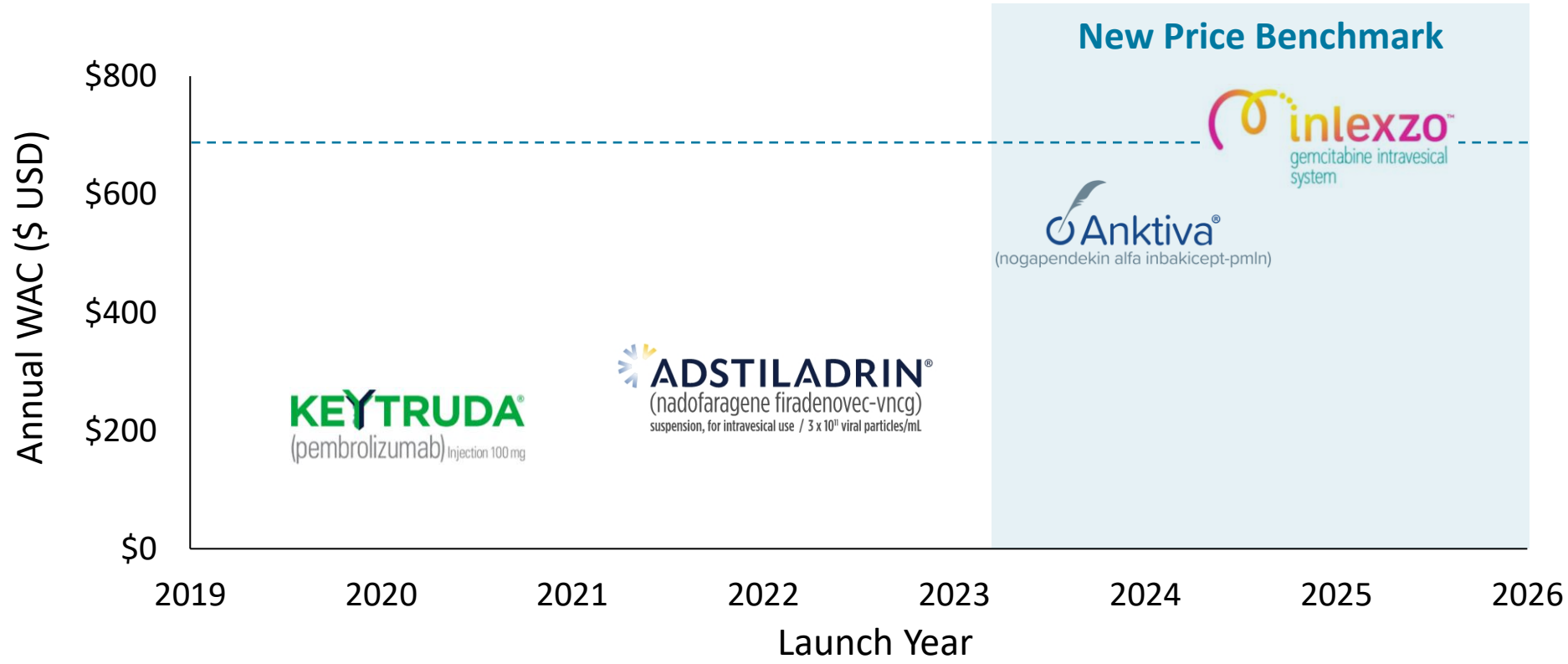

$1 Billion Net Sales with ≈2,000 Patients at New Price Point

Note: WAC = wholesale acquisition cost. Keytruda®, Adstiladrin®, Anktiva®, Inlexzo® are trademarks of their respective owners. New price point assumes price of ~$650K-$700K/per patient per year. Assume gross-to-net discount of 21% and therefore a net price of $545,000 per year. Source: enGene market research.

Vision: Detalimogene to Redefine Care in Community Practices

01

Clinical value

A meaningful and tolerable bladder-sparing option for all patients, supported by a differentiated **non-viral MOA** profile.

02

Practice value

Office-ready workflow, requires no new infrastructure and lower post-treatment burden.

Designed to meet real world community treatment challenges.

03

Patient value

Alignment with future sequencing and the desire to keep appropriate patients in **community care**.

04

Economic value

Potential for **favorable net cost recovery** with manufacturer support and flexible terms to support practices facing increasing financial and capacity pressures.

Designed for real-world community practice, enabling more patients to remain on a bladder-sparing path.

Clinical value references data presented as available in the database as of 29October2026. Data Collection and Cleaning is ongoing and is subject to change.

Segmentation and Value Pillars Inform Field Force Deployment

Account Characterization

~14,600
Practicing Urologists

75%
treat bladder cancer

Resource-Limited Practices
Workflow-Constrained Practices
Economics-Focused Practices
Clinical Excellence Practices
Health System / Hospital
Academic Medical Center

~11,000
Bladder Cancer Urologists

Value Pillars

01 Clinical value
Bladder-sparing, tolerable, differentiated non-viral profile

02 Practice value
Office-ready workflow with limited new infrastructure

03 Patient value
Supports sequencing and keeps patients in community care

04 Economic value
Favorable net cost recovery with flexible terms

Field Force



Field Force Planning: 40-60 Reps

40 Reps
~270 urologists / rep

60 Reps
~180 urologists / rep

Mapping out top accounts

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Value Pillars Inform enGene Commercialization Strategy

Clinical Value

Practice Value

Patient Value

Economic Value

DETALIMOGENE HYPOTHESIS

Commercial potential is driven by our broad alignment to the needs of all urologists

Clear Differentiation

- Clinical Efficacy
- Tolerability
- Operational Simplicity
- Practice Economics
- Low Patient Burden

FDA	Following a positive pre-BLA meeting enGene is working towards initiating BLA filing Q4 2026
Prescribers	Identifying key sites and account characterization engagement strategy
Education & Awareness	MSLs in field, education and scientific engagement
Field	Evaluation of precise and efficient field organization

Closing Remarks

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 of Response and Reduce Patient Burden
Near-Term Planned Catalysts	BLA Initiation: Q4 2026 Potential Approval Decision & Platform Designation: 2027 Surfactant Cohort 6-month Data: Mid-2027

Detalimogene product profile references data presented as available in the database as of 29October2026. Data Collection and Cleaning is ongoing and is subject to change.
Sources: Transparency market research NMIBC Market Outlook 2034.

enGene

Thank You