



Corporate Presentation
September 2025

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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 deemed sufficient to permit further testing, the limited, early Phase 1 testing to date is not a sufficient basis on which to predict efficacy or safety. 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 results of Phase 2 clinical testing, which are not expected to be available until 2026.

Detalimogene Voraplasmid for NMIBC

Designed to be a practice-changing therapy requiring no change in practice

Transformational Market Opportunity



**NMIBC market
forecasted to be >\$20B**

Near Term Commercial Opportunity

Anticipated Milestones:

Pivotal Cohort Update: Q4 2025

Cohort 2 & 3 Updates: Q4 2025

BLA Filing: H2 2026

Potential Launch: 2027

Highly Differentiated Investigational Product

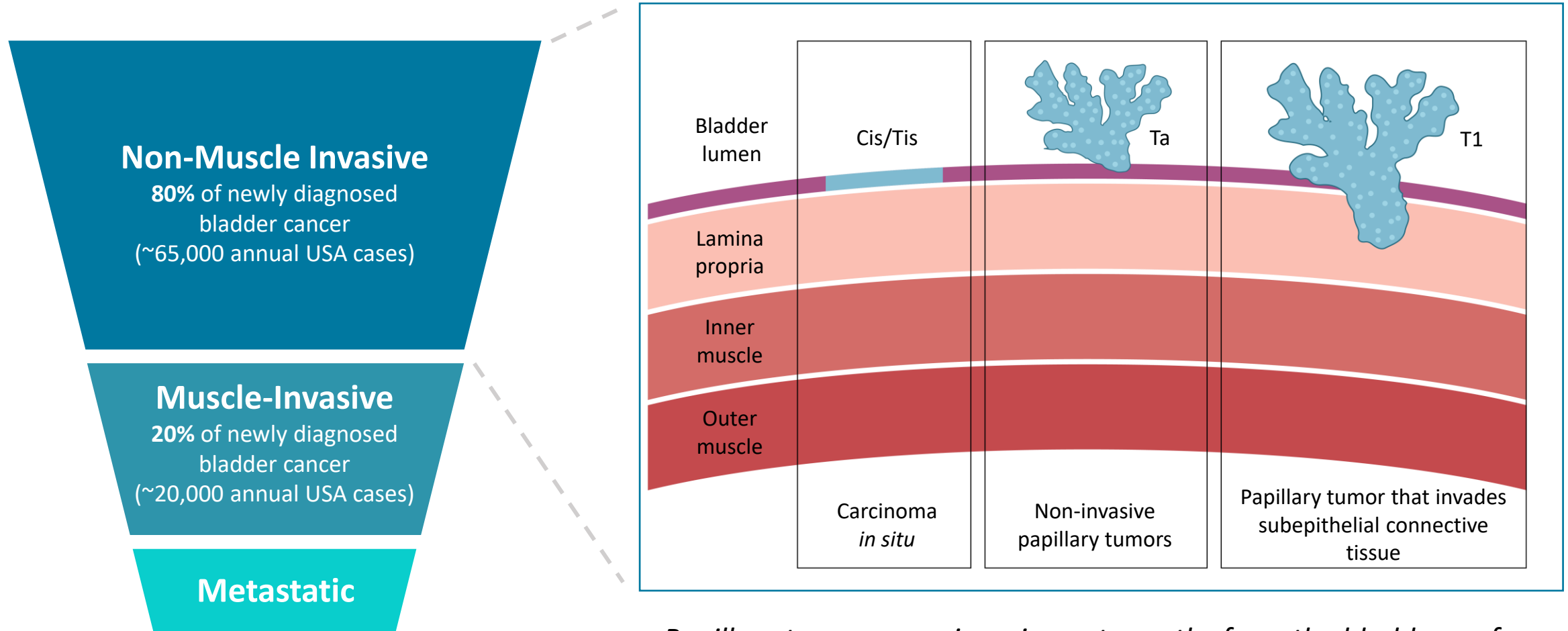


**Unique combination of clinical
activity, tolerability, ease of use**

Well-capitalized, with runway projected into 2027

NMIBC Represents 75-80% of Bladder Cancer Diagnosis

Estimated Bladder Cancer US Prevalence: ~730,000 Patients



- Papillary tumors: non-invasive outgrowths from the bladder surface
- Carcinoma in situ (CIS): flat, aggressive cancer that is not easily removed

Bladder Cancer- High Incidence, High Prevalence, High Cost to Society

Rank by Incidence	Indication
1	Breast
2	Prostate
3	Lung
4	Colorectal
5	Melanoma
6	Bladder
7	Kidney/Renal
8	Lymphoma (NHL)
9	Uterus
10	Pancreas

Bladder Cancer is among the most expensive cancers to manage per patient:



Estimated >\$6.5B
total annual cost US

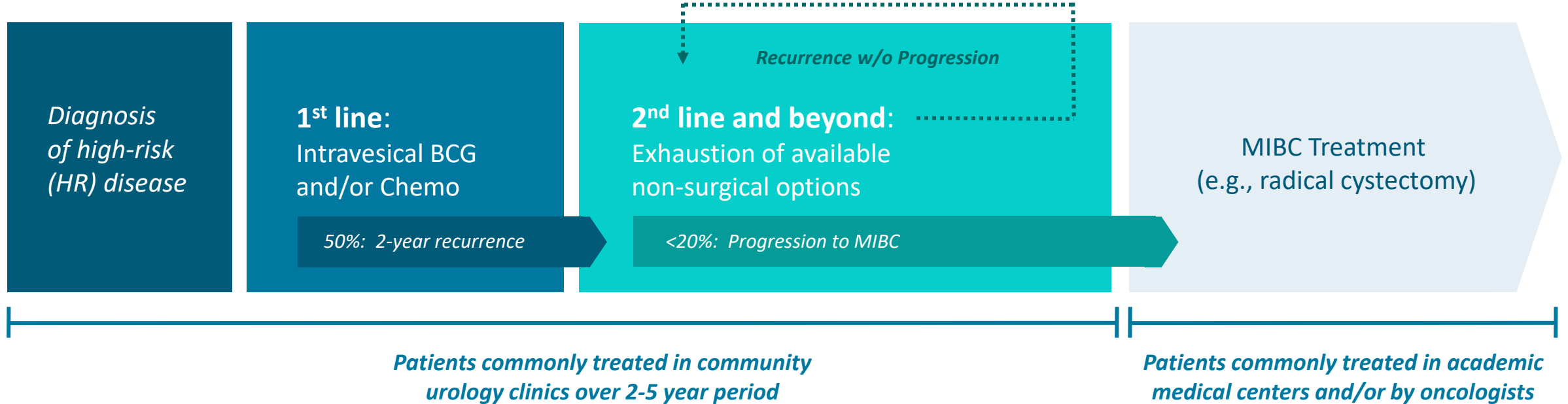


Top-10 Cancer
by US Incidence

Sources: Mossanen M, Gore JL, Curr Opin Urol. 2014 Sep;24(5):487-91; Clark O et al., Pharmacoecon Open. 2024 Aug 18; <https://seer.cancer.gov/statfacts/html/common.html#comparison>

High-Risk NMIBC: A Multi-year Journey Managed by Community Urologists

Goal: Treat Multiple Recurrences Non-Surgically and Delay Radical Cystectomy



- ~20% Progression over 10 years from NMIBC to MIBC
- 70-80% of urologists practice in community clinics

Radical Cystectomy: Life-Transforming Surgery of Last Resort



Image of Radical Cystectomy Surgery

- 10% mortality rate, 6-8 hour inpatient surgery
- High morbidity and complication rate:
 - Sexual dysfunction
 - Urostomy
 - Body image
 - Depression
 - Anxiety

Radical Cystectomy remains standard-of-care for BCG-Unresponsive High-Risk (HR) NMIBC with Cis

Currently Available Non-Surgical Treatments Have Major Limitations

1 st Line Treatment	Factors Limiting Use
BCG-TICE	Chronic global shortage leads to inadequate treatment and rationing
Intravesical Chemo (e.g., gemcitabine, mitomycin)	Poor efficacy and tolerability; used as BCG backstop
2 nd Line Treatment	Factors Limiting Use
Pembrolizumab (Keytruda)	Systemic agent; requires multi-disciplinary care teams to manage serious immune AEs (not available at most urology clinics)
Nadofaragene firadenovec-vncg (Adstiladrin)	Viral gene therapy; complex handling and storage, history of limited availability
nogapendekin alfa inbakicept-pmln (Anktiva)	Requires co-administration with BCG, which is subject to rationing

NMIBC Market Forecast based on internal estimates utilizing multiple source data

Additional Sources: Schneider, Bryan J., et al. J Clin Onc 39.36 (2021): 4073-4126; Merck Press Release (<https://www.merck.com/stories/facing-a-global-shortage-merck-commits-to-meeting-patient-demand/>); <https://www.auanet.org/about-us/bcg-shortage-info>; product USPI

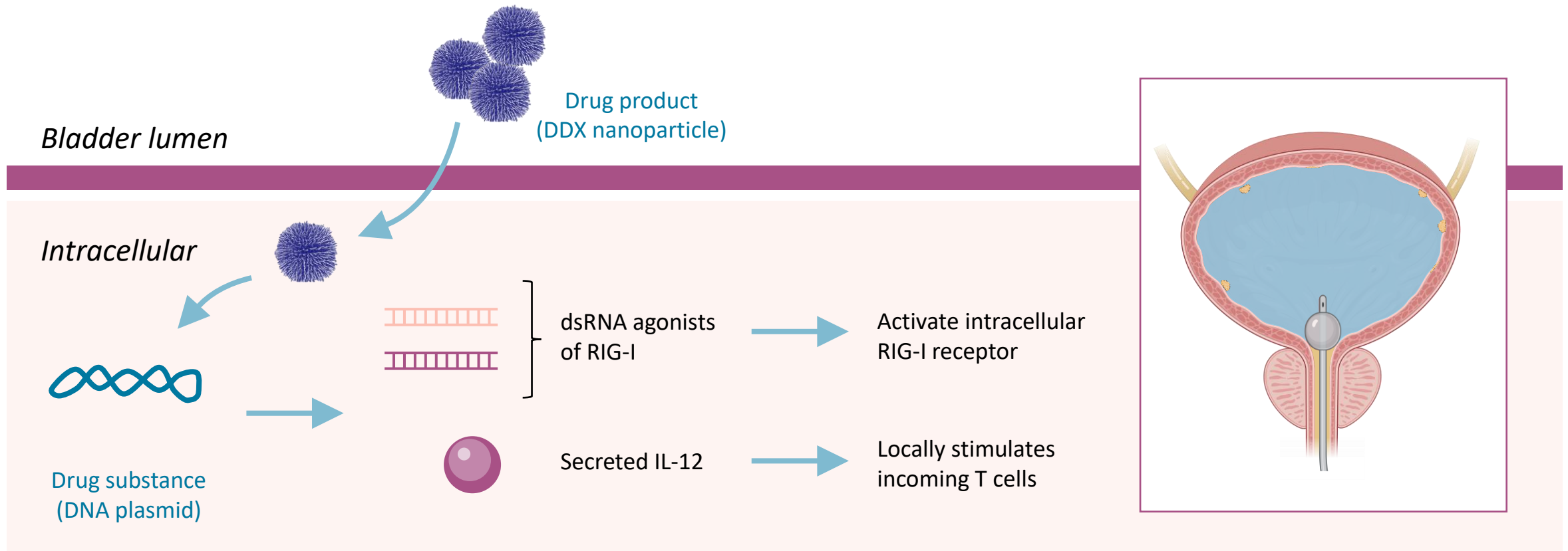
Detalimogene: Non-viral Investigational Therapy Designed To Be the First-Choice



- **Clinical activity and durability demonstrated:** Promising preliminary data from pivotal arm of LEGEND study*
- **Favorable safety profile observed:** LEGEND TRAEs were generally mild, largely instrumentation-related**
- **Potential best-in-class ease-of-use:** Non-viral genetic medicine; no specialized handling or cold-chain storage
- **Well-characterized, scalable manufacturing:** Cost-effective process supports wide availability

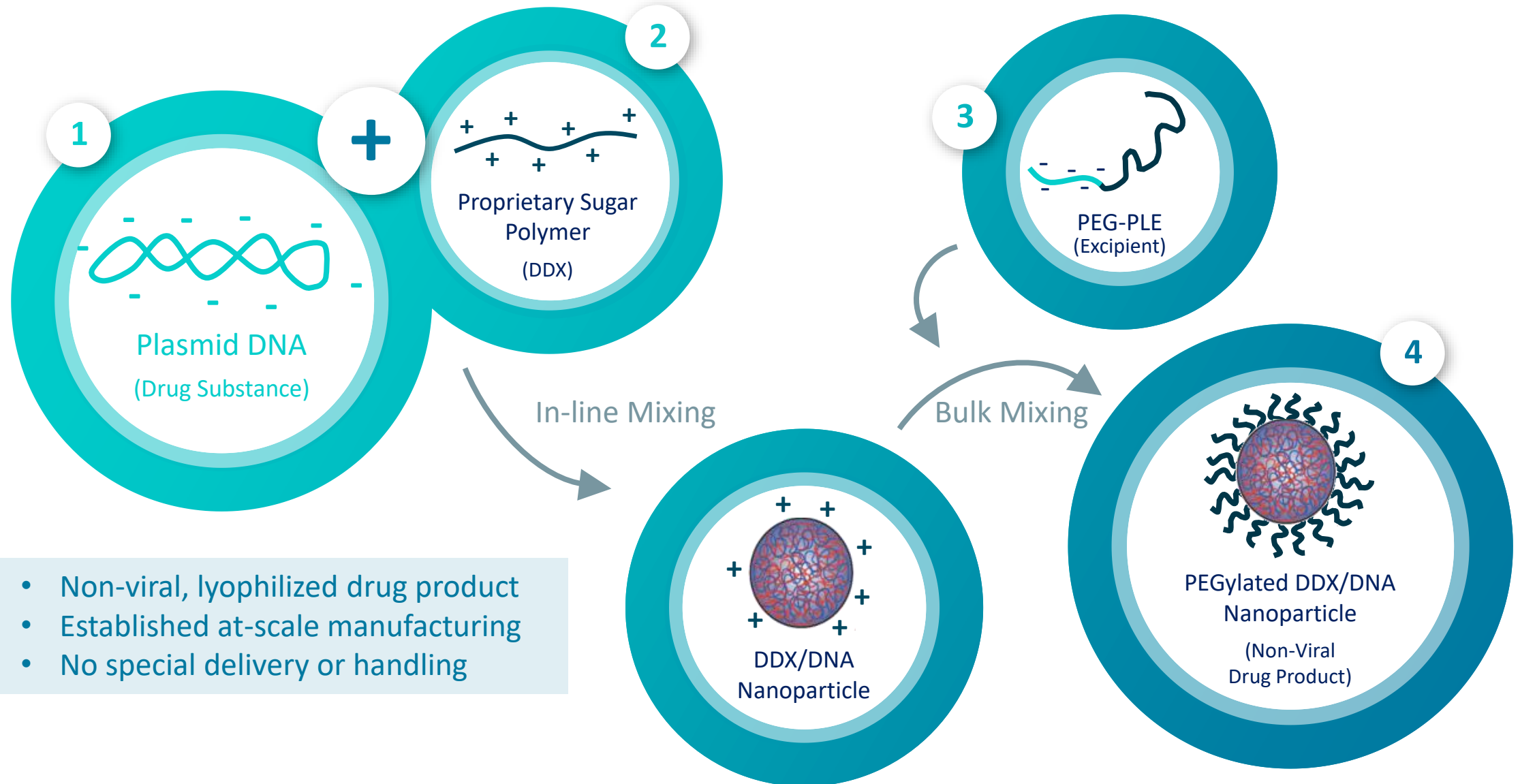
Detalimogene: Potential first-choice agent for urologists in a multi-year, multi-drug treatment journey, if approved

Non-Viral Activation of Both Innate and Adaptive Immunity

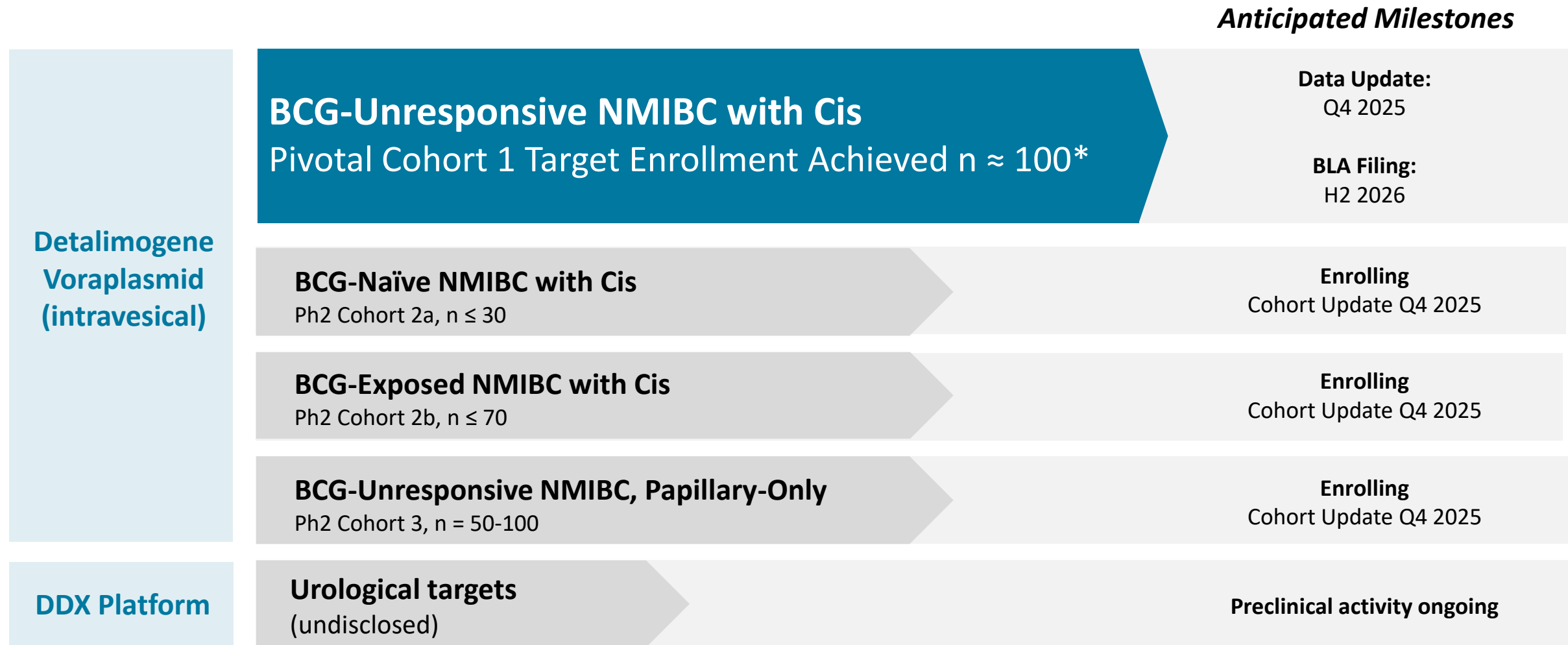


Unique mechanism of action uses DNA plasmid to encode large payload of three genes

Industrial-Scale, Well-Characterized Manufacturing Process



Multiple LEGEND Cohorts Demonstrate Detalimogene's Potential



Comprehensive IP Portfolio Through at Least 2040



Pivotal Study

Target Enrollment Achieved¹

Patients:

BCG-Unresponsive High-risk NMIBC with CIS

Design:

Global, single-arm, open label N $\approx$ 100

Dosing²:

- Year 1: 800 μ g/ml IVe at weeks 1,2,5,6 Q3M
- Year 2-3 (Maintenance): 800 μ g/ml IVe at weeks 1,2 Q3M

Primary Endpoints:

CR rate at 12-months; safety

1: Patients in the screening process remain eligible for potential enrollment in the trial.

1: IVe = Intravesical. LEGEND allows patients from any cohort who are in complete response at 12 months to continue receiving detolimogene on a dose-reduced maintenance schedule throughout their second year of treatment. At the end of year two, patients may optionally elect to remain on maintenance therapy for another year, for a total of three years of therapy.

LEGEND Pivotal Cohort Patient Demographics

Baseline characteristic	N=21
Gender, n (%)	
Male	15 (71.4)
Female	6 (28.6)
Age, years	
Mean (SD)	72.7 (9.4)
Median (range)	74 (59, 92)
Age categories, n (%)	
≤65	6 (28.6)
>65	15 (71.4)
ECOG, n (%)	
0	19 (90.5)
1	2 (9.5)
BCG Doses	
Median	11
Range	8, 33
Tumor Stage, n (%)	
T1 + Cis	3 (14.3)
Ta + Cis	3 (14.3)
Cis	15 (71.4)

Detalimogene was Generally Well-Tolerated in the LEGEND Study

(n = 42*)	Any Grade	Grade 1	Grade 2	Grade 3	Grade 4/5
Patients with ≥ 1 TRAE	20 (47.6%)	17 (40.5%)	9 (21.4%)	0 (0.0%)	0 (0)
TRAE Reported in >10% patients:					
Bladder Spasm	8 (19%)	4 (9.5%)	4 (9.5%)	0 (0)	0 (0)
Dysuria	9 (21.4%)	8 (19.0%)	1 (2.4%)	0 (0)	0 (0)
Fatigue	5 (11.9%)	3 (7.1%)	2 (4.8%)	0 (0)	0 (0)
Pollakiuria	5 (11.9%)	5 (11.9%)	0 (0)	0 (0)	0 (0)

- **No patient discontinuations due to TRAEs**
- **Favorable safety and tolerability profile**
- **TRAEs were reversible and largely consistent with catheterization**

TRAE = Treatment-Related Adverse Event

*Across all dosed patients in all LEGEND Phase 2 cohorts as of September 13, 2024 data cut-off

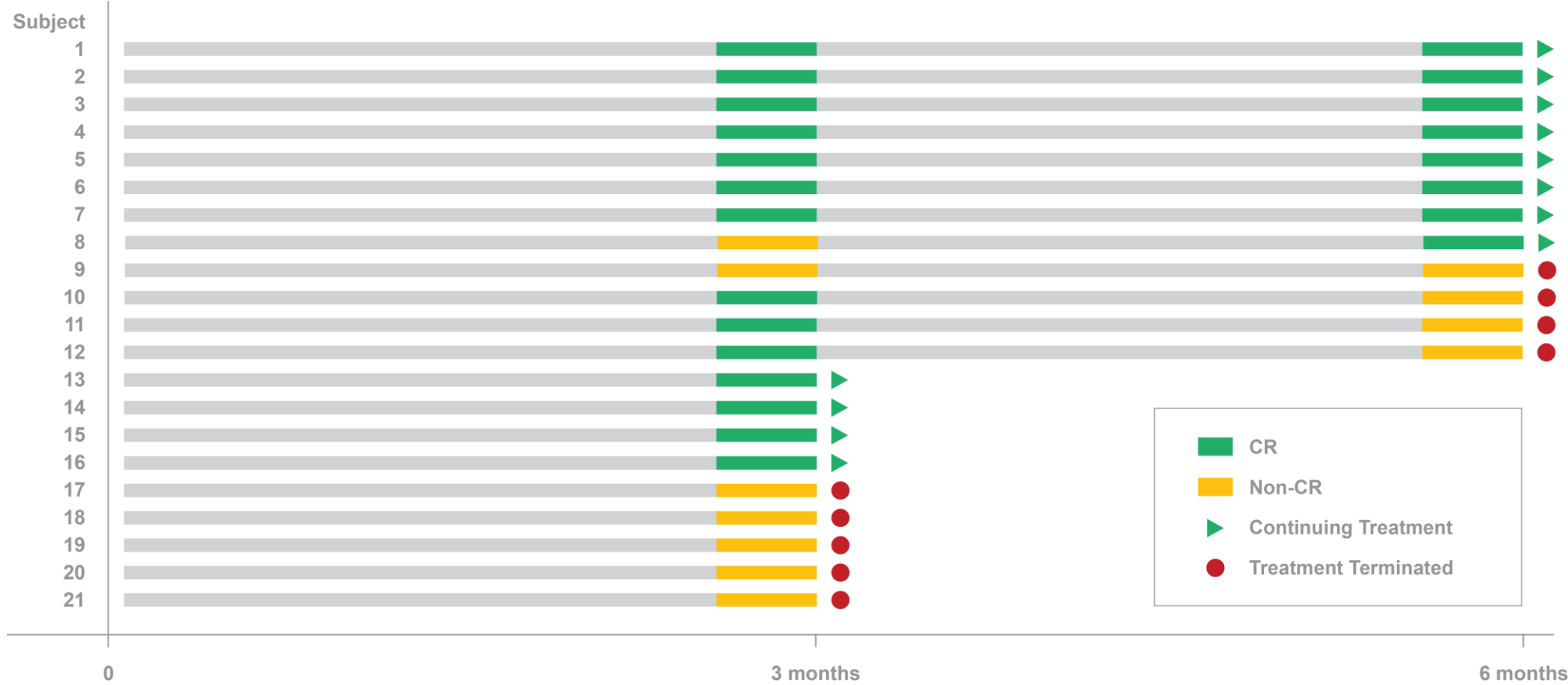
Treatment Related AEs of Approved and Investigational NMIBC Agents

	Detalimogene	Cretostimogene		TAR-200 ³	Keytruda ⁴	Adstiladrin ⁵	Anktiva + BCG ⁷
Trial	LEGEND	BOND-002 ¹	BOND-003 ²	SunRISe-1	KEYNOTE-057	NCT02773849	QUILT 3.032
Sample Size	N = 42	N = 67	N = 112	N = 85	N = 101	N = 157	N = 88
TRAEs (Any Grade)	48%	57%	63%	84%	66%	Not disclosed	Not disclosed
TRAEs (≥ Grade 3)	0%	5%	0%	13%	13%	<4% ⁶	3% ⁸

These data are presented for informational purposes and are not based on any head-to-head or comparator clinical studies. Cross-trial comparisons are inherently limited and may suggest misleading similarities or differences. Accordingly, no direct comparisons can be made.
 As of the LEGEND Study’s preliminary analysis of the pivotal cohort (data cutoff Sept 13th, 2024). 1: Packiam et al. Uro Onc, Vol. 36, 10 (2018):440-447. 2: CG oncology BOND-003 Investor Call presentation, accessed May 1. 3: Johnson & Johnson Apr 26, 2025 Press Release 4:; Balar et al, Lancet Onc, Jul;22(7):919-930. 5: Adstiladrin USPI, N = 157. 6: Ferring May 6, 2024 Press Release 7: Anktiva USPI, 8: ImmunityBio Apr 28, 2025 Press Release.

Detalimogene: Preliminary Pivotal Efficacy Results

Any Time	3 Month (n=21)	6 Month (n=17)	6 Month KM Estimate
71% CR Rate	67% CR Rate	47% CR Rate	51% CR Rate



Data relate to 3m and 6m efficacy-evaluable patients available as of September 13, 2024
KM = Kaplan-Meier Analysis; CR = Complete Response

LEGEND Protocol: Revisions Aligned with Treatment Standards

Focus Area	Prior LEGEND Protocol	Current LEGEND Protocol*
T1 disease at pre-enrollment screen	• Surgically resect lesion via TURBT • Enroll patient	• <i>Perform 2nd resection at lesion site and restage</i> • If T1 disease present, patient ineligible
Ta disease detected at 3 months	• Response deemed “Progressive Disease” • Discontinue patient from study	• Surgically resect lesion via TURBT • <i>Re-induce patient with detolimogene</i>
Assessment of Suspected Cis or other disease at 6 months	• Patient may be discontinued from study based only on visual impression of Cis	• <i>Discontinuation requires pathology confirmation of disease</i>

Detalimogene: Preliminary LEGEND Pivotal Data Show Promising Clinical Activity

	Detalimogene	Cretostimogene		TAR-200	Keytruda	Adstiladrin	Anktiva + BCG
Trial	LEGEND	BOND-002 ¹	BOND-003 ²	SunRISe-1 ³	KEYNOTE-057 ⁴	NCT02773849 ⁵	QUILT 3.032 ⁶
CR Rate, Anytime	71%	65%	76%	82%	41%	51%	62%
CR Rate, 6m	47%	44%	63%	59% ⁷	34%	41%	59%
CR Rate, 12m	TBD	28%	46%	46%	19%	24%	45%
Sample Size	N = 21	N = 46	N = 110	N = 85	N = 96	N = 98	N = 77

Before Protocol Refinement

Protocol Refinement

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*As of the LEGEND Study’s preliminary analysis of the pivotal cohort (data cutoff Sept 13th, 2024). 1: CG AUA 2023 Presentation. 2: CG oncology BOND-003 Investor Call presentation, accessed May 1. 6m CR rate derived from internal calculation based on BOND-003 investor presentation. 3: Johnson & Johnson Apr 26, 2025 Press Release. 4: Based on Keytruda USPI. 6m and 12m CR rates represent enGene-derived CR estimates based on data available in Balar et al., Lancet Onc 2021 Jul;22(7):919-930; 5: Based on Adstiladrin USPI. 6m and 12m rates from Boorjian et al, Lancet Onc 2021 Jan;22(1):107-117 with N=103 . 6: Based on Anktiva USPI. 6m and 12m CR rates represent enGene-derived CR estimates based on data available in Chamie et al., NEJM 2023 Jan;2(1):EVIDoa2200167. 7: Daneshmand et al., J of Clin Oncol 2025 Jul; 00:1-11.

Previous Single-Arm, Open-Label Studies Have Sufficed for FDA Approval*

	Pembrolizumab (Keytruda)	Nadofaragene firadenovec (Adstiladrin)	Nogapendekin alfa inbakicep (Anktiva) + BCG
Approval Date	January 2020	December 2022	April 2024
Study Design	Single Arm, Open label	Single Arm, Open label	Single Arm, Open label
Efficacy Evaluable Patients (N)**	96	98	77
12 Month Complete Response	19%	24%	45%



August 2024 Draft Guidance reconfirms single arm open label study sufficient for approval

* For BCG-unresponsive High-Risk NMIBC with Cis

** Study sizes reported based on evaluable patients as describe on USPI

Sources: Balar et al., Lancet Oncology 2021, 22:919-30; Boorjian et al. 2022 Lancet Oncology 2021 22(1) 107-17; Chamie, Karim, et al. NEJM evidence 2.1 (2022): EVIDoa2200167

Detalimogene: Designed to be the Urologist's and Patient's First Choice



Practical and
Differentiated Therapy
Designed for Busy Clinics



Clinical Activity
and Durability
Observed*



Generally
Favorable AE
Profile Observed*



Ease of Use for
Urologists and
Patients

Urologist-Friendly Design: Ideal For Use Early in Treatment Sequence



Detalimogene

- Clinical activity observed[†]
- Generally well-tolerated[†]
- “Off-the-shelf” ease of use

Cretostimogene*

- Complex process
- Cold chain storage possibly required
- Oncolytic virus biosafety (BSL-2)
- Possible need for urine, facilities decontamination

Detergent dwell + administration

TAR-200

- Procedure room and cystoscopy likely required to place and remove
- ≥Grade 3 AEs

Insertion and removal every 3 weeks

Adstiladrin**

- Clinic logistics of vial thaw
- Risk of financial loss due to prepared product expiry
- Premedication, biosafety precautions, urine bleaching

Estimated 4-10 hour total process

[†] LEGEND phase 1 and preliminary pivotal reported data

* BSL2-like handling recommendations based on CG corporate presentation accessed April 30 2025 and precedent described in USPI for Imlygic, an FDA-approved, locally administered oncolytic virus, as well as handling recommendations for oncolytic viruses as reported by the Oncology Nursing Society. Detailed preparation and/or administration instructions have not yet been reported for cretostimogene. Other information based on CG Oncology’s non-confidential investor presentation.

** Based on USPI. Once thawed, Adstiladrin vial must be used within 24 hours. Adstiladrin prescribing information also advises that “persons who are immunocompromised or immunodeficient may be at risk for disseminated infection from ADSTILADRIN due to low levels of replication-competent adenovirus.” 4-10 hour total process estimated based on vial thaw requirement timing and estimated pharmacy preparation times.

Patient Friendly Design That Makes for Ease of Experience



Detalimogene

- One hour of chair time total
- No need to bleach urine
- No induction period

Cretostimogene*

- Virus exposure precautions likely
- Detergent dwell required
- Urine bleaching requirements not reported

Detergent dwell + administration

TAR-200

- Potential foreign body sensation when urinating
- Risk of additional discomfort or complications due to AE profile

Requires device insertion and removal

Adstiladrin**

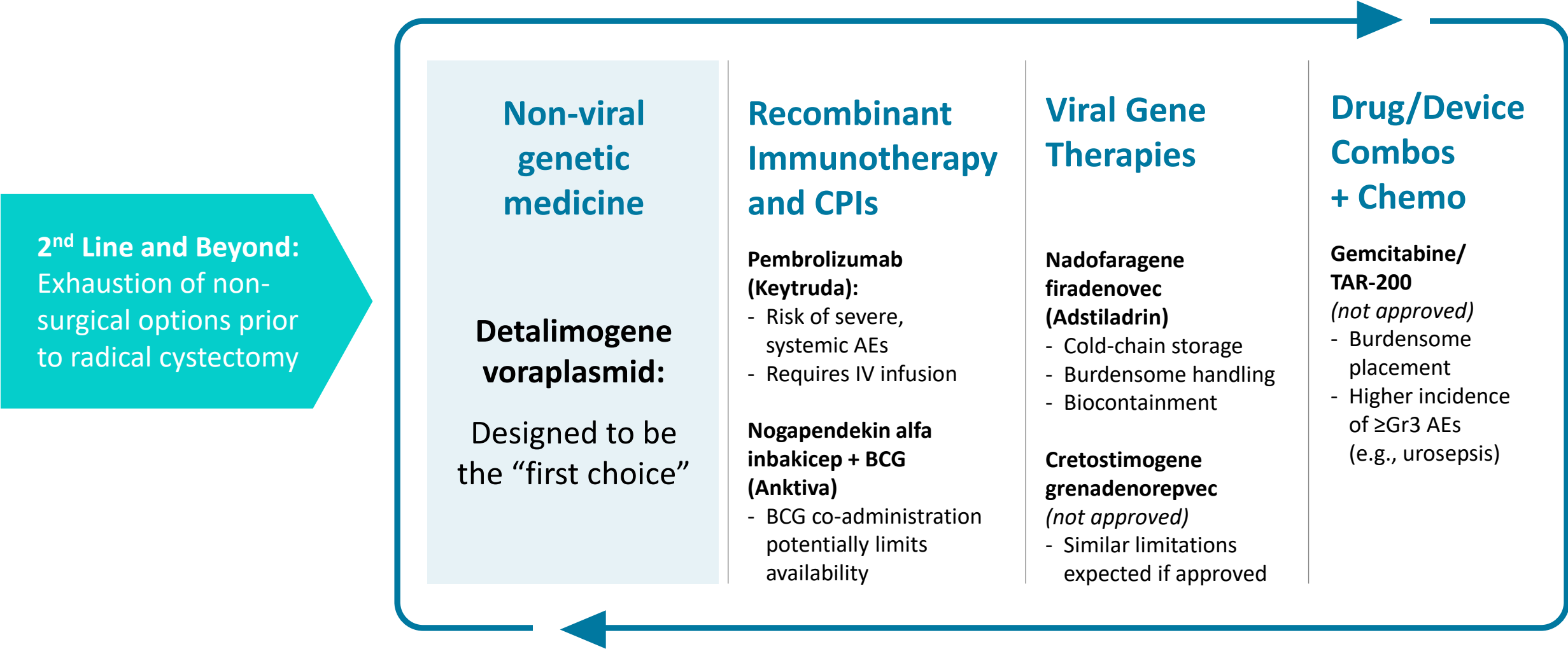
- Virus exposure precautions
- Extended clinic visit time
- 48 hours of urine bleaching

Estimated 4-10 hours in clinic

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Complementary Investigational Therapies Expected to Transform NMIBC Market and Allow for Sequential Treatments



Shift in NMIBC management paradigm drives projected market growth to >\$20B

Experience Developing and Commercializing Highly Successful Medicines



RON COOPER
Chief Executive Officer

Chief Executive Officer, Albireo Pharma
President, Europe, Bristol Myers Squibb



ANTHONY CHEUNG, Ph.D.
Chief Scientific Officer

Co-founder, enGene
Co-inventor on all key enGene patents
Former Member, ASGCT Industry Liaison Committee (2008-2014)
EY Entrepreneur of Year Finalist ('17)



AMY POTT
Chief Global Commercialization Officer

Head, Rare Disease, Global Commercial, Astellas
Head, Internal Medicine & Oncology, Commercial, Shire



RYAN DAWS
Chief Financial Officer

CFO Roles: Concert Therapeutics, Obsidian Therapeutics
Investment Banker Roles: Cowen, Stifel, Baird



ALEX NICHOLS, Ph.D.
Chief Strategy & Operations Officer

Co-Founder and CEO, Mythic Therapeutics
Co-Founder, Cogen Therapeutics Associate, Flagship Pioneering



JOAN CONNOLLY
Chief Technology Officer

Chief Technology Officer, Albireo Pharma
SVP Technical Operations, Stemline Therapeutics



LEE GIGUERE
Chief Legal Officer & Secretary

CLO, Obsidian Therapeutics
General Counsel, Chiasma Inc.
Other legal roles: Karyopharm Therapeutics, Boston Scientific, Goodwin Procter



JILL BUCK
Chief Development Officer

Head, Clinical Development Operations, Rare Disease, Ipsen
Other clinical development roles: Albireo Pharma, Ziopharm Oncology, Synageva Biopharma



MATTHEW BOYD
Chief Regulatory Officer

VP, Head of Regulatory Affairs, Zambon USA
VP, Regulatory Affairs, Albireo Pharma

Detalimogene Voraplasmid for NMIBC

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**Unique combination of clinical
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Additional Slides

Detalimogene is Designed to Streamline Administration and Ease the Experience for Patients and Clinicians

Detalimogene: As designed, no vial thaw, simple preparation; no pre/post treatment protocol

Preparation: can be conducted on open table or benchtop; no special handling

Instillation and dwell (60m)

(No post-treatment urine bleaching required)

BCG-TICE: Risk of infection for patients and caregivers; longer, uncomfortable dwell time; urine decontamination burden

Preparation: mask/gown minimally required ††

BCG instillation and dwell (120m) ††

6-hour period of required urine bleaching ††

Cretostimogene: (Based on publicly available data): Complex process with elevated biosafety; unclear vial thaw and urine decontamination requirements

Vial thaw

Preparation and Handling: BSL2-like handling *

DDM Infusion and dwell (15m)

Cretostimogene dwell (45-60m)

Urine bleaching requirements not reported

Adstiladrin: Vial thaw introduces preparation bottleneck; elevated biosafety procedures required; additional pre/post treatment burden for patients

Anticholinergic premedication**

3-10 hour vial thaw**

Preparation: “Universal biosafety precautions” required; USPI contains infection risk warning*

Adstiladrin instillation and dwell (60m)*

48-hour period of required urine bleaching*

†† Based on USPI.

* BSL2-like handling recommendations based on CG corporate presentation accessed April 30 2025 and precedent described in USPI for Imlygic, an FDA-approved, locally administered oncolytic virus. Detailed preparation and/or administration instructions have not yet been reported for cretostimogene. Other information based on CG Oncology’s non-confidential investor presentation.

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