enGene

Non-Viral Genetic Medicine

LEGEND Interim Data Update

May 7, 2026

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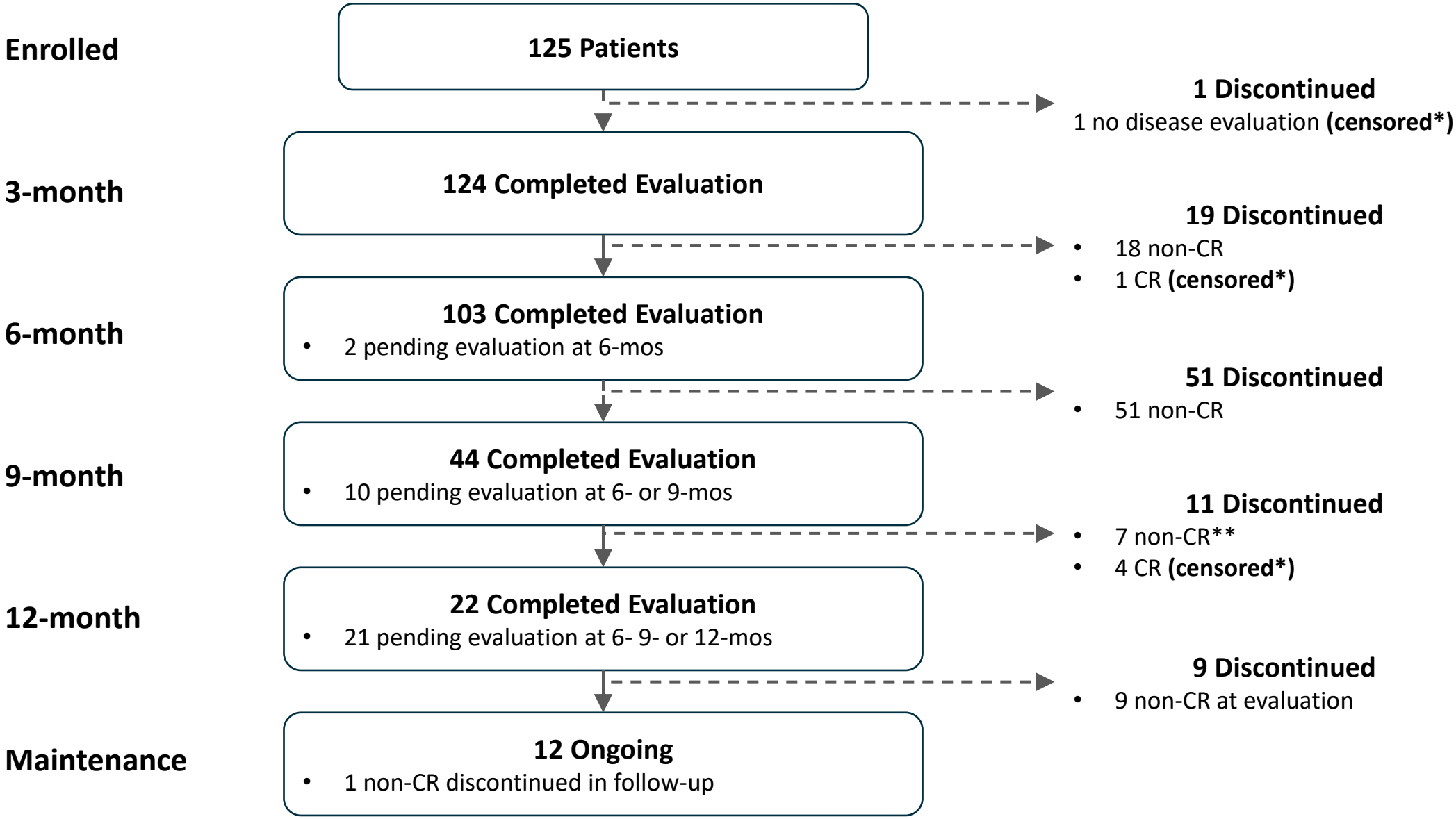
Lead Program (detalimogene voraplasmid)

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.

Introductory Remarks

LEGEND Phase 2 Cohort 1: CONSORT Diagram



*Patients who discontinued without any disease evaluation or who discontinued after a CR are excluded from subsequent landmark response analysis.
**One patient is displayed as non-CR at 9 months based on April 21 data analysis, and initiated Cycle 4. This patient has since been updated to CR post data analysis.

LEGEND Phase 2 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 (19.2%)
Male	101 (80.8%)
Race n (%)	
White	114 (91.2%)
Asian	4 (3.2%)
Black or African American	2 (1.6%)
Not Reported	5 (4.0%)
ECOG PS, n (%)	
0	119 (95.2%)
1	6 (4.8%)

Characteristics	Pivotal Cohort 1 (N=125)
Tumor stage, n, %	
CIS with Ta/T1 disease	49 (39.2%)
CIS only	76 (60.8%)
Reason for no cystectomy, %	
Ineligible	9 (7.2%)
Declined	116 (92.8%)
Prior BCG doses, n	
Median (Range)	12 (6-50)
Prior therapy other than BCG:	
Total	31 (24.8%)
Intravesical chemotherapy	21 (16.8%)
Systemic immunotherapy	8 (6.4%)
Viral gene therapy	5 (4.0%)
Other	4 (3.2%)
Prior NMIBC recurrence(s)	
Median (Range)	2 (0-11)

Note: BCG, bacillus Calmette-Guérin; CIS, carcinoma in situ; ECOG PS, Eastern Cooperative Oncology Group Performance Score; NMIBC, non-muscle invasive bladder cancer.
Data as of 21 April 2026; Data collection and cleaning is ongoing.

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	55.2%
Most frequent TRAEs (≥10%)	
Fatigue	21.6%
Dysuria	13.6%
Micturition urgency	12.0%
Pollakiuria	12.0%
Bladder spasm	11.2%

Most TRAEs were localized, brief, low-grade events

- 69 patients (55.2%) had any grade TRAEs
- Of those with TRAEs, 91.3% had Grades 1-2
- TRAEs resolved after a median of 8 days
- Only 6 patients (4.8%) had grade ≥3 TRAEs*

TRAEs leading to dose interruption or discontinuation were rare

- Dose interruption in 3 patients (2.4%)
- Discontinuation in 3 patients (2.4%)

TRAE= treatment-related adverse event.
*One patient had a treatment-related pyelonephritis/sepsis that led to a dose interruption. No grade ≥ 3 TRAEs led to discontinuation. Six patients had grade 3 TRAEs, including one patient that had a grade 4 TRAE (elevated ALT) that has since resolved.
Data as of 21 April 2026; Data collection and cleaning is ongoing

LEGEND Cohort 1 Interim Efficacy Data

		Any Time (N=124)	6 Month (N=121)	9 Month (N=113)	12 Month (N=98)
Total Population N=125	**CR Rate***	54.0% (CI: 44.9%, 63.0%)	43.0% (CI: 34.0%, 52.3%)	32.7% (CI: 24.2%, 42.2%)	13.3% (CI: 7.3%, 21.6%)
	KM Estimate		39.4%	31.6%	24.5%

- **Re-induction success rate** of 14.0% (6/43 non-CRs at 3 months responded following re-induction)
- **Low rate of progression** to muscle-invasive or more advanced disease (3.2%)
- **Preliminary Durability** for the 52 patients who were 6-month responders:
  - At the 9-month assessment, **37** CRs of 44** evaluable patients (8 patients pending 9-month assessment)
  - At the 12-month assessment, **13 CRs of 22** evaluable patients (11 patients pending 12-month assessment)
  - In total, 21 patients have the potential to reach the 12-month assessment, including 2 undergoing re-induction

* Patients who discontinued without any disease evaluation or who discontinued after a CR are excluded from subsequent landmark response analysis.
**Results do not include one patient with potential CR at 9 months that is currently considered a non-CR in the database.
CR=complete response; defined as negative cystoscopy and negative urine cytology, or positive cystoscopy/cytology with negative bladder biopsy.
CI: 95% Confidence Interval.
Data as of 21 April 2026; Data collection and cleaning is ongoing.

Patients Post October 2025 Analysis Underperformed Earlier Subgroups

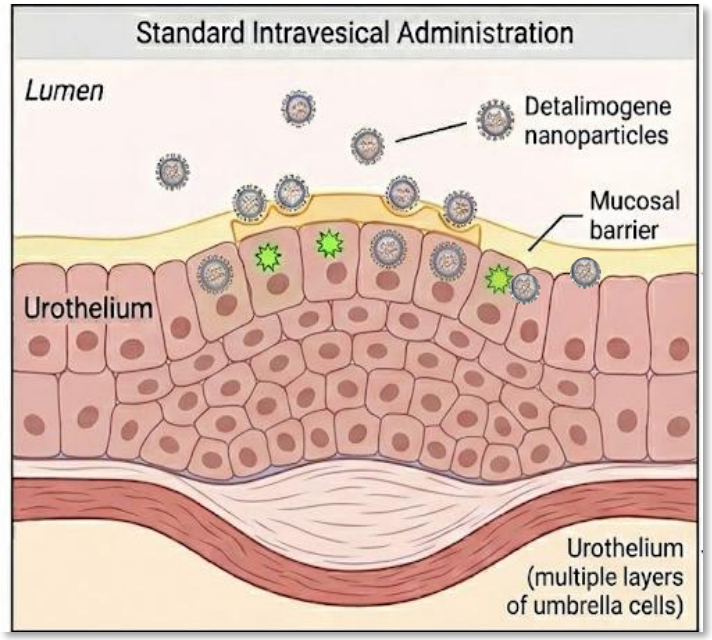
	Pre-Protocol Amendment October 2025 Analysis* N=31	Post-Protocol Amendment October 2025 Analysis* N=62	Newly Assessed Patients Since October 2025** N=32
Any time CR Rate	55%	63%	39%
6 Month CR Rate	41%	62%	32%

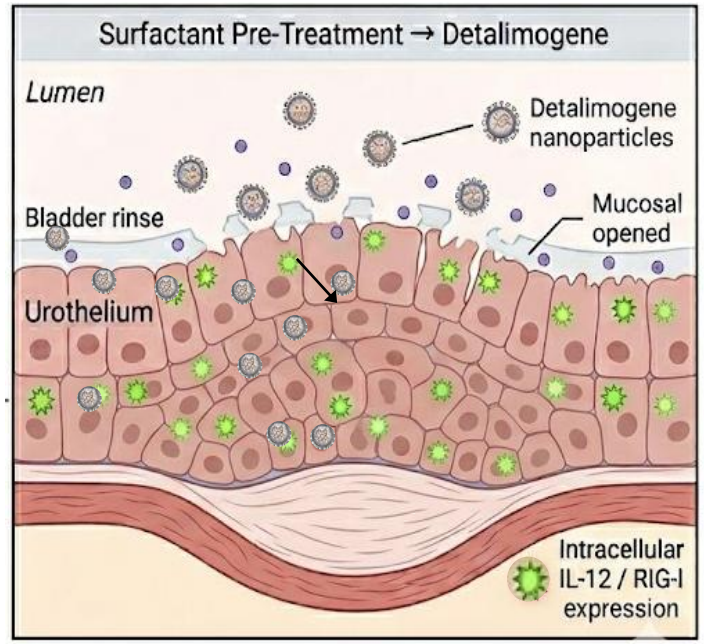
- Preliminary subgroup analysis of baseline demographics and key disease characteristics demonstrated no material differences
- Marginal differences in efficacy observed across pre-protocol (n=31) and post-protocol (n=94) amendment patients
- Analysis remains ongoing

*Data disclosed in press release dated November 11, 2025, and reflect a data analysis of October 24, 2025.
** Includes i) patients whose first post-baseline assessment took place following October 24, 2025, and ii) one patient that dropped out without any post-baseline assessment.
Data as of 21 April 2026; Data collection and cleaning is ongoing.

Bladder Rinse Opportunity

Surfactant Bladder Rinse Could Increase Transgene Expression





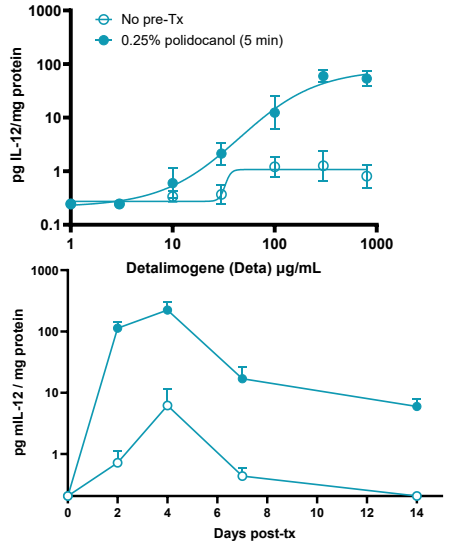
- Bladder lumen contains protective mucosal boundary layer
- DDX designed to spontaneously penetrate mucosal layer and transfect urothelium

- Surfactant bladder rinse designed to disrupt bladder mucosal barrier and further increase DDX permeability
- Potentially improves DDX penetration and urothelial transfection

Detalimogene and Surfactant Bladder Rinse (Polidocanol)

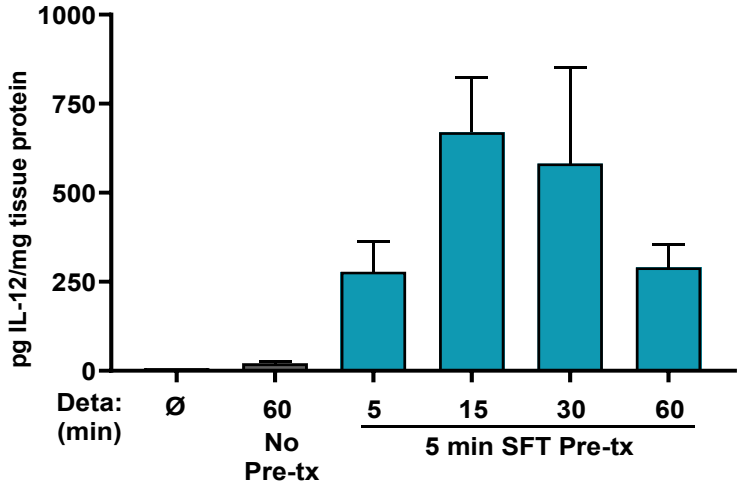
Designed to Improve Gene Expression, Shorten Dwell Time, and Improve Efficacy

Increases Magnitude & Duration of Gene Expression



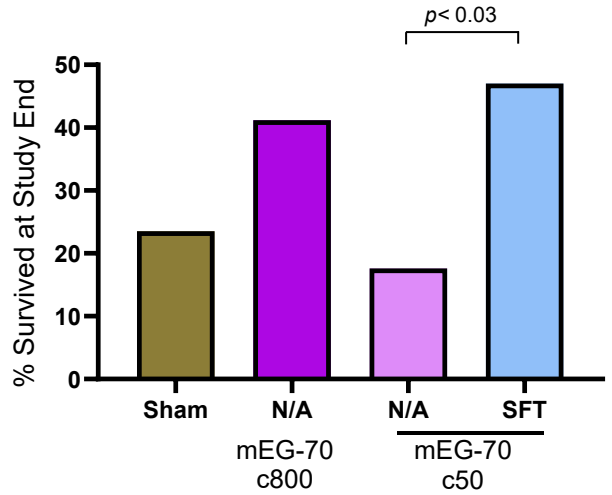
A 5-min bladder rinse → >10× increase in IL-12 expression for longer duration

Shortens Bladder Dwell Time



A 5-min bladder rinse reduced the deta dwell time required to achieve maximal IL-12 expression from 60 to 15 min.

Improves Efficacy



A 5-min bladder rinse (BR) rescued the efficacy of a sub-optimal dose of deta in an orthotopic bladder cancer model

Polidocanol is an approved sclerosing agent for treatment of varicose veins and has an extensive clinical track record

All data from mouse models.

Detalimogene and Surfactant Bladder Rinse LEGEND Cohort Underway

- 20 trial **sites activated** in US and Canada and actively recruiting patients
- Simple **5-min pre-treatment** of the bladder with 50 mL of 0.25% polidocanol solution prior to detalimogene administration
- Total detalimogene **dwell time shortened** from 60 to 30 minutes to reduce patient and office burden

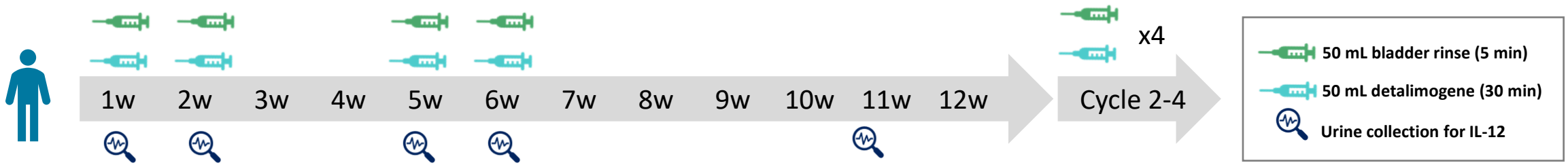
Trial Study Design

Target Population: Patients with BCG-unresponsive HR NMIBC with CIS +/- Papillary

Target Number of Sites: 35-40 US, Canada and EU

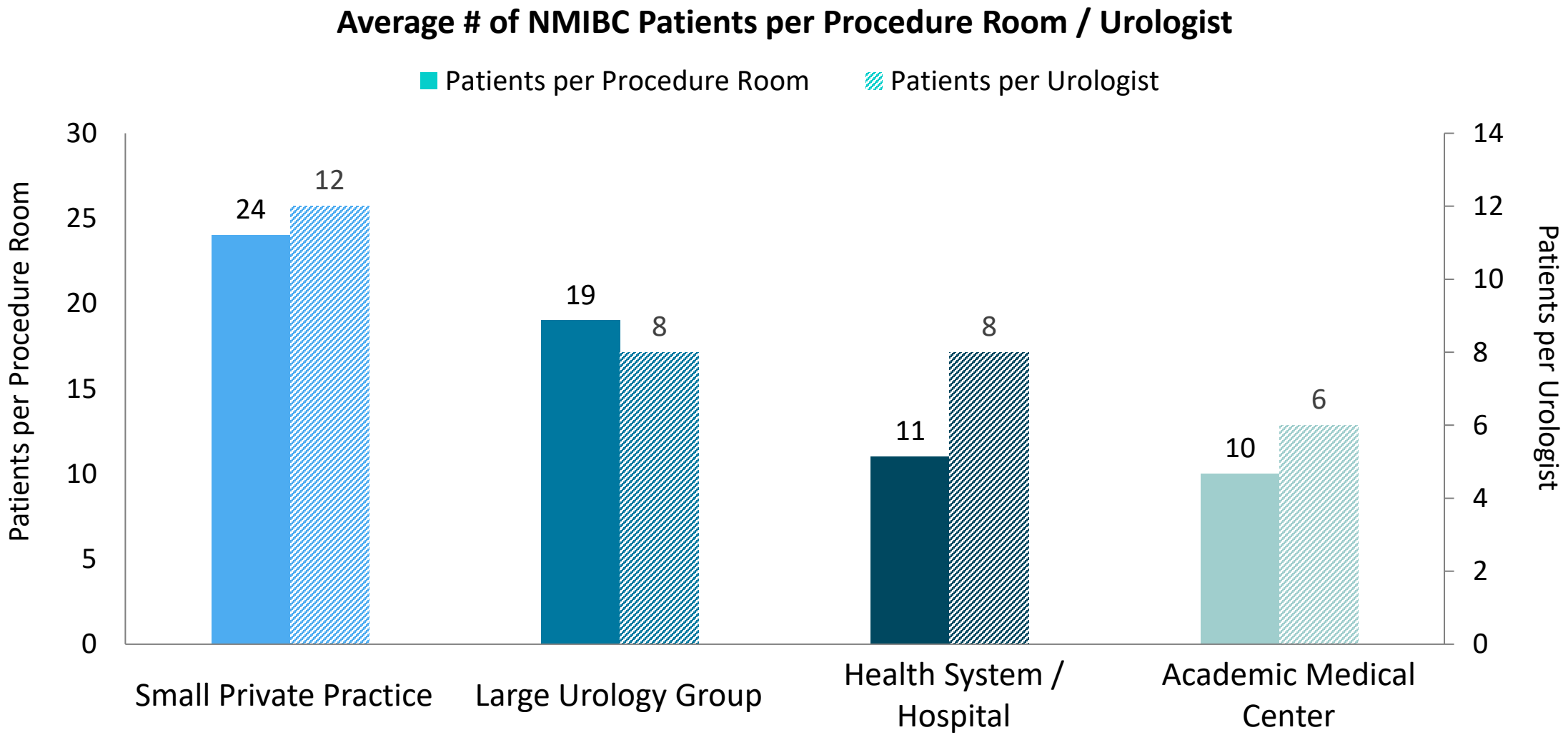
Enrollment: Potential to enroll up to 80 patients

Status: Actively enrolling



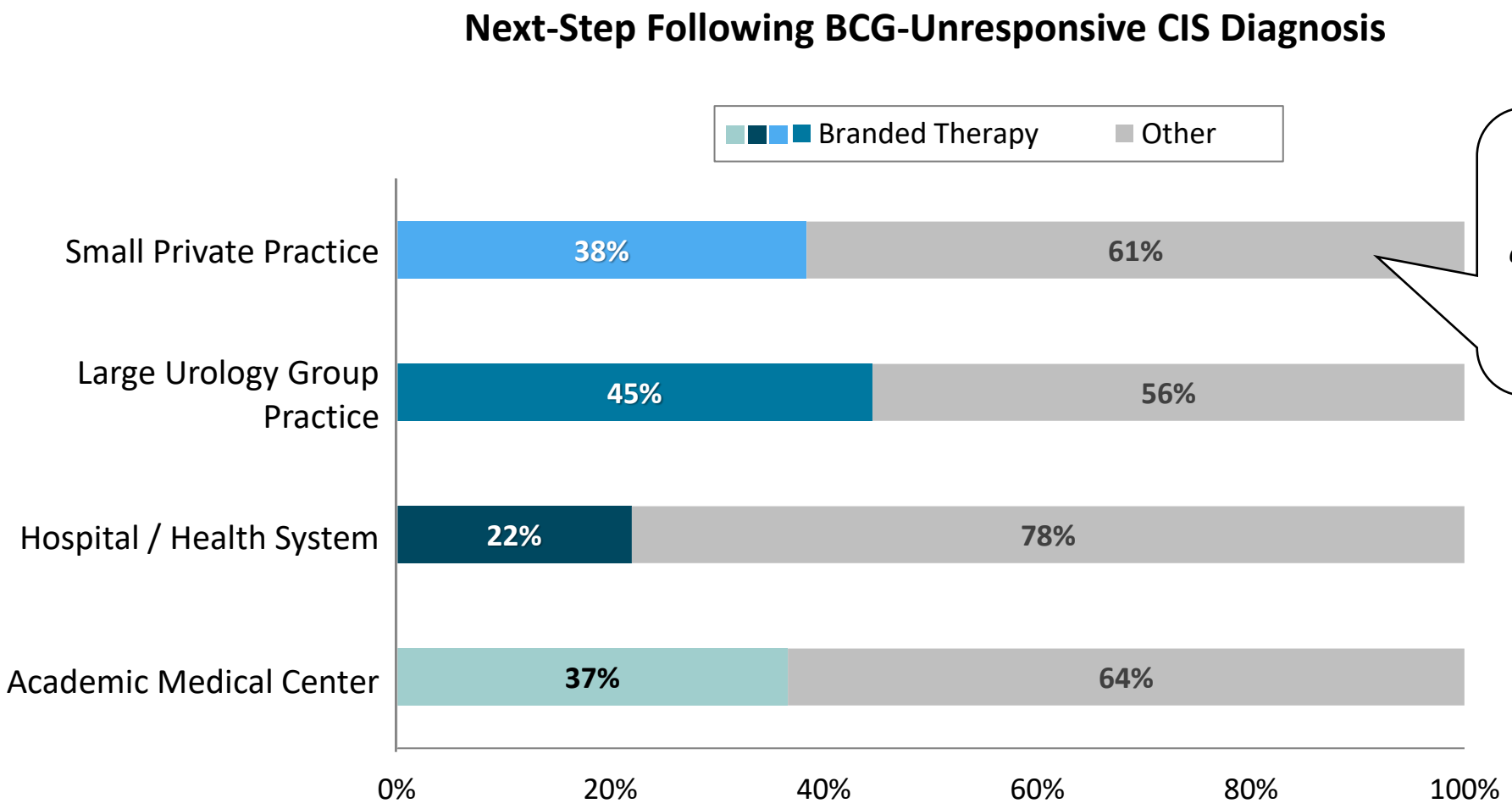
Market Research Insights

Community Urologists: Higher Volume with Fewer Resources and Staff



Source: enGene sourced market research (survey n=100 urologists and uro-oncologists).

Less Than Half of Urologists Prescribe Branded Therapies to BCG-UR Patients

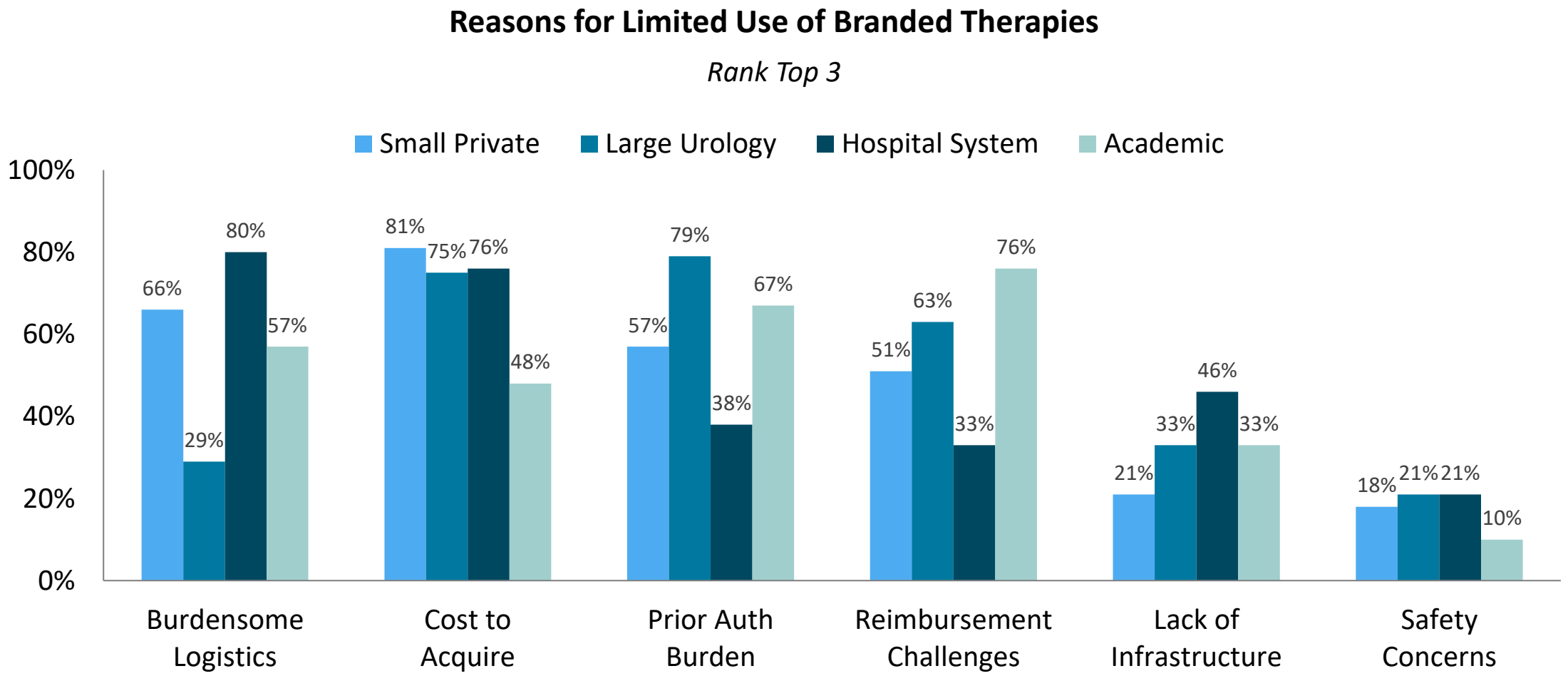


"I prescribe [Product X] and [Product Y]. I just cannot administer them in my office. I have to go to a hospital I have a contract with."

– Small Private Practice Urologist

Note: Branded therapies included Inlexzo, Adstiladrin, Anktiva , and Keytruda. Other included referral, chemotherapy, and radical cystectomy.
Source: Market Research (survey n=100 urologists and uro-oncologists)

Low Adoption of Branded Therapies Driven by Logistics and Cost to Acquire

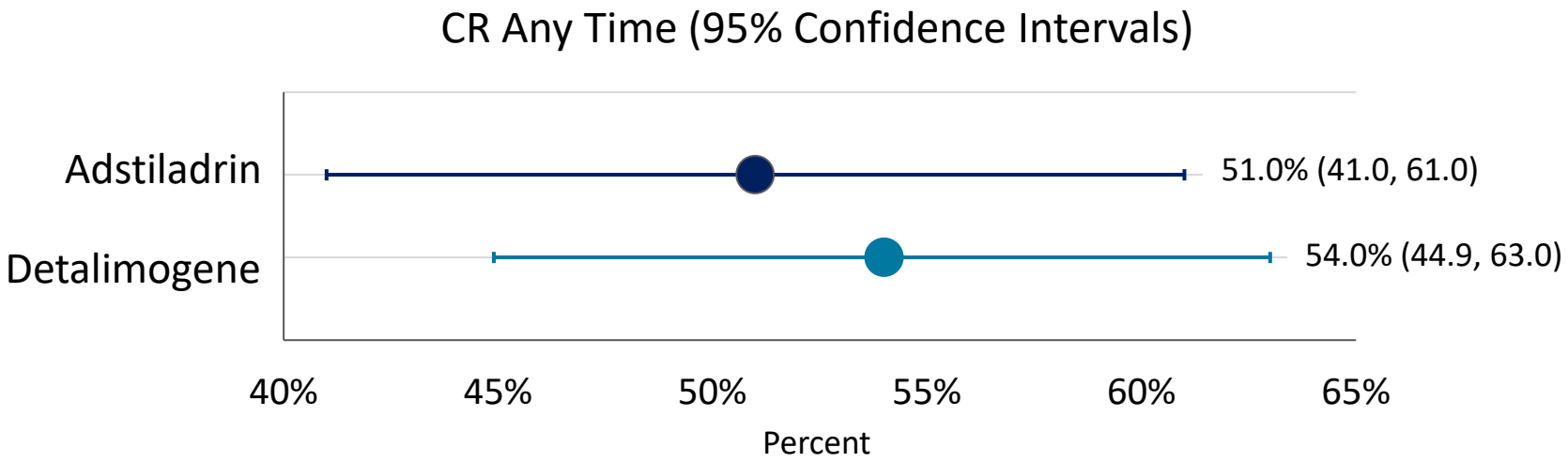


Source: Market Research (survey n=100 urologists and uro-oncologists).

Market Research Findings: Opportunities for Detalimogene

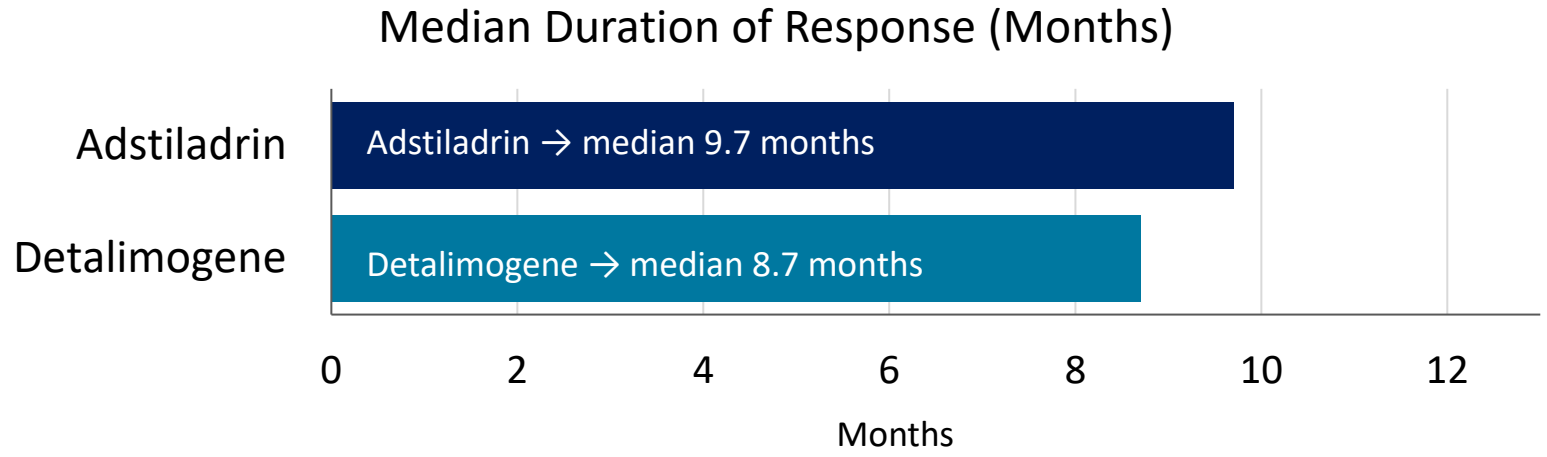
Challenge	Detalimogene Opportunity
 **Limited Resources**	**Accessible in lower-resource settings:** Nurse-administered without specialized procedure-room or BSL-2 hood requirements
 **Burdensome Logistics**	**Minimal logistical burden:** No vial thaw, bench-top preparation, and refrigerated stability
 **Cost to Acquire**	**Commercial flexibility through potential low COGS:** Supports access strategies such as consignment, reimbursement guarantees, and flexible billing

Preliminary Efficacy and Durability Estimates



Product	12 Months Landmark
Adstiladrin (n=98)	24%
Detalimogene (n=125)	25% est**

** KM estimate



Product	DOR % ≥ 12 Months
Adstiladrin (n=98)	46%
Detalimogene (n=125)	25% est** (CI: 11%, 41%)

** KM estimate

Data as of 21 April 2026; CI: 95% Confidence Interval.
Data collection and cleaning is ongoing. 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 should be made.

Closing Remarks and Q&A

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