UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8–K

CURRENT REPORT
Pursuant to Section 13 OR 15 (d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 7, 2019

SESEN BIO, INC.
(Exact name of registrant as specified in its charter)

Delaware	001-36296	26-2025616
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

245 First Street, Suite 1800 Cambridge, MA	02142
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (617) 444-8550

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8–K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a–12 under the Exchange Act (17 CFR 240.14a–12)

☐ Pre–commencement communications pursuant to Rule 14d–2(b) under the Exchange Act (17 CFR 240.14d–2(b))

☐ Pre–commencement communications pursuant to Rule 13e–4(c) under the Exchange Act (17 CFR 240.13e–4(c))

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001	SESN	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☑

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☑

Item 8.01 – Other Events.

Corporate Presentation

On August 7, 2019, Sesen Bio, Inc. (the "Company") gave an updated corporate presentation at the Canaccord Genuity 39th Annual Growth Conference in Boston, Massachusetts. The Company posted the presentation on its website www.sesenbio.com. A copy of the presentation is filed herewith as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 – Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description**
99.1	Sesen Bio, Inc. Presentation Made at the Canaccord Genuity 39th Annual Growth Conference on August 7, 2019

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: August 7, 2019

Sesen Bio, Inc.

By: /s/ Richard F. Fitzgerald
Richard F. Fitzgerald
Chief Financial Officer and Treasurer


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2019 Canaccord Genuity
Global Growth Conference
Thomas Cannell DVM, President and CEO
August 7, 2019
NASDAQ S
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FORWARD-LOOKING STATEMENTS

This presentation contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this presentation, including statements regarding our strategy, future operations, clinical development of our protein therapies, timing or probability of regulatory approval, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions are intended to identify forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, although not all forward-looking statements contain these identifying words.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make as a result of various important factors, including: the uncertainties inherent in the initiation and conduct of clinical trials, the possibility that the available preliminary data of the Phase 3 VISTA Trial are not indicative of final data from all patients in the Phase 3 VISTA Trial and/or that the final data may not be positive with regard to the safety or e Vicinium®, the possibility that the FDA may require a change in our registration and/or that the safety or efficacy data for Vicinium submitted as part of a BLA m considered sufficient by the FDA, our ability to successfully develop our candidates and complete our planned clinical programs, the potential advar favorability of our product candidates, our ability to obtain marketing approval product candidates, expectations regarding our ongoing clinical trials, availab timing of data from clinical trials, the adequacy of any clinical models, exp regarding regulatory approvals, our ability to obtain, maintain and protect our in property for our technology and products, other matters that could affect the performance of the Company, other matters that could affect the availa commercial potential of the Company's product candidates, and other factors in the "Risk Factors" section of the Company's Annual Report on Form 10-K, a reports on file with the Securities and Exchange Commission (SEC). The forwar statements contained in this presentation are made as of the date hereof, and S assumes no obligation to update any forward-looking statements whether as a new information, future events, or otherwise except as required by applicable law

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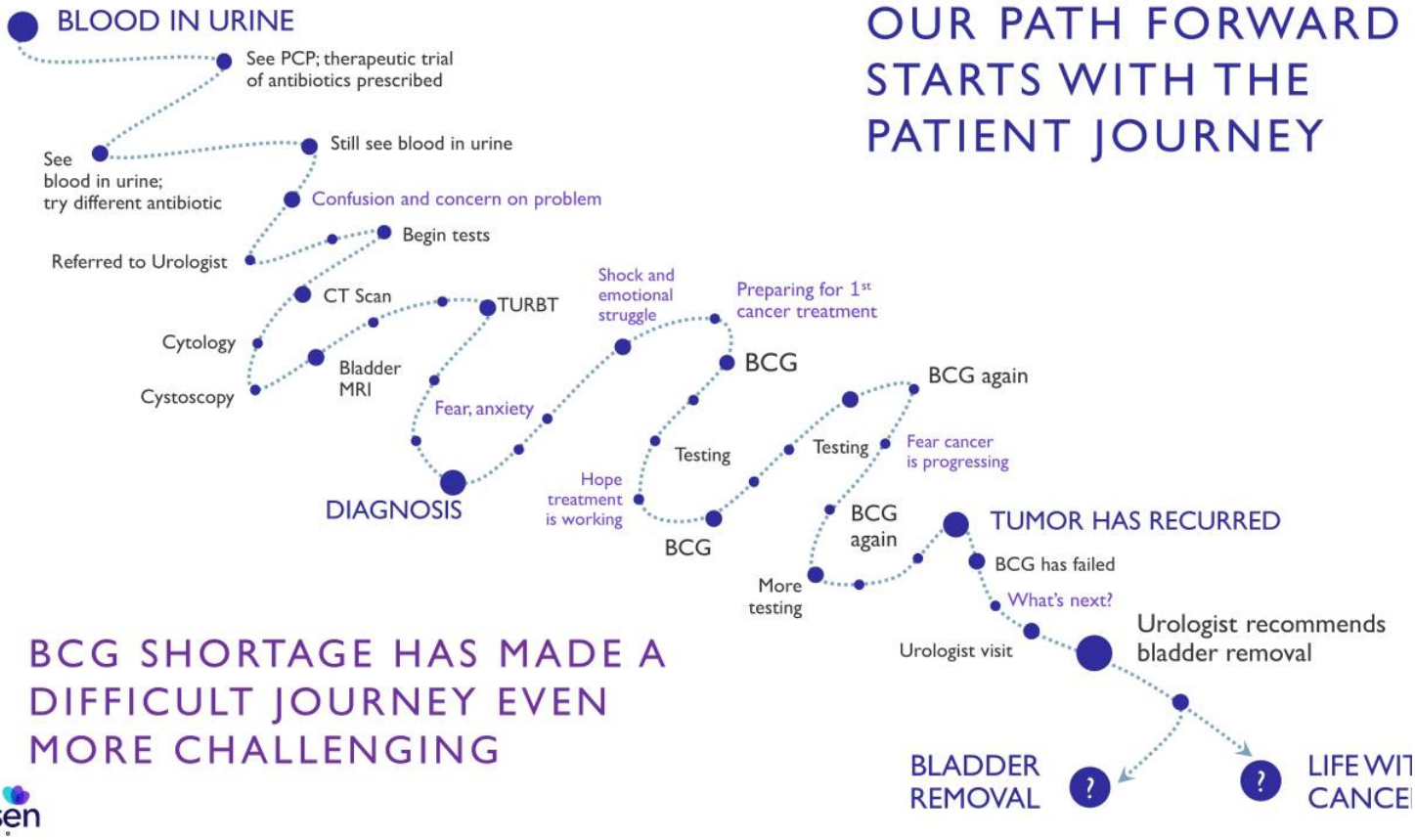
OUR PATH FORWARD STARTS WITH THE PATIENT JOURNEY



BCG SHORTAGE HAS MADE A DIFFICULT JOURNEY EVEN MORE CHALLENGING

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AUGUST 2019 AGENDA

1. Positive interactions with FDA on May 20 June 6th results in greater confidence in ou regulatory and commercial pathway
2. Updated Phase III data demonstrate a compelling benefit-risk profile with the po to be BCG and cystectomy-sparing*
3. New market research supports strong commercial viability
4. Simple, reliable and inexpensive manufactu process

*Updated preliminary Phase III data are as of the May 29, 2019 data cut. May 29th data cut will be used for the initiation of BLA submission in 4Q 2019 with no further data cuts prior to submissi

2019 Regulatory Update for Vicinium for NMIBC

May 20th Type C CMC Meeting: FDA Accepts Analytical Comparability Plan to Support the BLA and Commercialization of Vicinium for NMIBC

- Reached alignment with FDA on primary objective of meeting: acceptance of analytical comparability plan for commercial supply of Vicinium to support the significant global demand
  - No additional clinical trials deemed necessary at this time, subject to final comparability data to be included in the BLA submission

June 6th Type B pre-BLA Meeting: FDA Recommends Accelerated Approval Pathway and Rolling Review

- Reached alignment with FDA on key objectives for the approval path of Vicinium including:
  - Review under Accelerated Approval Pathway
  - No additional clinical trials necessary at this time for purposes of a BLA submission
  - Nonclinical data, clinical pharmacology data, and the safety database are sufficient to support a BLA submission
  - Rolling Review of submission along with anticipated initiation of BLA submission in the fourth quarter of 2019
  - Pre-approval inspection (PAI) may be performed at the time of PPQ manufacturing, further de-risking the CMC review timeline

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Updated Phase III data will be the basis for the initiation of the BLA submission anticipated in 4Q 2019

Oncology Products Reviewed by FDA 2006 - 2015

Phase	Probability of Approval
Products at end of Phase I	5%
Products at end of Phase II	8%
Products at end of Phase III	33%
Products with BLA Submission	82%

As part of a comprehensive analysis done for the Biotechnology Innovation Organization (BIO), a total of 9,985 clinical and regulatory phase transitions (phase advancement or development suspension) were recorded and analyzed from 7,455 development programs, across 1,103 companies.

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Sources: FDA applications for oncology products 2006 – 2015. Thomas D.W. *et al.*, Clinical development success rates 2006-2015. 2016. Bio, BioMedTracker and Amplion.

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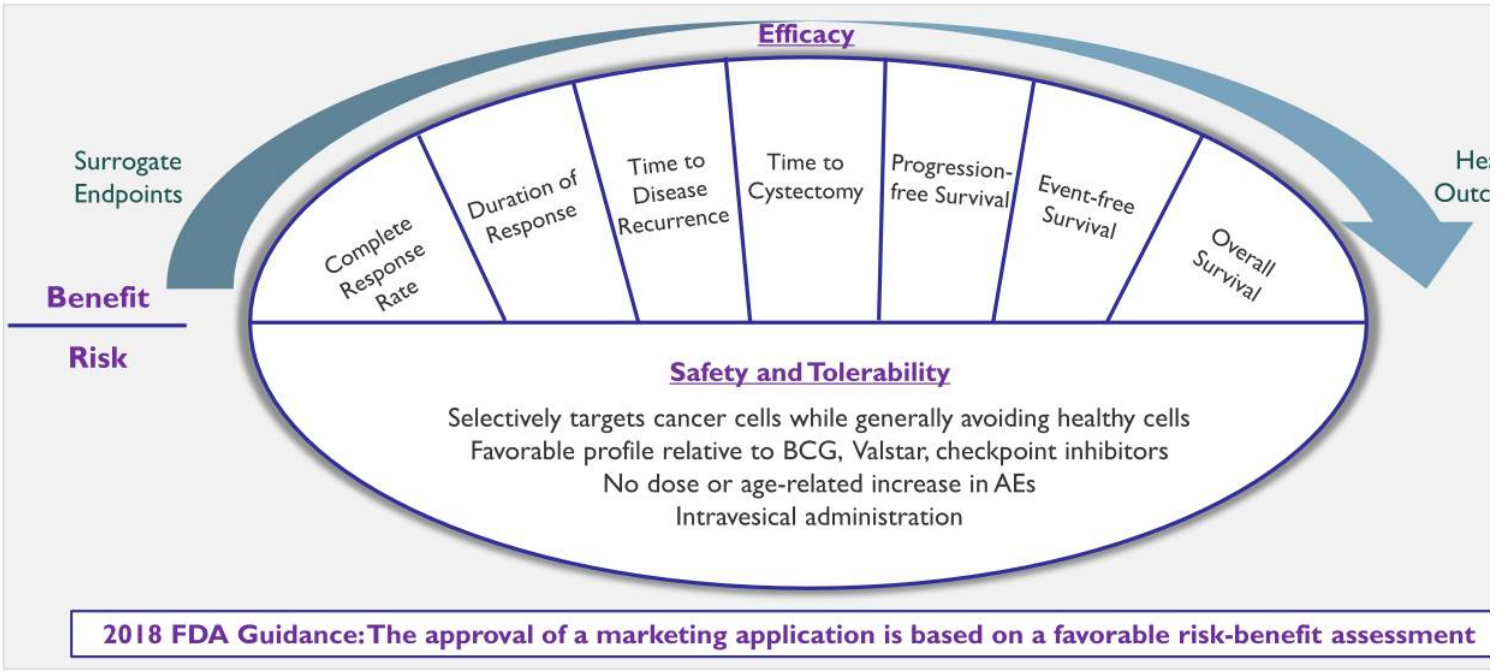
Vicinium demonstrates a strong benefit-risk profile in our Phase III Trial



2018 FDA Guidance: The approval of a marketing application is based on a favorable risk-benefit assessment

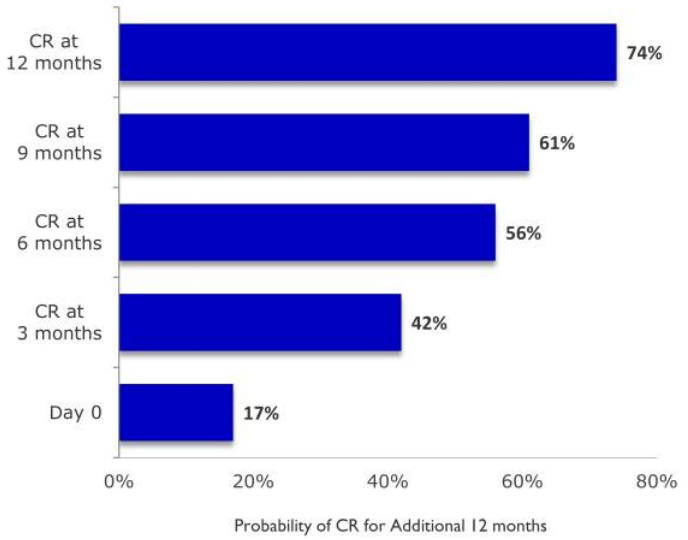
Phase III clinical trial is an open-label, multicenter, single-arm Phase III registration trial for the treatment of high-risk NMIBC patients who are designated to be BCG-unresponsive after adequate treatment with BCG. Adequate BCG is defined as at least two courses of BCG with at least five doses in the first course and two in the second. Preliminary data as of May 29, 2019 data cut.

We believe the totality of Phase III data suggest a strong benefit-risk profile

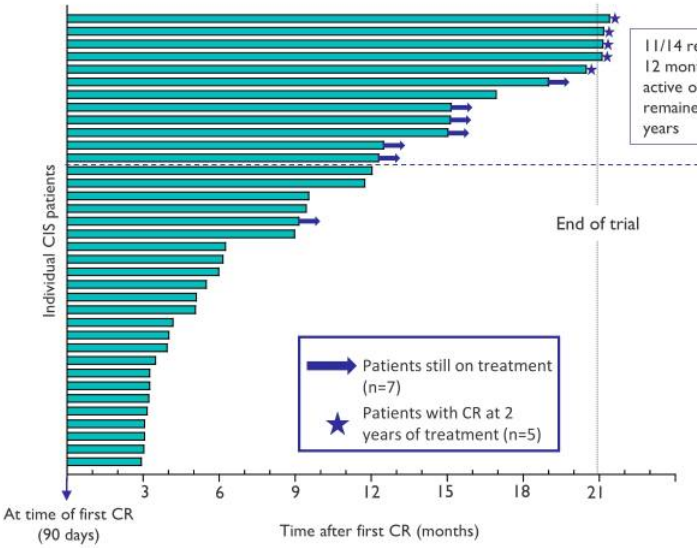
Endpoint	How Endpoint is Measured	Results
Complete Response Rate (CRR) Primary Endpoint CIS patients	Defined as the proportion of patients who show no evidence of high-risk disease, or disease progression (e.g., T2 or more advanced disease).	• 40% CRR at 3 months • Lower bound of 95% CI rules out clinically unmeaningful CRR • Higher complete response rate in patients receiving less BCG
Duration of Response (DoR) Primary Endpoint CIS patients	Defined as the time from complete response to treatment failure.	• 52% duration of 9 months (12 months of therapy) • 39% duration of 15 months or greater (18 months of therapy) • The longer the CR, the higher the probability of remaining disease-free
Time to Disease Recurrence Secondary Endpoint Papillary patients	Defined as the time from the date of first dose of study treatment to treatment failure.	• Median time to recurrence is 402 days • 50% probability of remaining recurrence-free for 12 months • 37% probability of remaining recurrence-free for 24 months or greater
Time to Cystectomy (TtC) Secondary Endpoint All Cohorts	Defined as the time from the date of first dose of study treatment to surgical bladder removal.	• Average patient is cystectomy-free for 930 days • Responders have an 88% probability of remaining cystectomy-free at 3 ye • Average responder remains cystectomy-free for 1,035 days vs 631 days fo non-responders
Progression-Free Survival (PFS) Secondary Endpoint All Cohorts	Defined as the time from the date of first dose of study treatment to disease progression (e.g. T2 or more advanced disease) or death as a first event.	• 96% of patients are progression-free at 12 months • 90% of patients progression-free for 24 months or greater • Median PFS has not been reached
Event-Free Survival (EFS) Secondary Endpoint All Cohorts	Defined as the time from the date of first dose of study treatment to treatment failure or death as a first event.	• 29% of patients are event-free at 12 months • 22% of patients remain event-free at 18 months • 21% of patients remain event-free for 24 months or greater
Overall Survival (OS) Secondary Endpoint All Cohorts	Defined as the time from the date of first dose of study treatment to death from any cause.	• Overall survival is 98% at 12 months • Overall survival is 96% for 24 months or greater • Median OS has not been reached
Safety Secondary Endpoint All Cohorts	Full review of all safety data from Phase III	• 2% treatment-related SAEs • 4% treatment-related Grade 3-5 AEs • Increased dosing in Phase III did not increase severity of AEs
Tolerability Secondary Endpoint All Cohorts	Full review of all tolerability data from Phase III	• AEs generally low grade • Low rate of discontinuations for AEs • No age-related increase in AEs

Duration of Response: The longer you have a complete response, the higher the probability of remaining cancer-free

Probability of Maintaining Complete Response (CR) for at Least One Additional Year*



Each time point a CR is confirmed, the probability of maintaining a CR increases



Duration of response is defined as the time from complete response to treatment failure.
*Data reflect an *ad hoc* analysis of pooled results of patients in cohorts 1&2.

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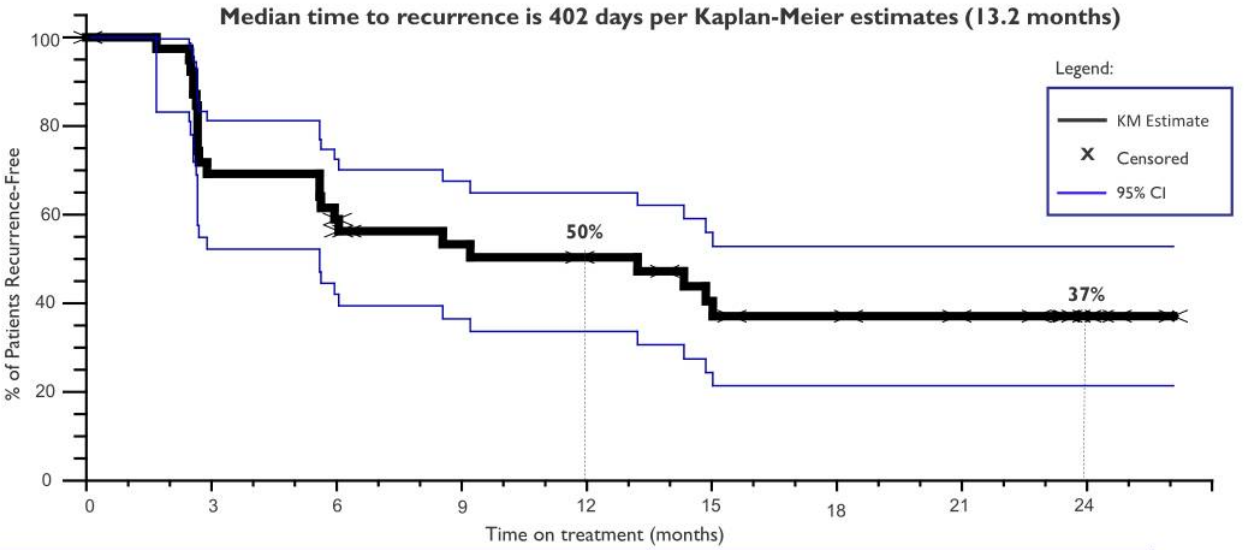
Time to Disease Recurrence: For high-risk papillary patients who were treated with Vicinium, 50% are disease-free at 1 year



KM Evaluable Patients:	40	27	23	18	16	12	10	8	4

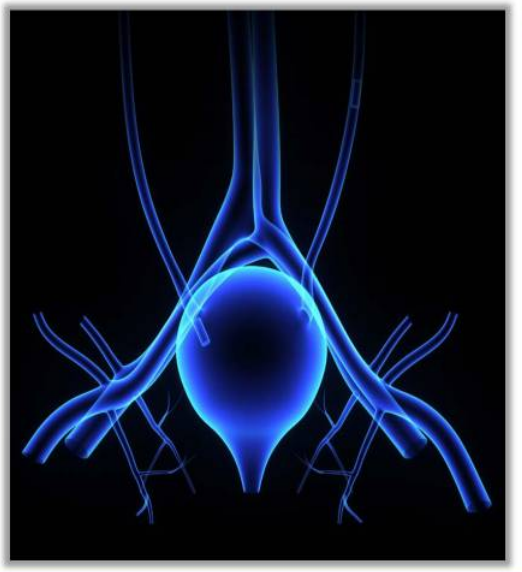
2018 FDA Guidance: Sponsors can include patients with completely resected lesions and no evidence of CIS in these single-arm trials but should not include them in the evaluation of the primary efficacy endpoint.

Time to disease recurrence: defined as the time from the date of the first dose of study treatment to treatment failure.
Median time to disease recurrence 95% confidence intervals are 170 – Not estimable (NE) days. Not estimable means the upper bound for the 95% confidence interval has not reached the median.
Note: Data reflect results of patients in cohort 3 (n = 40) with high-grade Ta or T1 tumors (without Carcinoma *in situ*) that recurred within 6 months of adequate BCG.

Our Phase III data suggests Vicinium is cystectomy-sparing by significantly delaying or avoiding cystectomy for patients

Your Bladder: A Hero Organ

- Self-controlled storage organ in the body
- Holds urine for release so the body is not exposed to harmful toxins and waste
- Part of the urinary system; partners with lungs, skin, and intestines to keep chemicals and water in the body balanced and healthy
- Integrated with male and female reproductive systems



Radical Cystectomy: Life-Altering S

- Often a 10 hour or longer surgery
- In women, removal of the entire bladder includes removal of the uterus, fallopian tubes, ovaries and cervix, part of the vaginal wall, and surrounding tissue
- In men, removal of the entire blad includes removal of the prostate, seminal vesicles, and surrounding tissue
- Radical cystectomy requires life-lo catheterization and urinary diversi

2018 FDA Guidance: The goal of therapy in patients with BCG-unresponsive NMIBC is to avoid cystectomy

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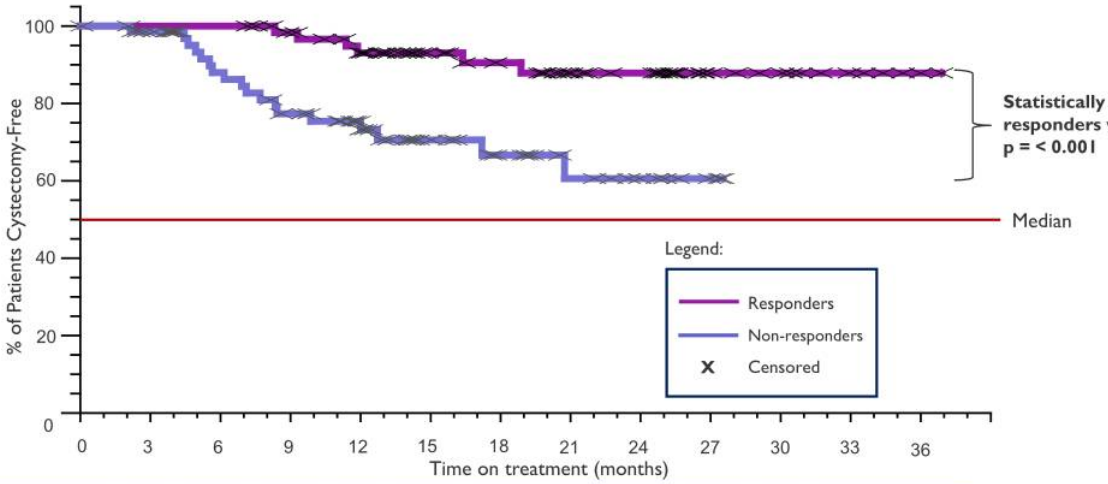
Sources and Additional Information: Bladder Cancer Advocacy Network (BCAN). *Bladder Removal Surgery.* May 2017.

Time to Cystectomy: Responders have an 88% probability of remaining cystectomy-free 3 years after starting treatment

The average responder remains cystectomy-free for 1,035 days vs 631 days for non-responders



KM Evaluable Responder Patients:	63	63	63	58	52	39	34	27	23	13	9	4	2
KM Evaluable Non-responder Patients:	70	64	50	42	34	21	15	10	6	2	0	0	0

Time to cystectomy: defined as the time from the date of first dose of study treatment to surgical bladder removal. Data consist of patients from all cohorts (n=133).

Key Survival Endpoints: Early survival data are encouraging regarding health outcomes for patients treated with Vicinium

Progression-Free Survival	
Time Point (Evaluable Patients)	Progression-Free Survival (95% CI)
6-months (52)	99% (97%-100%)
12-months (25)	96% (90%-100%)
18-months (11)	90% (76%-100%)
24-months (5)	90% (76%-100%)

Event-Free Survival	
Time Point (Evaluable Patients)	Event-Free Survival (95% CI)
6-months (128)	40% (31%-48%)
12-months (121)	29% (21%-37%)
18-months (114)	22% (15%-30%)
24-months (102)	21% (13%-28%)

Overall Survival	
Time Point (Evaluable Patients)	Overall Survival (95% CI)
6-months (122)	99% (98%-100%)
12-months (106)	98% (96%-100%)
18-months (68)	96% (92%-100%)
24-months (40)	96% (92%-100%)

Progression-free survival: defined as the time from the date of first dose of study treatment to disease progression (i.e. T2 or more advanced disease) or death as a first event.
Event-free survival: defined as the time from the date of first dose of study treatment to treatment failure or death as a first event.
Overall survival: defined as the time from the date of first dose of study treatment to death from any cause.
Note: Data consist of patients from all cohorts (n=133).

Safety and Tolerability: Our Phase II and Phase III clinical trials are highly consistent for safety and tolerability

Increased dosing and duration of exposure does not appear to lead to an increase in incidence or severity of AEs

Treatment-related serious adverse events reported:

- Phase II Clinical Trial: 6 SAEs reported, none determined to be related to treatment by the investigator.
- Phase III Clinical Trial: 3 patients reported 4 events including grade 4 cholestatic hepatitis, grade 5 renal failure[1], grade 3 acute kidney injury[2], and grade 2 pyrexia.

Category	Phase II (n=46)	Phase III (n=133)
Any AE	43 (94%)	117 (88%)
Grade 3-5 AEs	9 (20%)	29 (22%)
Treatment-related AEs	30 (65%)	66 (50%)
Treatment-related Grade 3-5 AEs	3 (7%)	5 (4%)
Any SAE	6 (13%)	19 (14%)
Treatment-related SAEs	0 (0%)	3 (2%)
Discontinuations due to AEs	0 (0%)	4 (3%)

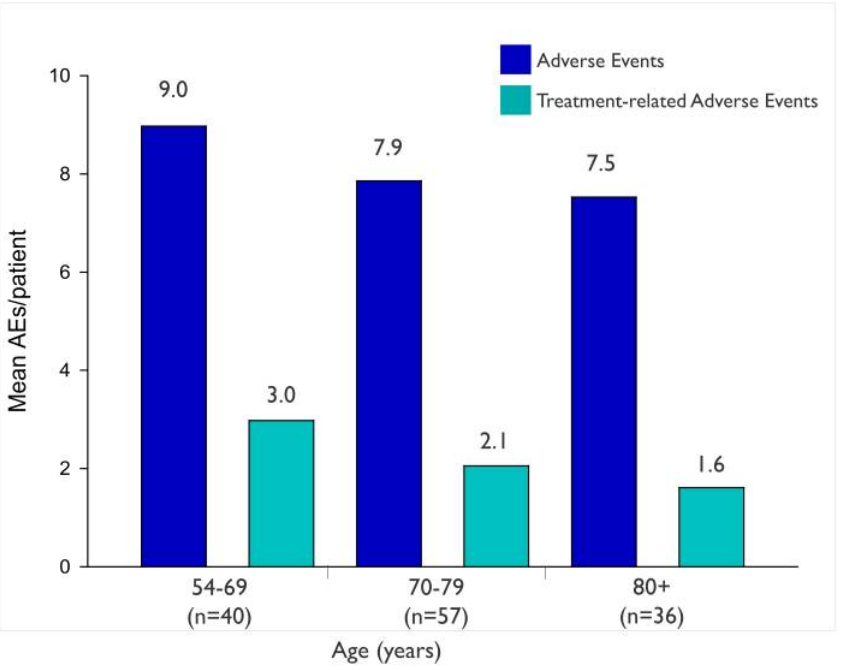
Vicinium Treatment Exposure:

Average Instillations per Patient	12	27
Average Duration of Exposure (days)	189	240

[1]90-year-old man started the trial Mar. 2016. In May 2016, admitted for renal failure and started dialysis. Two weeks later, patient opted to discontinue dialysis, entered hospice and died in Jun. 2016. Case reported to DSMB, FDA and Health Canada. [2]74-year-old man started the trial Nov. 2016. In Dec. 2016, admitted for acute kidney injury. In 2017, protocol amended to enhance monitoring, and educated investigators. No new serious related renal events since.

Safety and Tolerability: No age-related increase in adverse events in our Phase III trial

The average patient in the VISTA trial was ~74 years old



Note: Data consist of patients from all cohorts 1, 2 & 3 (n=133).
Mean AEs for all patients: 8.1 (range 0-54), Mean treatment-related AEs for all patients: 2.2 (range 0-51).

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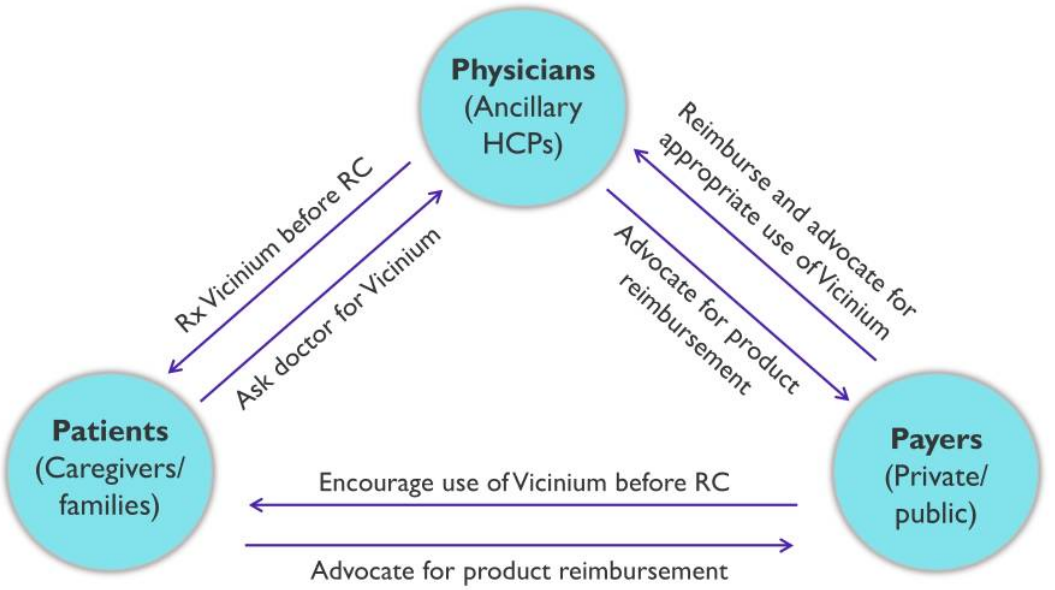
Virtuous Cycle: High possibility that all three key segments are advocates & take action



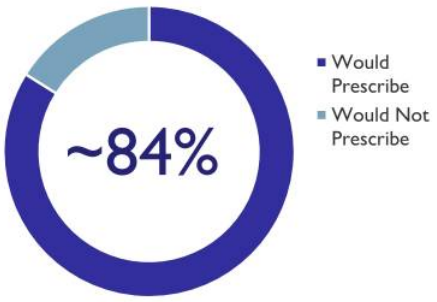
Sources:
Sesen Bio internal market research: Patient Journey Insights, Blue Print qualitative study May 2018, n=24; Sesen Market Opportunity, Monitor Deloitte qualitative and quantitative (n=34) study October 2018; Community Urologist in-depth interviews (IDIs), October 2018, n=5; Sesen Bio Qualitative Market Research Urologist/KOL IDIs February 2019, n=11. Sesen Bio Qualitative Market Research Urologist IDIs June 2019, n=30.

Note: RC= Radical Cystectomy

Safety, MOA and efficacy are all key drivers in intent to prescribe for high-prescribing Urologists

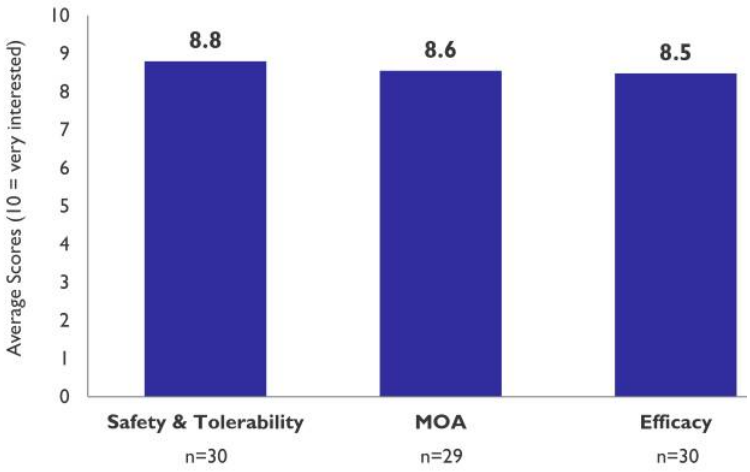
Physician Intent to Prescribe

After reviewing the data, high-prescribing Urologists state they would prescribe Vicinium to



of their patients

Key Drivers of Physician Intent to Prescribe



Source: Sesen Bio Qualitative market research, Urologist IDIs June 2019, n = 30.

High-prescribing Urologists recognize the significant value across safety, MOA and efficacy

Safety & Tolerability	*"This is another bladder intravesical treatment available with an even **lower risk of side effects than BCG** and has a greater ability to prevent recurrence."* *"…the fact that it is specifically targeted towards cancer cells makes it seem as if **potential adverse events that we would see with BCG would be much less likely with this product**."*
Mechanism of Action	*"It's a **very directed therapy that targets the cancer cells**... if you look at the clinical efficacy, it is certainly impressive in terms of the various outcomes."* *"It's a therapy that is enhancing your own immune system through cellular mediation, T cellular mediation, **to attack the cancer cells and not injure the healthy cells**."*
Efficacy	*"The things to me that were most impressive is that [the] efficacy data is reflecting patients who have already failed traditional therapy. So you're **taking the worst possible patients and still showing significant efficacy**…"* *"After patients have failed two courses of BCG, we have Valstar, but the **data isn't even anywhere close to this data**…"*

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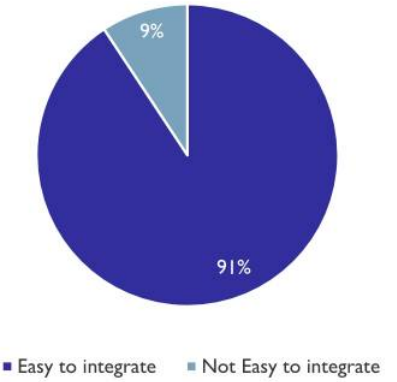
Source: Sesen Bio Qualitative market research, Urologist In-depth Interviews (IDIs) June 2019, n = 30.

Vicinium has the potential to provide continuity of care for patients with NMIBC

Treatment Protocol	Treatment with BCG	Treatment with Vicinium
Directed by Urologist	✓	✓
Administration by Urology nurse	✓	✓
Bladder infusion via urinary catheter	✓	✓
2-hour infusion, hold, and rotation	✓	✓
Response assessment every 3 months	✓	✓

>90% of high-prescribing Urologists s
that Vicinium would be very easy t
integrate into their practice.*



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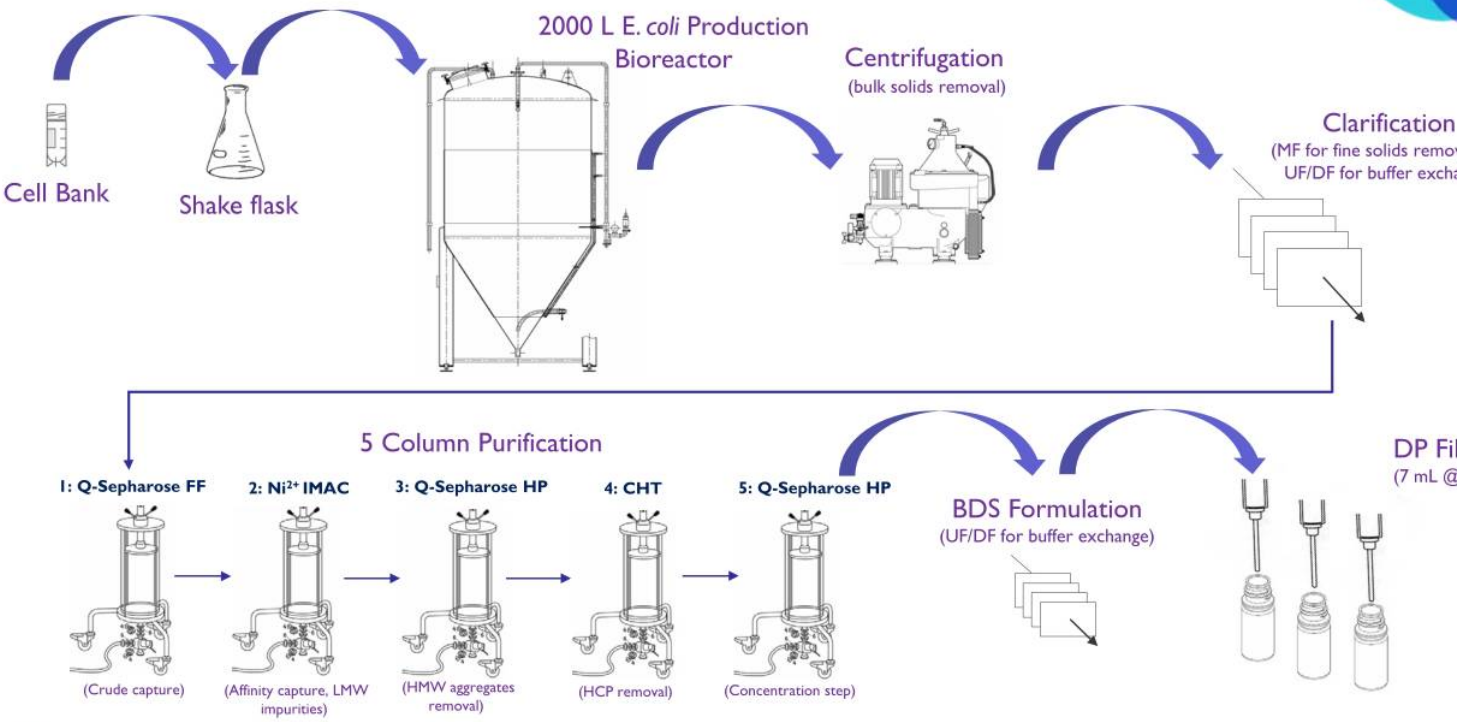
Microbial manufacturing of Vicinium is simple, reliable and inexpensive



MF, microfiltration; UF, ultrafiltration; DF, diafiltration; FF, Fast-flow; IMAC, immobilized metal affinity chromatography; HP, High-performance; CHT, ceramic hydroxyapatite; BDS, bulk drug substance; DP, drug product; LMW, low molecular weight; HMW, high molecular weight; HCP, host-cell protein.

Source: Arjune Premsukh, Joelle Lavoie JM, Jeannick Cizeau, Joycelyn Entwistle, Glen MacDonald. Protein Expression Purification. 2011 Jul;78(1):27-37.

SESEN BIO KEY HIGHLIGHT

1. Positive interactions with FDA on May 20 June 6th results in greater confidence in ou regulatory and commercial pathway
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2019 Outlook

Strengthened Financial Position

	June 30, 2019	December 31, 2018
Cash and Cash Equivalents	$64.9M	$50.4M

Upcoming Milestones

- Three key regulatory events anticipated in 4Q 2019:
  1. Type B CMC meeting to align on the submission strategy of the CMC module
  2. Type C clinical meeting to discuss the post-marketing confirmatory trial
  3. Initiation of BLA submission
- Expected Advisory Committee (ODAC) meeting post-BLA submission
- Potential OUS partnerships as early as 1H 2020

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Recent and Upcoming IR Events

Recent 2019 IR Presentations

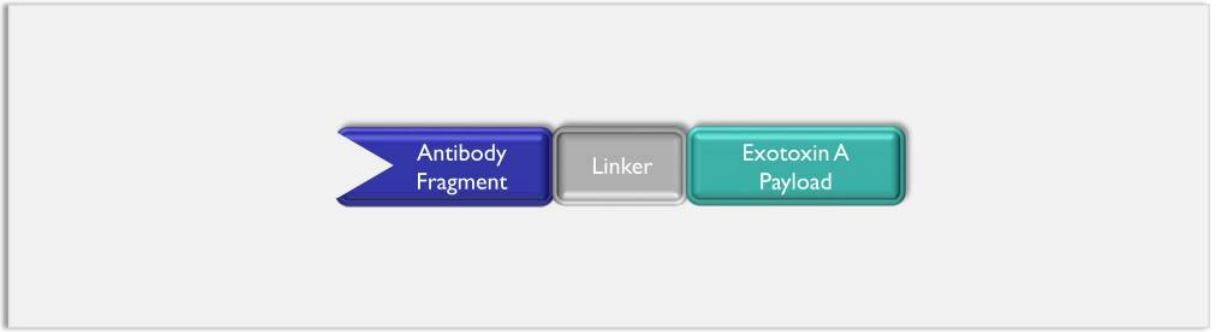
- Business Update - January 3
- 1Q 2019 Business Update - March 4
- 2Q 2019 Business Update - May 13
- Regulatory Meeting Update - June 10
- Canaccord Genuity Conference - August 7

Anticipated 2019 IR Presentations

- Investor Conference - September
- 3Q 2019 Business Update - November
- Regulatory Meeting/BLA Update - December

Appendix

Vicinium is a single fusion protein that selectively targets cancer cells



- Antibody fragment (scFv) targeting EpCAM linked to a cytotoxic payload (Pseudomonas exotoxin A) to form a single protein
- EpCAM over-expressed in cancer cells
- Highly selective targeting of cancer cells while generally sparing normal cells
- Inhibits protein synthesis, and kills both rapidly proliferating and slow-growing cancer cells
- Effective against multi-drug resistant cancer cells
- High potency relative to other available agents

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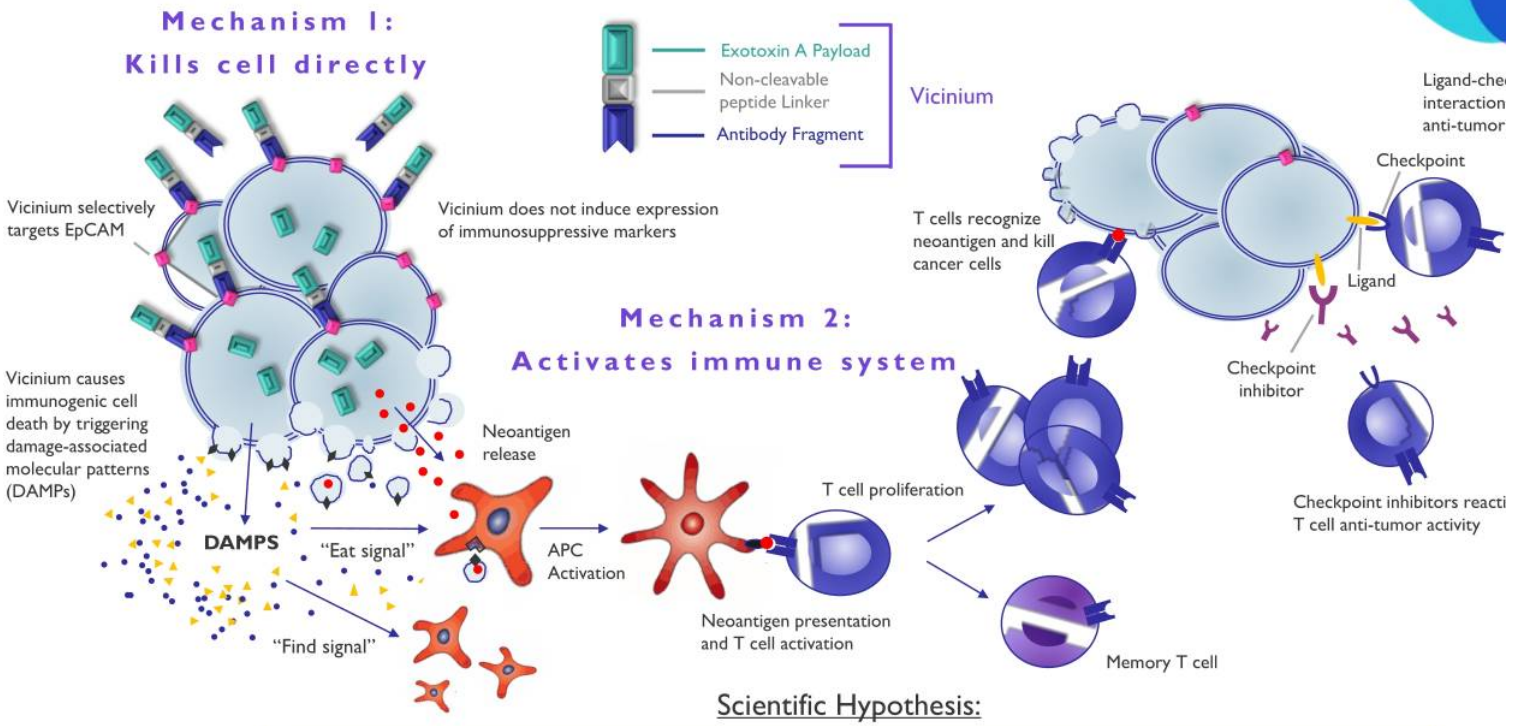
Vicinium: Dual Mechanism of Action



Scientific Hypothesis:

Induction of immunogenic cell death by Vicinium may facilitate a T-cell mediated anti-tumor response that could synergize with the ability of checkpoint inhibitors to relieve immunosuppression

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Latest global BCG shortage expected to last at least through remainder of 2019

BCG Shortage Current Events:

- Since 2012, Merck has been the sole supplier of BCG in the US and the majority of countries worldwide.
- Merck has changed its TICE BCG distribution strategy, now allocating exclusively to distributors and wholesalers based on product supply and historical purchasing patterns.
- Merck anticipates this global supply constraint to continue throughout 2019.
- Prominent groups such as AUA, BCAN, and the LUGPA are advocating with the FDA and payers to find solutions.
- The AUA has issued updated guidance for high-risk NMIBC to maximize patient care, including decreased dosing, delayed maintenance therapy, first line use of alternative therapies, and earlier surgical intervention via radical cystectomy.

Sources and Additional Information:
Wall Street Journal. *Sanofi to Stop Production of Bladder Cancer Drug BCG*. Peter Loftus. 2016.
https://www.auanet.org/practice-resources/bcg-info/bcg-shortage-notice
https://www.bcan.org/2019-bcg-shortage-bladder-cancer/

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Our long-term relationship with the agency has allowed us to shape our nonclinical and clinical program in alignment with FDA guidance

2018 FDA Guidance	Vicinium Clinical Program
Conduct nonclinical studies to assess toxicity in animal models	✓
Conduct nonclinical studies to demonstrate anti-tumor activity	✓
Conduct nonclinical studies to determine optimal dose and schedule	✓
Examine anti-tumor activity and optimal dose schedule in early phase clinical trial	✓
Papillary cohort endpoint of recurrence-free survival (time to event endpoint)	✓
CIS studied in single-arm trial with CRR & DoR as primary endpoints	✓
Papillary cohort not in primary efficacy endpoint	✓
Prefer intravesical vs. systemic	✓
Specifically define trial entry criteria	✓
Definition of BCG-unresponsive disease	✓
2004 WHO classification for tumor grading	✓
Central pathology review of biopsy tissue and urine cytology	✓
Collect data on patients' previous anti-cancer therapies	✓
Enroll patients who reflect clinically relevant patient population	✓
Optimize risk-benefit balance with dose selection	✓
Definition of CRR	✓
Collect time to cystectomy data	✓
Lower bound of 95% confidence interval rules out clinically unimportant CRR	✓
Nonclinical studies to determine need for evaluation of systemic toxicity	✓
Consistent efficacy and safety data across Phase I, II and III trials	✓

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Source: FDA Guidance: BCG-Unresponsive Non-muscle Invasive Bladder Cancer: Developing Drugs and Biologics for Treatment Guidance for Industry, February 2018.
CRR, Complete Response Rate; DoR, Duration of Response; BCG, bacillus Calmette-Guérin; WHO, World Health Organization.

Phase III Trial: Patient Demographics

CHARACTERISTICS	COHORT 1 CIS that was refractory or recurred within 6 months of adequate BCG	COHORT 2 CIS that recurred >6 months but ≤11 months of adequate BCG	COHORT 3 Papillary tumors (without CIS) that were refractory or recurred within 6 months of adequate BCG
Total patients enrolled	86	7	40
Evaluable patients at 3-months	86	7	40
Evaluable patients at 6-months	86	7	40
Evaluable patients at 9-months	86	7	40
Evaluable patients at 12-months	86	7	40
Mean age (years)	73	67	75
Males/Females	63/23	6/1	34/6
Mean prior treatment for NMIBC			
BCG cycles (courses)	3 (range 2-13)		3 (range 2-13)
BCG cycles (instillations)	16 (range 8-45)		15 (range 7-48)
Intravesical chemotherapy	1 (range 0-23)		1 (range 0-6)
TURBT	4 (range 0-28)		4 (range 0-10)

TURBT: transurethral resection of bladder tumor
Note: Data are as of May 29, 2019 data cut

Phase III Trial: Evaluable Patient Data Tables by Cohort for Carcinoma *in situ*

Cohort 1 (n=82) Complete Response Rate		
Time Point	Evaluable Patients	Complete Response Rate (95% Confidence Interval)
3-months	n=82	39% (28%-50%)
6-months	n=82	26% (17%-36%)
9-months	n=82	20% (12%-30%)
12-months	n=82	17% (10%-27%)

Cohort 2 (n=7) Complete Response Rate		
Time Point	Evaluable Patients	Complete Response Rate (95% Confidence Interval)
3-months	n=7	57% (18%-90%)
6-months	n=7	57% (18%-90%)
9-months	n=7	43% (10%-82%)
12-months	n=7	14% (0%-58%)

Response-evaluable population includes any mITT subject who completed the induction phase
Note: Data are as of May 29, 2019 data cut

Additional Vicinium Clinical Data

Preliminary Phase II vs. Phase III Complete Response Rate		
Time Point	Phase II Pooled CRR (95% Confidence Interval)	Phase III Pooled CRR (95% Confidence Interval)
3-months	40% (26%-56%)	40% (30%- 51%)
6-months	27% (15%-42%)	28% (19%-39%)
9-months	18% (8%-32%)	21% (13%-31%)
12-months	16% (7%-30%)	17% (10%-26%)

Dosing:

Phase II:
Cohort 1: 6 weekly induction doses, 6 weeks off; if a CR achieved, proceed to maintenance dosing of every 3 months for 9 months; those with residual disease at 3 months had option of to start maintenance or receive a second induction course.
Cohort 2: 12 weekly induction doses; if a CR achieved, proceed to maintenance dosing of every 3 months for 9 months.

Phase III:
Biweekly induction doses for 6 weeks followed by weekly dosing for 6 weeks; if a CR achieved, proceed to maintenance of every other week dosing for 2 years total.

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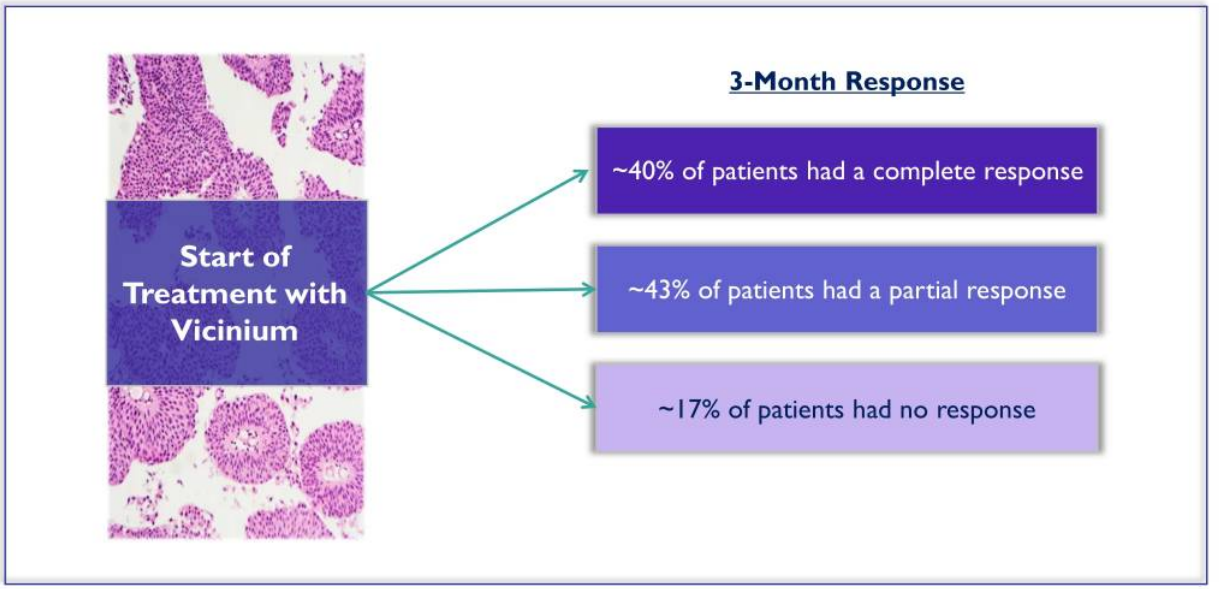
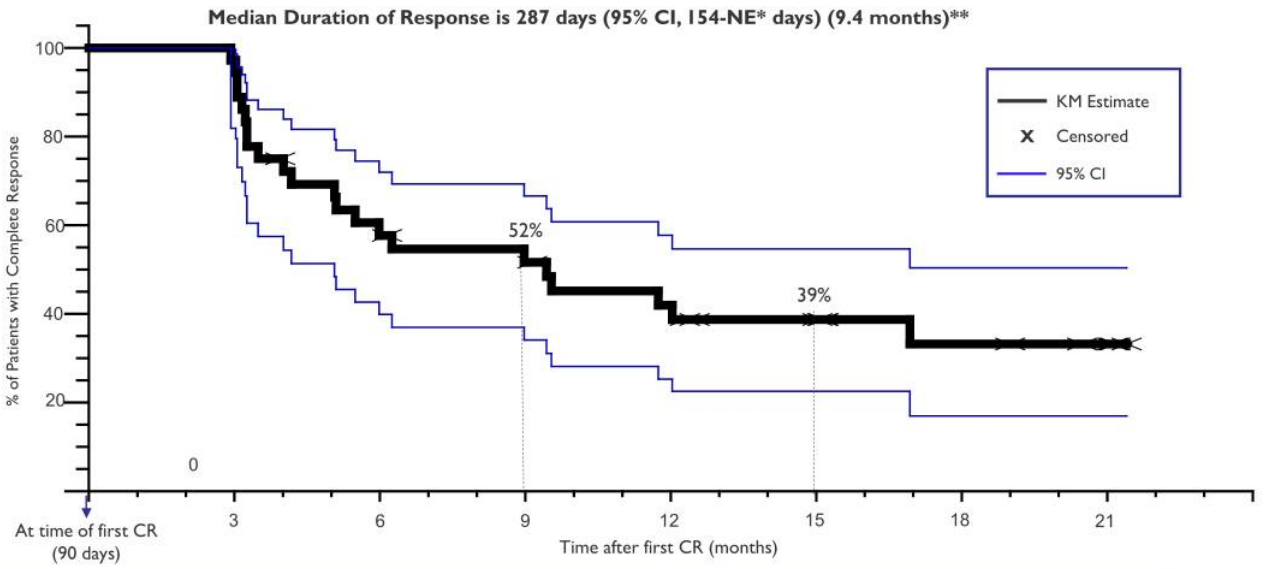
Note: Phase III data are as of May 29, 2019 data cut

Complete and Partial Response: In our Phase II clinical trial, 83% of patients had a complete or partial response



*Note: Data are from Phase II clinical trial, n=45 (~40% of patient had a complete response at 3 months; 60% of patients did not have a complete response and, of those, 71% of patients had a partial response). Partial response, as measured by bladder mapping, is defined by non-complete response patients who had either a reduction in tumor size or did not experience an increase in bladder area affected. Bladder mapping was not done as part of the Phase III trial, therefore partial response data are not available.

Duration of Response: 52% of CIS patients who had a complete response at 3 months remained disease-free for a total of 12 months after starting treatment

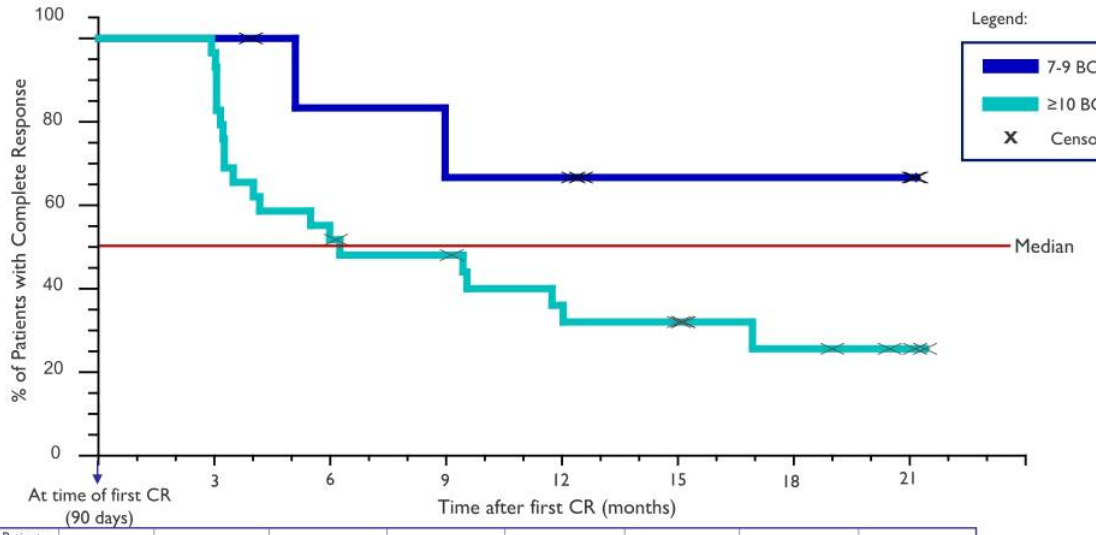


KM Evaluable Patients:	36	35	21	16	13	10	6	4

Duration of response is defined as the time of complete response to treatment failure.
*Not Estimable, the upper bound for the 95% confidence interval has not reached the median.
**Note: Data reflect an *ad hoc* analysis of pooled results of patients in cohorts 1&2. Median duration of response for the primary endpoint, Cohort 1 (n=86) is 273 days (95% CI=122-NE), and duration of response for Cohort 2 (n=7) is 290 days (95% CI=167-NE), based on the Kaplan-Meier method.

Duration of Response: Vicinium is generally more efficacious in CIS patients treated with less BCG

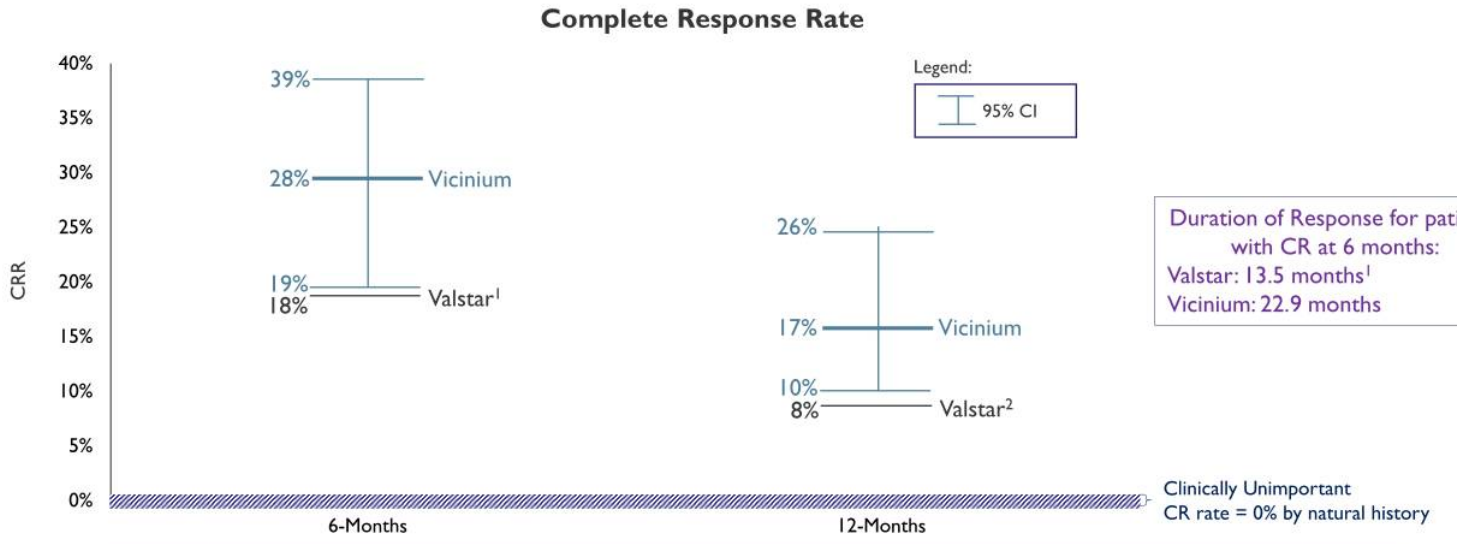
The BCG shortage may cause a new normal wherein patients receive less BCG



KM Evaluable Patients 7 – 9 BCG Instillations:	7	7	5	4	4	2	2	2
KM Evaluable Patients ≥10 BCG Instillations:	29	28	15	13	9	8	4	2

Duration of response is defined as the time of complete response to treatment failure.
*Note: Data reflect an *ad hoc* analysis of pooled results of patients in cohorts 1&2.

Complete Response Rate: We believe our 95% confidence interval rules out the CRR for Valstar and a clinically unmeaningful CRR



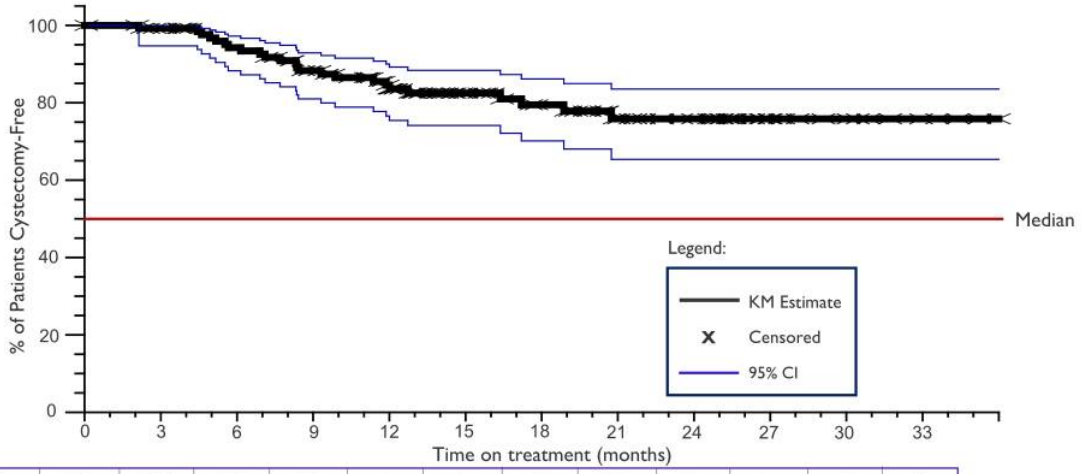
Duration of Response for pati with CR at 6 months:
Valstar: 13.5 months[1]
Vicinium: 22.9 months

2018 FDA Guidance: For single-arm trials of patients with BCG-unresponsive NMIBC in patients with CIS that use complete response rate as the primary endpoint, the lower bound of the 95 percent confidence interval around the observed response rate should rule out a clinically unimportant complete response rate.

Sources:
[1]Valstar prescribing information. 6-month complete response data used as basis for FDA approval of Valstar in 1998. [2]Everyday Urology. Volume 1 Issue 3. *Emerging Therapy for BCG-Unresponsive Non-Muscle Invasive Bladder Cancer.* Dinney 2016.
Data are as of May 29, 2019 data cut

Time to Cystectomy: Patients treated with Vicinium remain cystectomy-free for an average of 930 days (~31 months) after treatment with Vicinium

>75% of patients remain cystectomy-free for at least 2.5 years



KM Evaluable Patients:	133	127	113	100	86	60	49	37	29	15	10	5

2018 FDA Guidance: The goal of therapy in patients with BCG-unresponsive NMIBC is to avoid cystectomy.

Time to cystectomy: defined as the time from the date of first dose of study treatment to surgical bladder removal. Data reflected consist of patients from all cohorts 1, 2 & 3 (n=133).
Note: Average time to cystectomy from transurethral resection of bladder tumor (TURBT) for NMIBC patients with high-risk papillary disease in Europe is ~105 days (National Institute of Health, *Timing of radical cystectomy in Central Europe - multicenter study on factors influencing the time from diagnosis to radical treatment of bladder cancer patients*, Poletajew S, et al., 2015.)
Additional FDA guidance states that although delay in radical cystectomy is considered a direct patient benefit, the variations in patient and health care provider preferences can confound the interpretation of this endpoint in randomized trials and particularly in single-arm trials. Nevertheless, sponsors should collect these data, which may provide supportive evidence of effectiveness.

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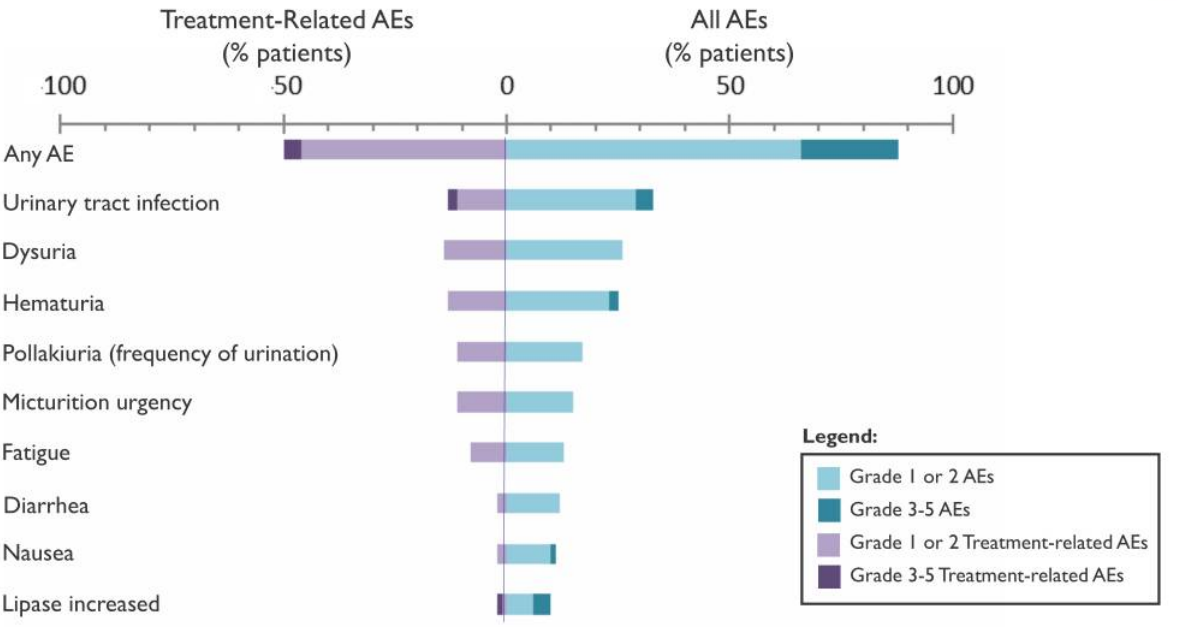
Safety and Tolerability: In our Phase III trial, AEs were generally low grade and resulted in a low rate of discontinuation

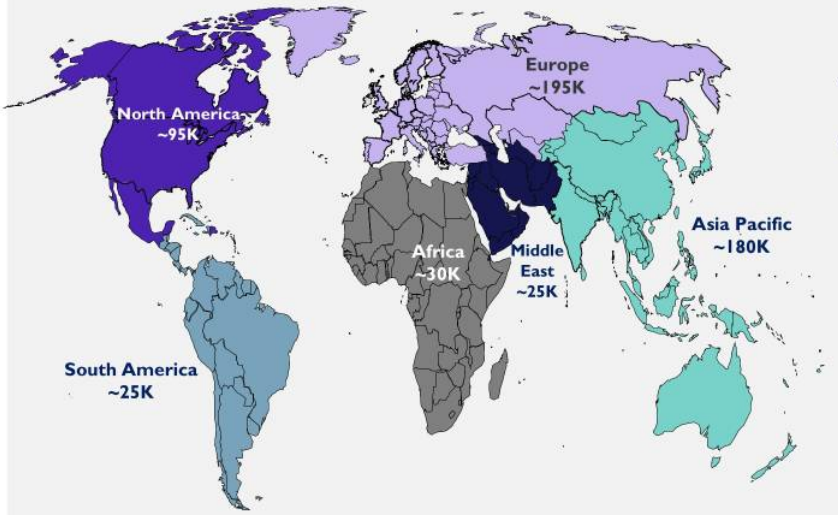


Safety profile of Vicinium is favorable relative to BCG, Valstar and checkpoint inhibitors

Note: AE = Adverse Event

Bladder cancer is highly prevalent with tremendous unmet medical need

~550,000 New Cases Each Year Globally[1]

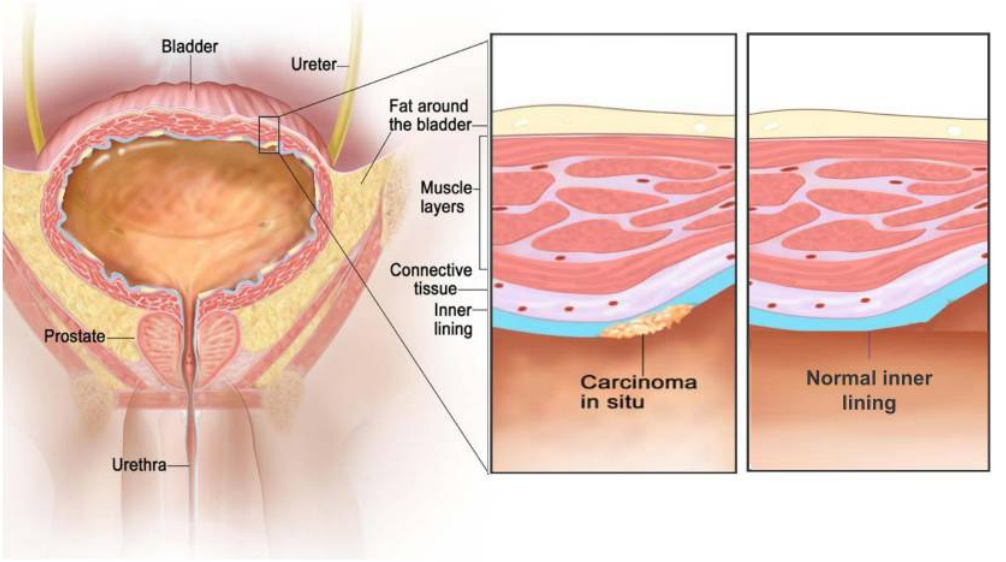


- $4B+ in annual treatment costs for bladder can in the US alone[2]
- 75-85% diagnosed as NMIBC[3]
- Limited treatment options for high-risk NMIBC
  - Only three approved treatments in the last 100 y
  - BCG remains standard-of-care in many countries
    - 50% patients fail within the 1st year[4]
    - 90% of patients fail within 5 years[4]
  - Radical cystectomy is recommended option after
  - Global BCG shortage limiting access and full dos for patients

Sources: [1]World Cancer Research Fund. Bladder Cancer Statistics. 2019. [2]Mossanen M. Curr Opin Urol. 2014. [3]Therapeutic Advances in Urology. *Best Practices in the Treatment of Non-muscle Invasive Bladder Cancer.* 2012. [4]Lightfoot A. The Scientific World Journal. 2011.

Carcinoma *in situ*: the most difficult form of NMIBC to treat

Carcinoma *in situ* vs. Normal Bladder Lining:



Clinical Trial Implications:

- Field change disease often involving the entire bladder li that is very difficult to treat
- Failed on two or more course of BCG, which is the gold standard for treatment of high risk NMIBC
- Rigorous local and independe central review of all urine cytology and biopsy samples
- Complete response definition means that the bladder is completely cancer free at eac timepoint

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Note: Diagram is for illustrative purposes

Radical cystectomy remains recommended treatment option after BCG failure

60-70% lifetime risk of cystectomy associated with NMIBC[1]

- Long, complex surgical procedure (10+ hours)
- Significant rates of morbidity (30-60% within 90 days) and mortality (2-9% within 6 months)[2]
  - 64% complication rate within 90 days[3]
  - ~35% of patients require ER visits and 26% require readmission[3]
  - Additional complications can occur as most patients with NMIBC are elderly and often have co-morbidities
- Tremendous impacts to patient quality of life
  - Life following radical cystectomy requires catheterization and urinary diversion

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Source:
[1]Aldousari, S. Can Urol Assoc. J. 2010 Feb. [2]Steinberg P. Expert Rev Anticancer Ther. 2012. [3]Falchook, A. *Bladder Cancer: Mortality, Morbidity, and QoL After Treatment.* 2014.

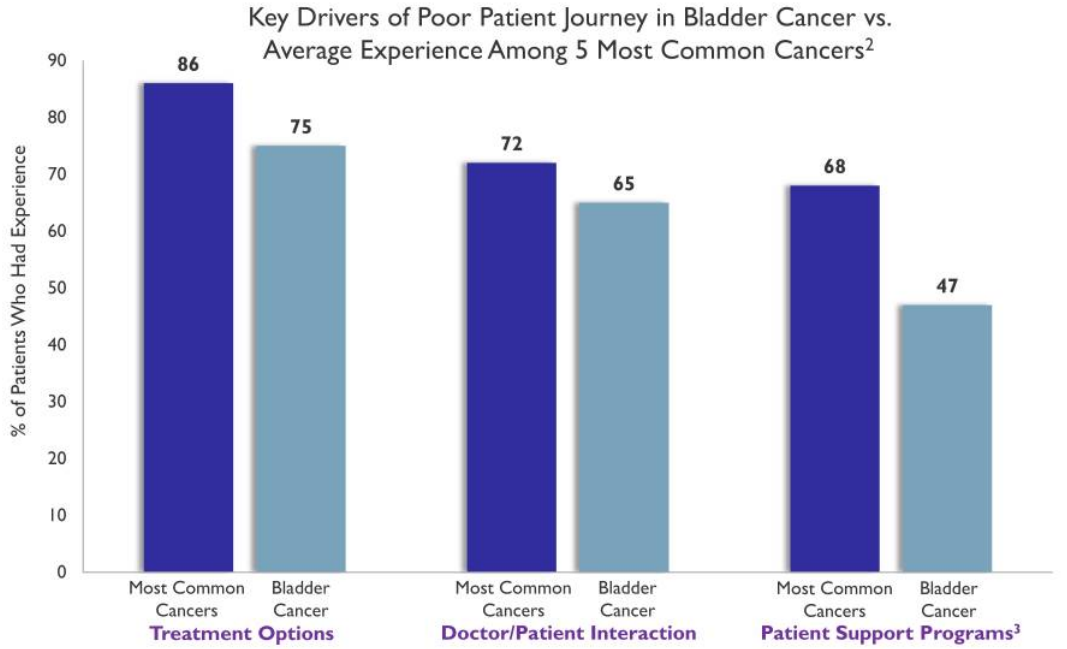
Significant unmet need for innovative medical therapies to treat NMIBC

Only 3 products have ever been approved by the FDA for NMIBC

Product	FDA Approval	Additional Product Information
Thiotepa	1959	Rarely used in current treatment regimens
BCG*	1989 (Tice)	Recommended first line treatment
Valstar	1998	Used only when radical cystectomy is contraindicated

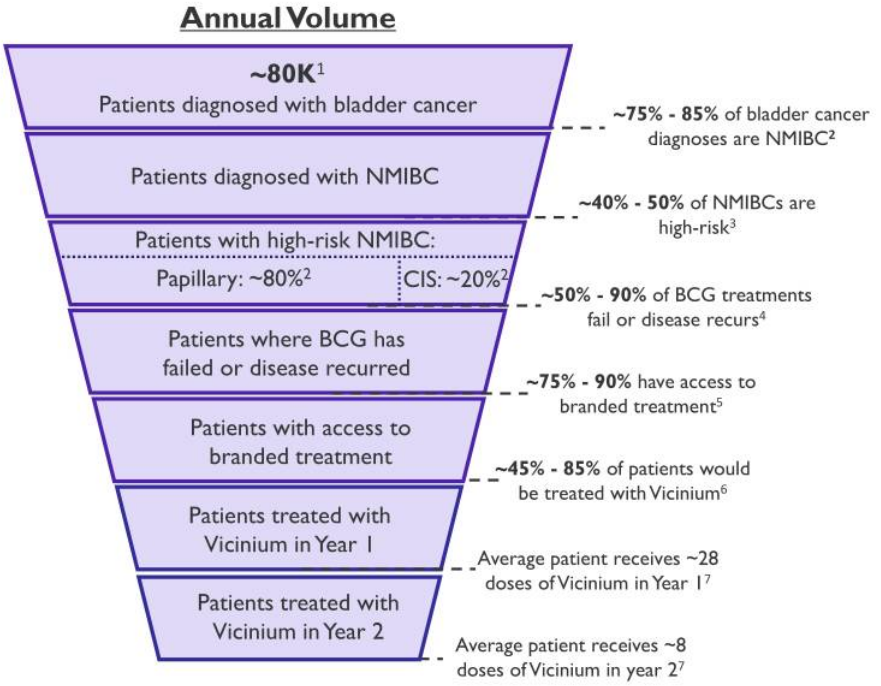
Source:
National Institute of Health. *Development of Systemic and Topical Drugs to Treat Non-muscle Invasive Bladder Cancer*. Jarow et. al. 2015.
*Note: BCG Connaught strain was approved in 1990 and supply withdrawn from the US market in 2012.

Patient surveys have shown that the experience of those with bladder cancer is one of the poorest[1]



Sources: [1]Cancer Patient Experience Survey 2011/12. Department of Health. N=71,793. https://www.quality-health.co.uk/resources/surveys/national-cancer-experience-survey/201112-national-cancer-patient-experience-survey-1/201112-national-cancer-patient-experience-survey-reports/495-cancer-patient-experience-survey-national-report-2011-12/file. [2]Most common cancers include breast, lung, prostate, colorectal, and skin cancers. SEER Database. https://seer.cancer.gov/statfacts/html/urinb.html. [3]Includes self-help groups and financial assistance.

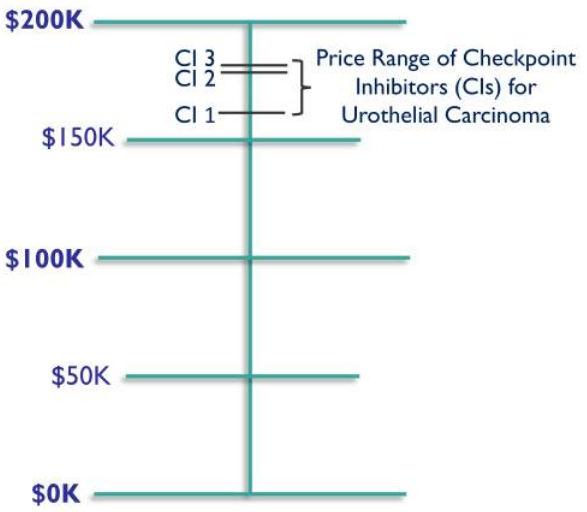
Addressable Market (US)



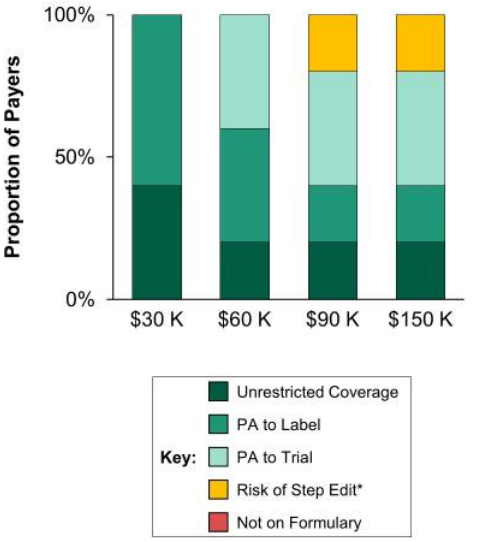
Sources:
[1]National Cancer Institute, SEER Cancer Stat Facts: Bladder Cancer, 2017. [2]Therapeutic Advances in Urology. *Best Practices in the Treatment of Non-muscle Invasive Bladder Cancer.* 2012. [3]Aldousari, S. et al (2010). Update on the management of non-muscle invasive bladder cancer. *Can Urol Assoc J*, 4(1), 56-64. [4]Memorial Sloan Kettering Cancer Center. *Bladder Cancer Management After BCG Failure.* 2014. [5]ClearView Analysis March 2019. [6]Sesen Bio Qualitative market research, Urologist IDIs June 2019 n = 30. [7]Phase III trial data as of May 29, 2019 data cut.

Pricing and Reimbursement (US)

Price Reference
(Annual Cost)[1]



Payer Management Responses to Pricing[2]



Sources:
[1]Center for Medicare and Medicaid Services (CMS) Average Selling Price (ASP) Price List. CI price benchmarks are based on Keytruda, Opdivo and Tecentriq.
[2]Payer Interviews, ClearView Analysis, n=10, March 2019.

*Note: Payers cited a possibility of using a step edit, but could not be certain, as the ability to use a step edit is new to their organization's Medicare Advantage medical benefit.
PA = Prior Authorization

We estimate the OUS opportunity for Vicinium is 2-3 times larger than the US

Geography	Est. Incidence Relative to U.S.[1]	Est. Price Relative to U.S.[2]
EU5	1.2 – 1.4	0.50 – 0.71
Japan	0.4 – 0.6	0.60 – 0.70
Rest of Europe (Not including EU5)	1.0 – 1.2	0.60 – 1.10
North America (Not including U.S.)	0.1 – 0.3	0.55 – 0.70
South America	0.2 – 0.4	0.50 – 1.00
Asia (Not including Japan)	1.6 – 1.8	0.40 – 0.60
Africa	0.3 – 0.5	~0.75[3]
Middle East	0.2 – 0.4	1.10 – 1.20
Oceania	0.05 – 0.2	0.55 – 0.70

Sources: Ferlay. Intern. J. Canc. 2015; UN World Population Reports; SEER; GLOBOCAN; RedBook; Lauertaxe; Ameli; NICE; Vademecum; AIFA; NHI; CADTH; ANVISA; CBiP; Danish Medicines Agency; The Pharmaceutical Benefits Scheme; Saudi Food & Drug Authority; South African Medicine Price Registry; FiercePharma; ClearView Analysis. [1]Relative incidence is calculated from total bladder cancer, and does not account for differences in the distribution of patients between NMIBC and MIBC. [2]Pricing multiplier is based on publicly available pricing information; averaged based on ex-manufacturer price of Keytruda and Opdivo, and is likely to vary greatly for each pharmaceutical, and across different countries within each region. [3]South Africa price multiplier was based on Keytruda only, as Opdivo has not yet been priced.

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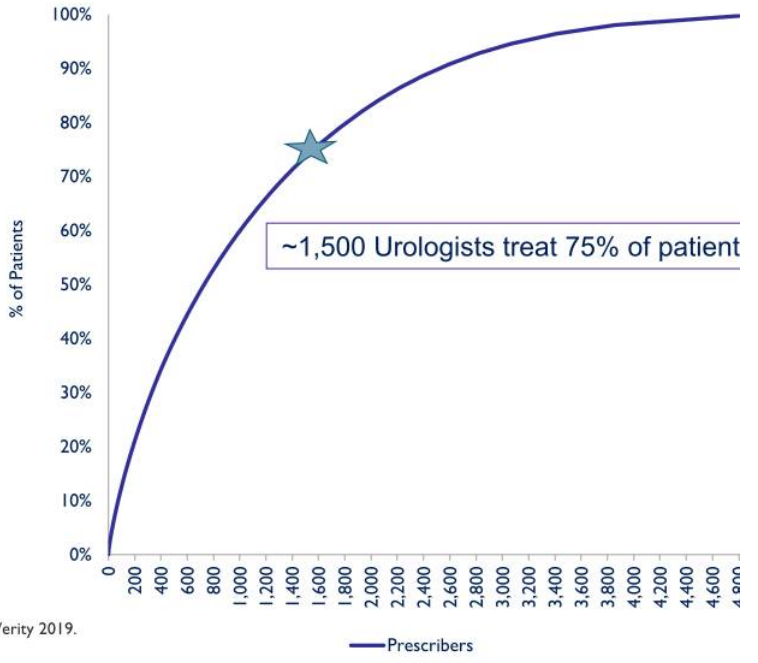
Only ~1,500 Urologists account for the bulk of NMIBC treatment and are concentrated in group practices allowing for a very efficient commercial model

~60% of Urology practices have ≥5 Urologists[1]

BCG Prescribers[2]



Source:
[1]AUA State of the Urology Workforce and Practice in the United States. 2017. [2]Health Verity 2019.

The Comparability Strategy for Vicinium has been accepted by the FDA*

Guidance

"If a manufacturer can provide assurance of comparability through analytical studies alone, nonclinical or clinical studies with the post-change product are not warranted."[1]

Sesen's analytical comparability plan is comprised of 4 key elements:

1. Analytical Release Testing
   - Assesses the purity, biological activity and general characteristics of the protein (e.g. purity by HPLC, endotoxin content)
2. Biophysical Characterization
   - Assesses the structural characteristics of the protein (e.g. Peptide Mapping, Differential Scanning Calorimetry)
3. Forced Degradation Studies
   - Assesses the degradation pathway of the protein when exposed to stress conditions (e.g. purity by HPLC after temperature and pH extremes)
4. Stability Studies
   - Assesses the stability of the protein under long-term and accelerated storage conditions (e.g. purity by HPLC after storage at -20°C and 2-8°C)

***At the May 20, 2019, Type C CMC meeting, Sesen reached agreement with the FDA on the Analytical Comparability Plan. Subject to final comparability data to be provided in the BLA submission, no additional clinical trials to establish comparability are deemed necessary at this time.**

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[1]International Conference on Harmonisation (ICH) Q5E, Comparability of biotechnological/biological products subject to changes in their manufacturing process.
HPLC, high performance liquid chromatography.

We have experienced partners for the global manufacturing and supply of Vicinium

FUJIFILM Diosynth biotechnologies

- Licensed for commercial production of 8 approved products
- 25+ years developing and manufacturing biologics
- 310+ protein-based therapeutics in development and/or manufacturing
- Proven track record with FDA and worldwide regulatory agencies

Baxter

Baxter's BioPharma Solutions Business:

- 160 clinical and commercial programs
- 60+ years of experience in manufacturing of oncology products
- ISPE 2016 Facility of the Year Award at site of Vicinium manufacture
- Proven track record with FDA and worldwide regulatory agencies

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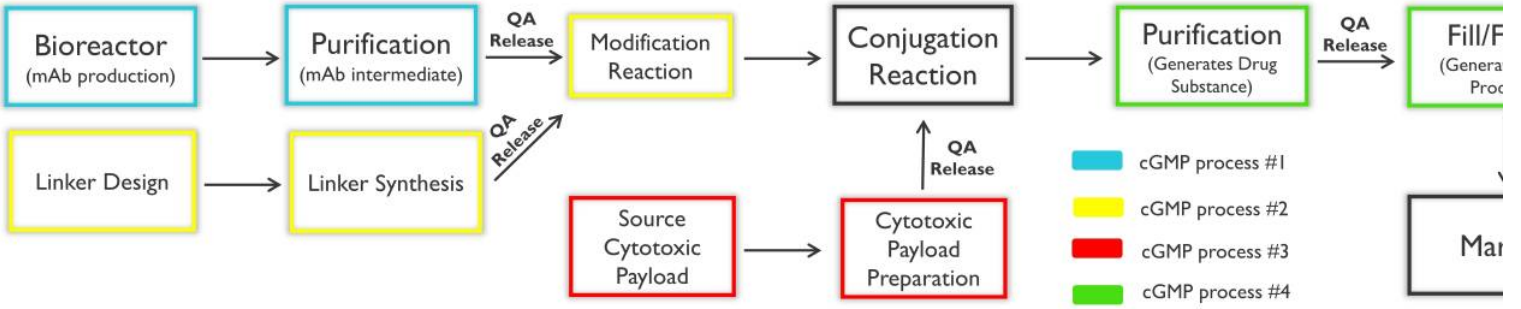
Vicinium: A single cGMP Manufacturing Process

Vicinium cGMP manufacturing process producing a single fusion protein
• Inexpensive • Reliable • Simple (linear)

Single cGMP process

ADCs: complex (branched) cGMP manufacturing - multiple cGMP processes involving process intermediates



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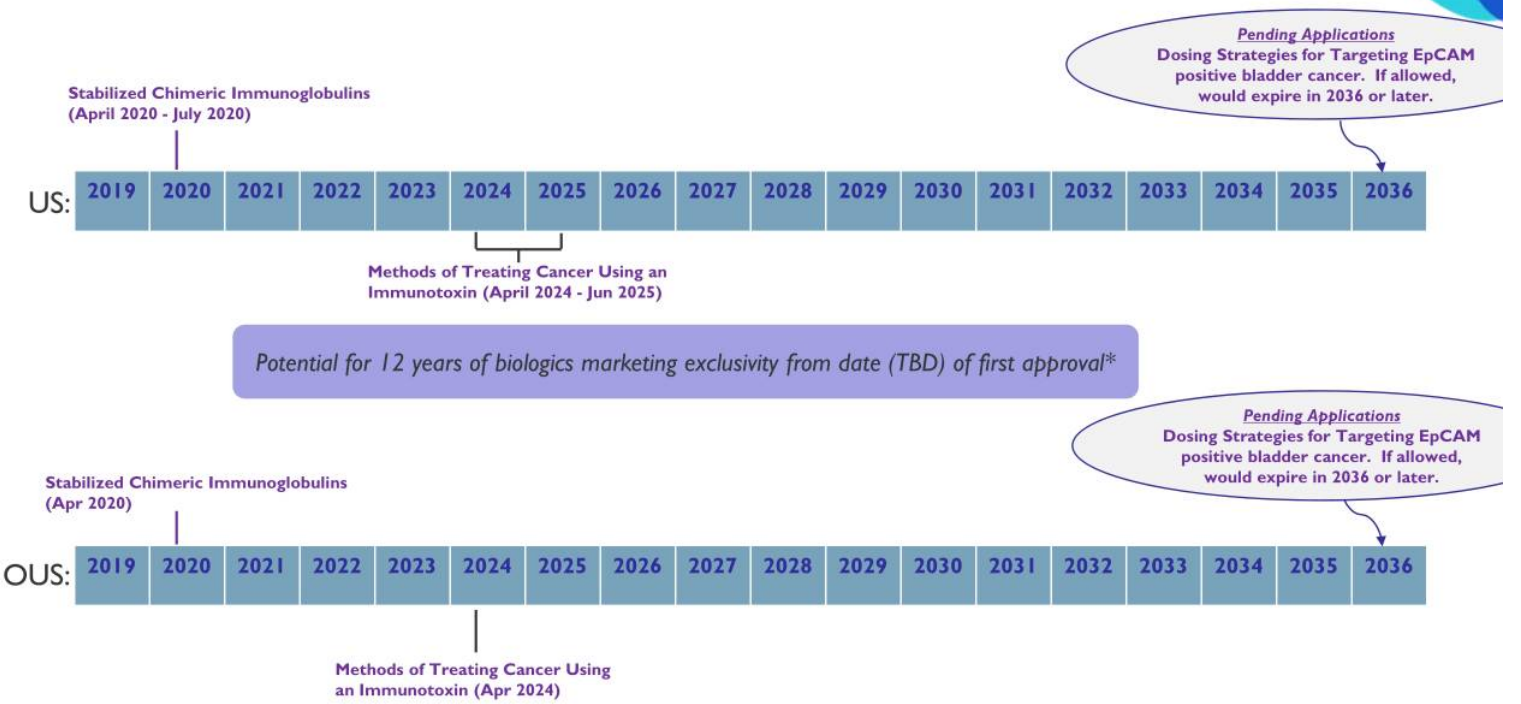
Vicinium Patent Life



Note: Patent life assessment reflects independent analysis by Hogan Lovells US LLP.
*Data exclusivity granted by FDA under the Biologics Price Competition and Innovation Act of 2009 (codified at 42 U.S.C. § 262(k))