Sesen b i o

June 2019 Regulatory Update

June 10, 2019

NASDAQ SESN





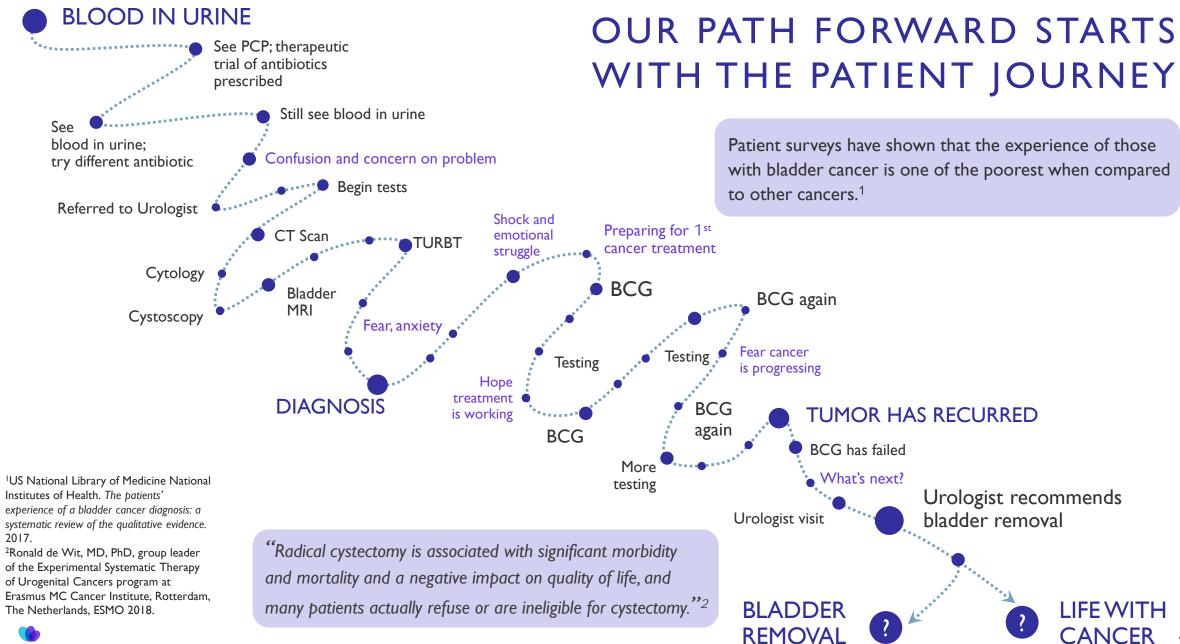
FORWARD-LOOKING STATEMENTS

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 efficacy of

Vicinium[®], the possibility that the FDA may require a change in our registration strategy and/or that the safety or efficacy data for Vicinium submitted as part of a BLA may not be considered sufficient by the FDA, our ability to successfully develop our product candidates and complete our planned clinical programs, the potential advantages or favorability of our product candidates, our ability to obtain marketing approvals for our product candidates, expectations regarding our ongoing clinical trials, availability and timing of data from clinical trials, the adequacy of any clinical models, expectations regarding regulatory approvals, our ability to obtain, maintain and protect our intellectual property for our technology and products, other matters that could affect the financial performance of the Company, other matters that could affect the availability or commercial potential of the Company's product candidates, expectations regarding the adequacy of our existing capital resources to fund our operating plan into 2020, and other factors discussed in the "Risk Factors" section of the Company's Annual Report on Form 10-K, and other reports on file with the Securities and Exchange Commission (SEC). The forward-looking statements contained in this presentation are made as of the date hereof, and Sesen Bio assumes no obligation to update any forward-looking statements whether as a result of new information, future events, or otherwise except as required by applicable law.





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2019 Outlook



Cash runway into 2020, with no outstanding debt

	March 31, 2019	March 31, 2018
Cash and Cash Equivalents	\$42.4M	\$19.7M

 As of 6/7/2019: \$3.4M in additional cash proceeds from shares issued pursuant to warrant exercises*

Recent milestones with FDA

Type of FDA Meeting	Completed Meeting Date
Type C CMC Meeting	May 20, 2019
Type B Pre-BLA Meeting	June 6, 2019



*As of March 31, 2019, the Company had outstanding warrants to purchase 9.3M shares of common stock at a weighted average exercise price of \$1.17 per share. Subsequent to March 31, 2019 through June 7, 2019, 3.3M shares of common stock were issued upon warrant exercises, which resulted in aggregate net proceeds to the Company of \$3.4M.

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 plans to initiate submission of the BLA in the fourth quarter of 2019

Upcoming Milestones

- Two additional meetings with the FDA planned for 2H 2019:
 - Type B CMC meeting to discuss the submission strategy of the CMC module
 - Type C meeting to discuss the details of a post-marketing confirmatory trial in support of the Accelerated Approval Pathway for Vicinium
- Initiation of BLA submission in the fourth quarter of 2019
- Expected meeting and review with the FDA Oncologic Drug Advisory Committee post BLA submission
- Potential OUS partnerships as early as 1H 2020



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





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

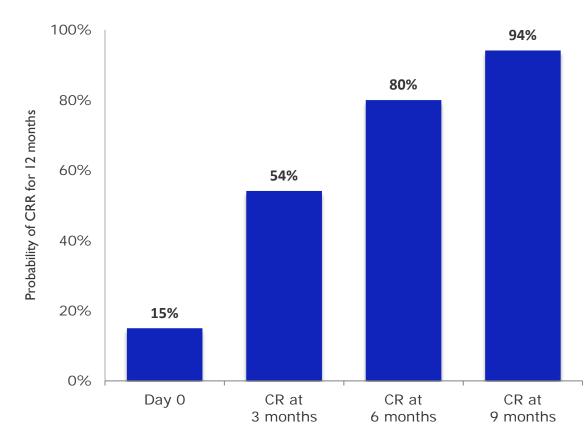
PIII All Cohorts

Endpoint	How Endpoint is Measured	Preliminary 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).	 39% CRR at 3 months Lower bound of 95% CI rules out clinically unmeaningful CRR Higher complete response in patients receiving less BCG 	
Duration of Response (DoR) Primary Endpoint CIS patients	Defined as the time of complete response to treatment failure.	 ~50% duration of 9 months or greater (12 months of therapy) ~40% duration of 21 months or greater (24 months of therapy) The longer the duration, 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 Nearly 40% probability of remaining recurrence-free for 24 months 	
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 854 days >75% of patients cystectomy-free at 2.5 years Responders ~15x more likely to be cystectomy-free		
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.	 ~95% of patients are progression-free at 12 months >85% of patients progression-free at 24 months 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.	 30% of patients are event-free at 12 months 22% of patients remain event-free at 18 months 20% of patients remain event-free at 24 months 	
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.	 >99% of patients have overall survival at 12 months >90% of patients have overall survival >2.5 years 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 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 	

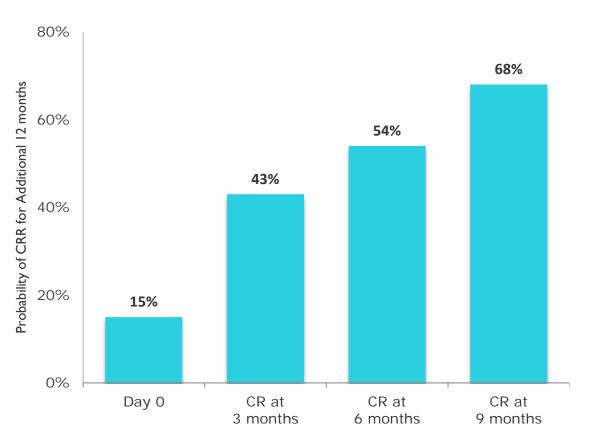
Note: Data reflected are as of March 1, 2019 data cutoff

Duration of Response: For patients treated with Vicinium for three months, at each time point a CR is confirmed, the probability of maintaining a CR increases





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

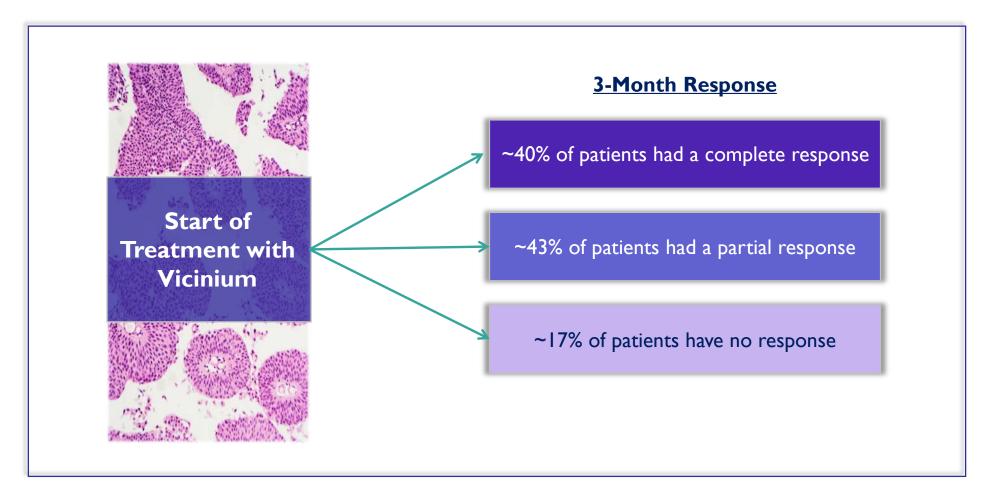




*As estimated by Kaplan-Meier (starting at time of designated CR) Note: Data reflected are as of March 1, 2019 data cutoff PIII

CIS Patients

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





*Note: Data referenced 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. Note: Data reflected are as of March I, 2019 data cutoff

PII CIS Patients



BCG Shortage Current Events:

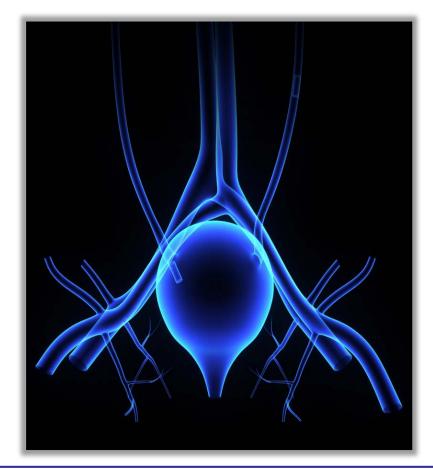
- Since 2012, Merck has been the sole supplier of BCG in the US and the majority of countries worldwide.
- Merck has changed its TICE BCG distribution strategy, now allocating exclusively to distributors and wholesalers based on product supply and historical purchasing patterns.
- Merck anticipates this global supply constraint to continue throughout 2019.
- Many prominent groups such as AUA, BCAN, LUGPA, etc. 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/ We believe our Phase III data suggests Vicinium may be 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 Surgery

- 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 bladder includes removal of the prostate, seminal vesicles, and surrounding tissue
- Radical cystectomy requires life-long catheterization and urinary diversion

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





June 2019 Company Highlights

- Positive interactions with FDA on May 20th and June 6th resulting in greater confidence in our regulatory and commercial pathway
- 2. Long-term relationship with the FDA enables high level of alignment with regulatory guidelines
- 3. Vicinium appears to demonstrates compelling benefit-risk profile with the potential to be BCG and cystectomy-sparing



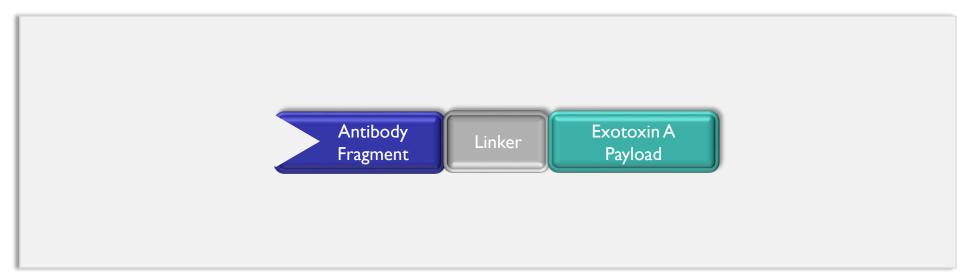
Additional Information





- I. Updated Phase III data further demonstrate a compelling benefit-risk profile*
- 2. Strong regulatory and commercial rationale
- 3. Manufacturing process expected to be reliable and inexpensive

Vicinium is a small, single protein strand that selectively targets cancer cells

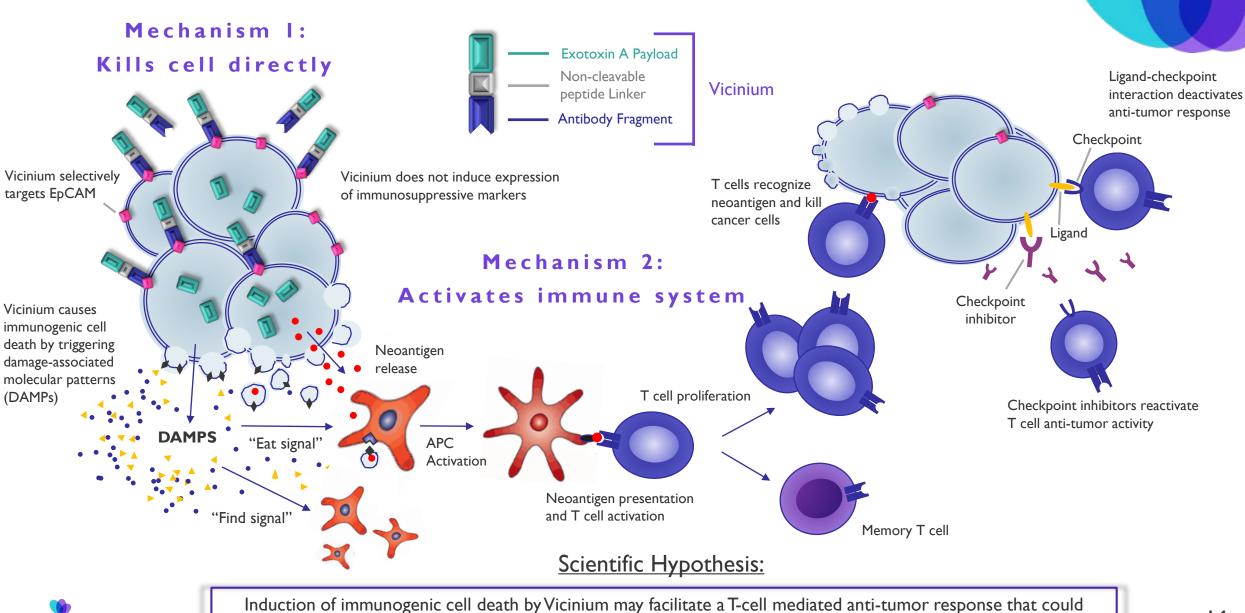


- Antibody fragment (scFv) targeting EpCAM linked to a cytotoxic payload (Pseudomonas exotoxin A) to form a single protein
- EpCAM over-expressed in cancer cells
- Highly selective targeting of cancer cells while generally avoiding normal cells
- Inhibits protein synthesis, and kills both rapidly proliferating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



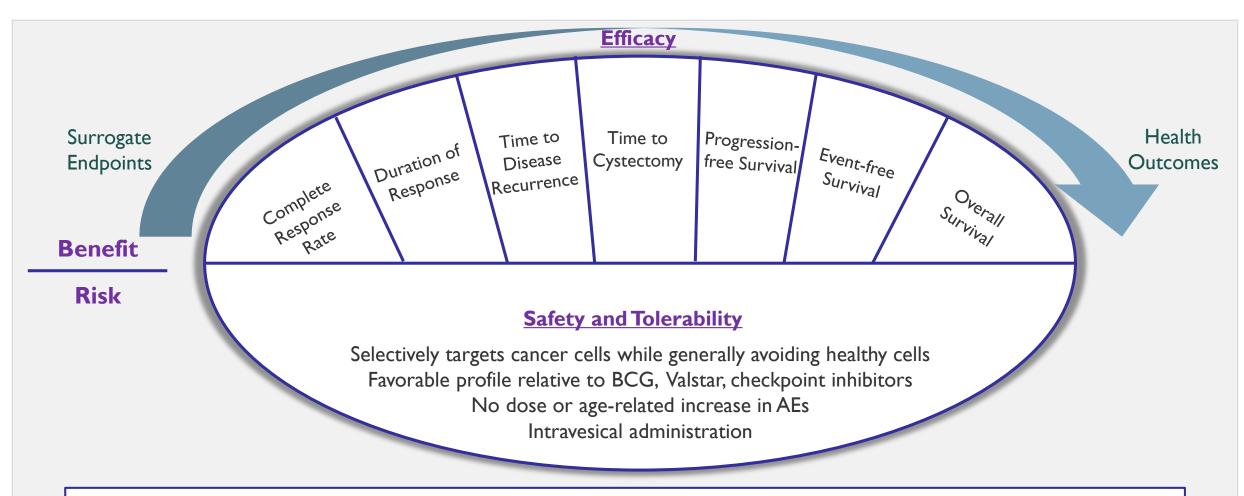
Vicinium: Dual Mechanism of Action

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synergize with the ability of checkpoint inhibitors to relieve immunosuppression

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

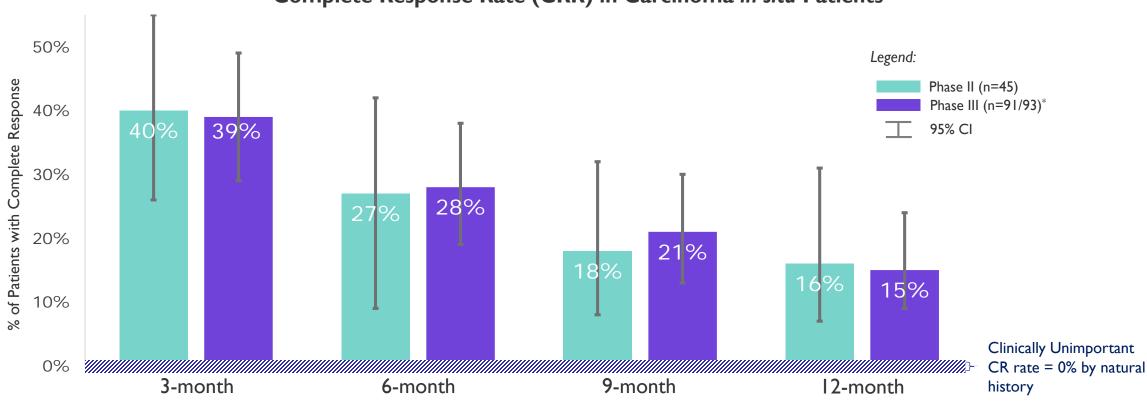


FDA Guidance: The approval of a marketing application is based on a favorable risk-benefit assessment.



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 March 1, 2019.

Complete Response Rate: Our Phase II and Phase III clinical trials are highly consistent for Complete Response Rate

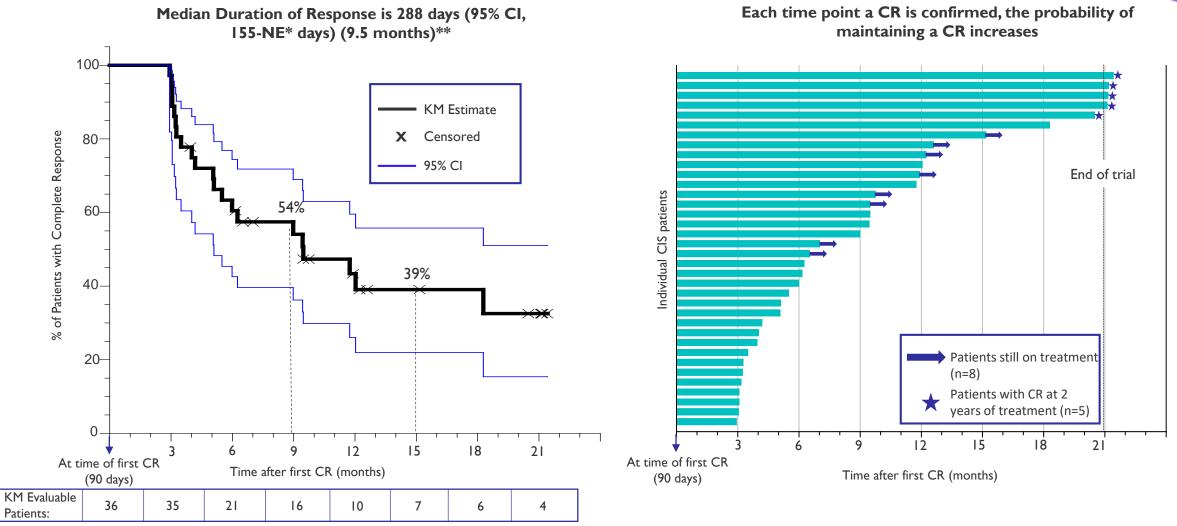


Complete Response Rate (CRR) in Carcinoma in situ Patients



*Note: Phase III data reflect an ad hoc analysis of pooled results of patients in cohorts 1&2 with Carcinoma in situ (with or without papillary disease) that were determined to be refractory or recurred less than 11 months after their last course of adequate BCG. As of the March 1, 2019 data cut, 91 of 93 patients have completed the 12-month diagnostic test. For cohort-specific complete response rates, including confidence intervals, refer to slide 27.

PII & PIII CIS Patients **Duration of Response:** 54% of CIS patients who were complete responders at 3 months remained disease-free for a total of 12 months after starting treatment



Duration of response is defined as the time of complete response to treatment failure.

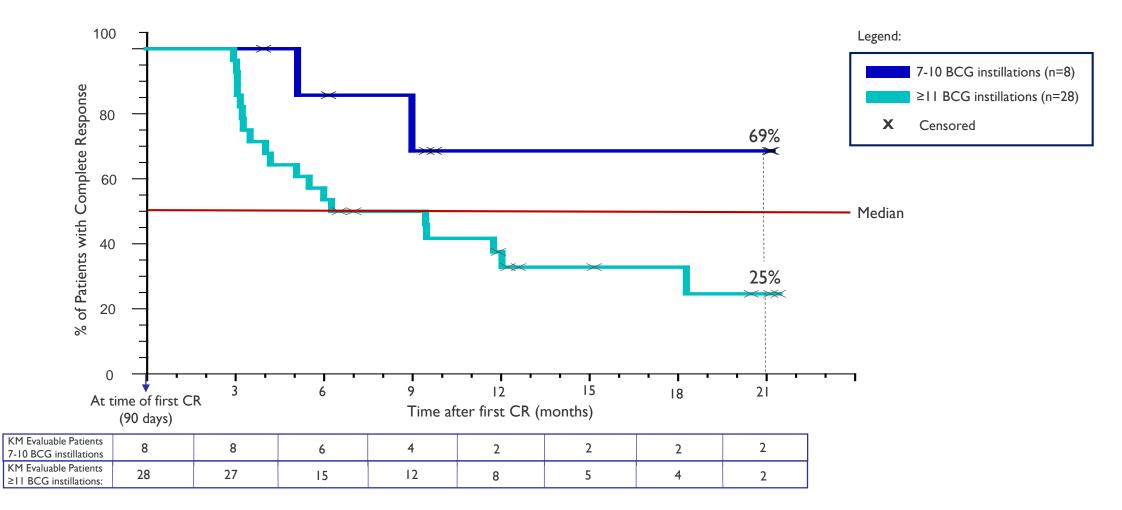


*Not Estimable, the upper bound for the 95% confidence interval has not reached the median.

**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 287 days (95% CI=127-NE), and duration of response for Cohort 2 (n=7) is 288 days (95% CI=167-NE), based on the Kaplan-Meier method.

PIII CIS Patients

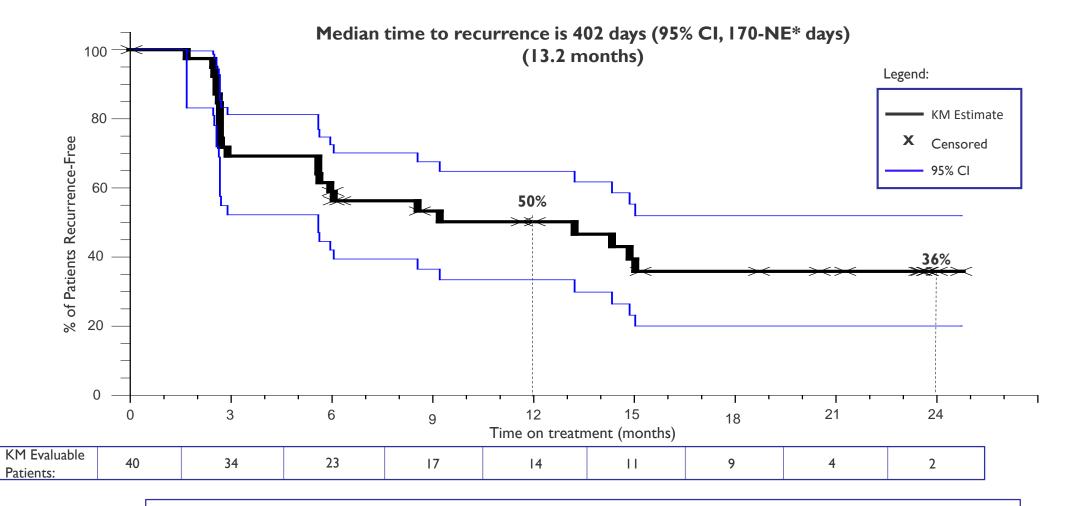
Duration of Response: Vicinium is generally more efficacious in CIS patients treated with less BCG





Note: Data reflected consists of Cohorts 1&2 patients (n=93) *Not Estimable, the upper bound for the 95% confidence interval has not reached the median. PIII CIS Patients

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



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.

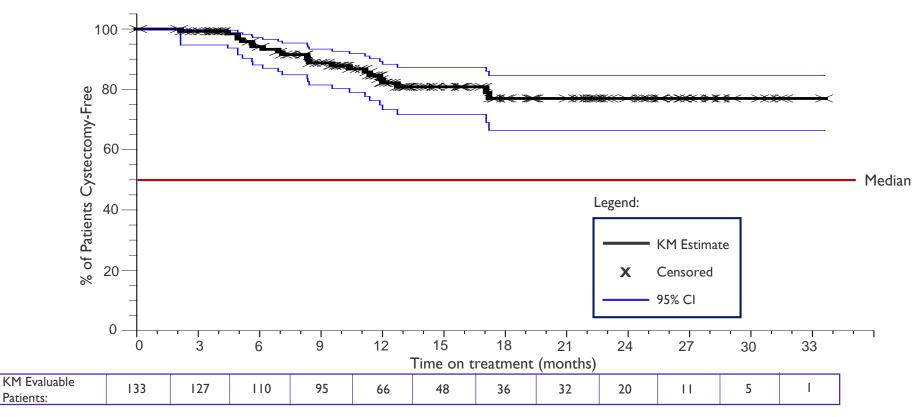
*Not Estimable, the upper bound for the 95% confidence interval has not reached the median.

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.

PIII Papillary

Patients

Time to Cystectomy: The average patient remains cystectomy-free for 854 days (~28 months) after treatment with Vicinium



Responders are ~15 times more likely than non-responders to remain cystectomy-free at 2.5 years

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.

PIII All Cohorts

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

rogression-Free Survival		
Time Point	Evaluable Patients	Progression-free Survival (95% CI)
6-months	50	99% (97%-100%)
12-months	21	96% (89%-100%)
18-months	9	88% (71%-100%)
24-months	4	88% (71%-100%)
vent-Free Survival		
Time Point	Evaluable Patients	Event-free Survival (95% CI)
6-months	128	41% (32%-49%)
12-months	119	30% (22%-38%)
18-months	111	22% (14%-29%)
24-months	99	20% (12%-28%)
30-months	97	20% (12%-28%)
verall Survival		
Time Point	Evaluable Patients	Overall Survival (95% CI)
6-months	116	99% (98%-100%)
12-months	85	99% (98%-100%)
18-months	52	96% (92%-100%)
24-months	29	96% (92%-100%)
30-months	14	91% (81%-100%)

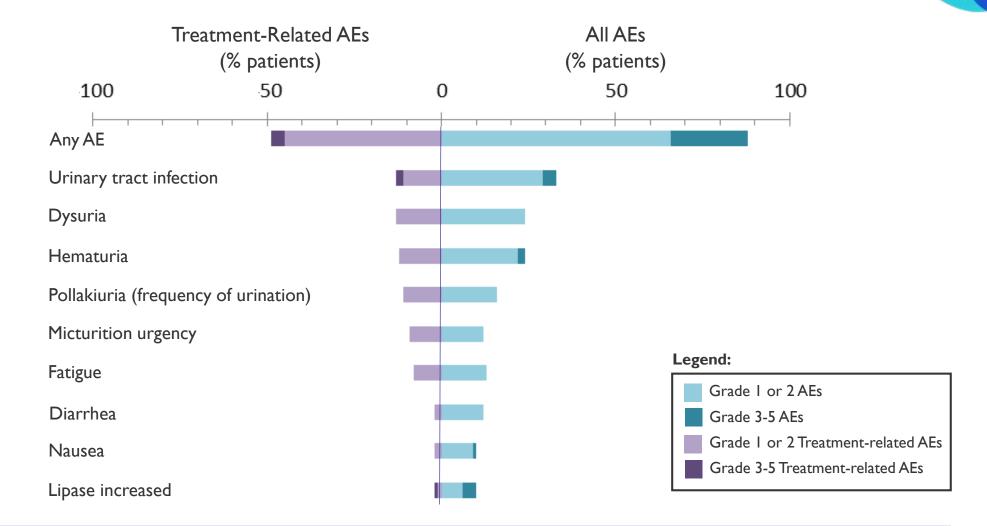


Progression-free survival: defined as the time from the date of first dose of study treatment to disease progression (i.e. T2 or more advanced disease) or death as a first event. Event-free survival: defined as the time from the date of first dose of study treatment to treatment failure or death as a first event.

Overall survival: defined as the time from the date of first dose of study treatment to death from any cause.

Note: Data reflected consist of patients from all cohorts 1, 2 & 3 (n=133).

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.



PIII All Cohorts

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

Increased dosing in the Phase III trial does not 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 failure¹, grade 3 acute kidney injury², 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%)	65 (49%)
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%)	5 (4%)



¹90-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. ²74-year-old man started the trial Nov. 2016. In Dec. 2016, admitted for acute kidney injury. In 2017, protocol amended to enhance monitoring, and investigators educated. No new serious related renal events since.

Phase III Trial: Patient Demographics

	COHORT I	COHORT 2	COHORT 3
CHARACTERISTICS	CIS that recurred within 6 months of adequate BCG (Refractory)	CIS that recurred >6 months but ≤11 months of adequate BCG (Relapsing)	Papillary tumors (without CIS) that 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	85	7	39
Evaluable patients at 12-months	84	7	39
Median age (years)	73	67	75
Males/Females	63/23	6/1	34/6
Median prior treatment for NMIBC BCG cycles (courses) BCG cycles (instillations) Intravesical chemotherapy TURBT	3 (range 2-14) 12 (range 8-45) 0 (range 0-23) 3 (range 0-28)		3 (range 2-10) 12 (range 8-48) 0 (range 0-6) 3 (range 0-10)



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

Cohort 1 (n=86) Complete Response Rate		
Time Point	Evaluable Patients	Complete Response Rate (95% Confidence Interval)
3-months	n=86	37% (27%-48%)
6-months	n=86	26% (17%-36%)
9-months	n=85	19% (11%-29%)
12-months	n=84	15% (9%-25%)

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%)



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%)	39% (29%- 49%)
6-months	27% (15%-42%)	28% (19%-38%)
9-months	18% (8%-32%)	21% (13%-30%)
12-months	16% (7%-30%)	15% (9%-24%)

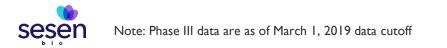
Dosing:

Phase II:

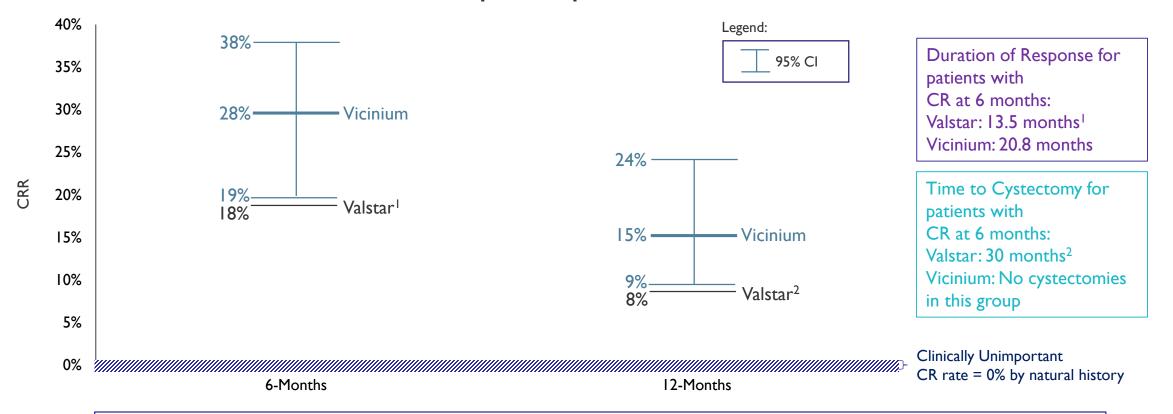
Cohort 1:6 weekly induction doses, 6 weeks off; if a CR achieved, proceed to maintenance dosing of every 3 months for 9 months; those with residual disease at 3 months had option of to start maintenance or receive a second induction course. Cohort 2: 12 weekly induction doses; if a CR achieved, proceed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



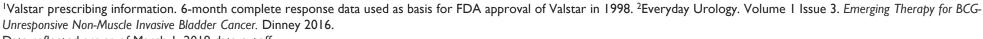
Complete Response Rate: We believe our 95% confidence interval rules out the CRR for Valstar and a clinically unmeaningful CRR



Complete Response Rate

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.

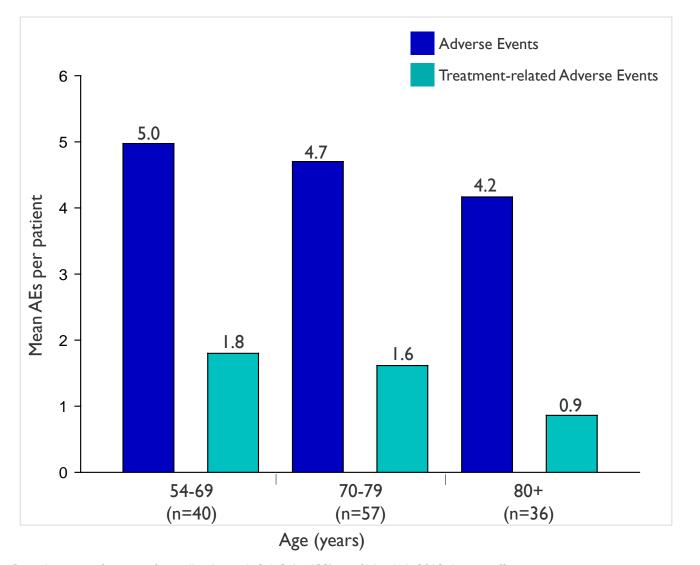
Sources:



Data reflected are as of March 1, 2019 data cutoff

PIII CIS Patients

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





Note: Data reflected consist of patients from all cohorts 1, 2 & 3 (n=133) as of March 1, 2019 data cutoff. Mean AEs for all patients: 4.6 (range 0-26), Mean treatment-related AEs for all patients: 1.5 (range 0-17). PIII All Cohorts

ADDENDUM TABLE OF CONTENTS

 Updated Phase III data further demonstrate a compelling benefit-risk profile

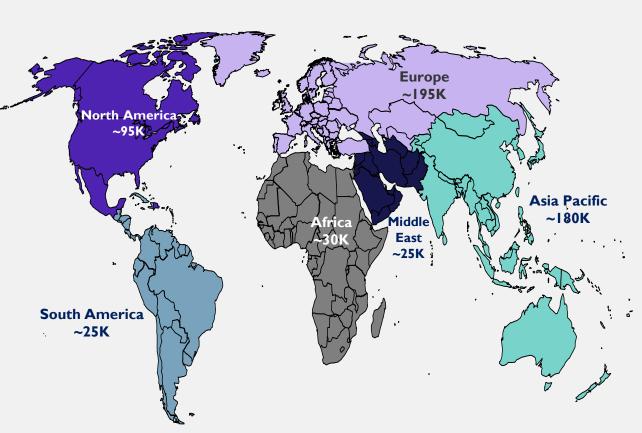
2. Strong regulatory and commercial rationale

3. Manufacturing process expected to be reliable and inexpensive

Bladder cancer is highly prevalent with tremendous unmet medical need



~550,000 New Cases Each Year Globally¹

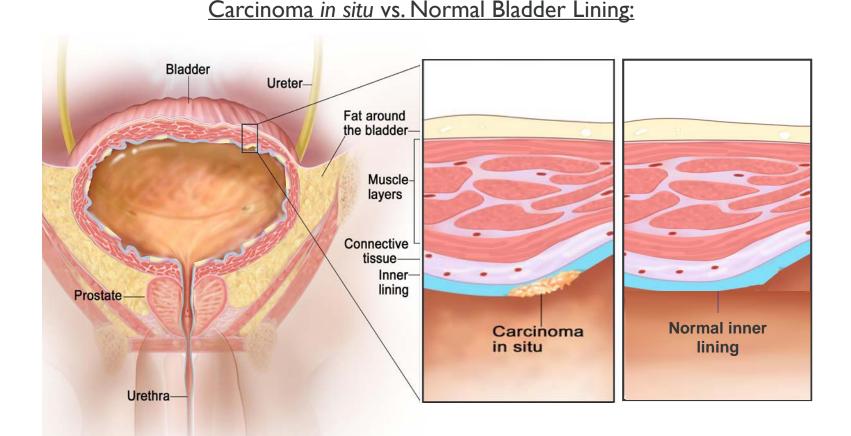


- \$4B+ in annual treatment costs for bladder cancer in the US alone²
- 75-85% diagnosed as NMIBC³
- Limited treatment options for high-risk NMIBC
 - Only three approved treatments in the last 100 years
 - BCG remains standard-of-care in many countries
 - 50% patients fail within the 1st year²
 - 90% of patients fail within 5 years²
 - Radical cystectomy is recommended option after BCG
 - Global BCG shortage potentially limiting access and full dosing for patients



Sources: ¹World Cancer Research Fund. Bladder Cancer Statistics. 2019. ²Mossanen M. Curr Opin Urol. 2014. ³Therapeutic Advances in Urology. Best Practices in the Treatment of Non-muscle Invasive Bladder Cancer. 2012.

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



Clinical Trial Implications:

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



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
Surgery: Radical Cystecto	omy	Recommended second line treatment
Valstar	1998	Used only when radical cystectomy is contraindicated

Source:



Radical cystectomy remains recommended treatment option after BCG failure



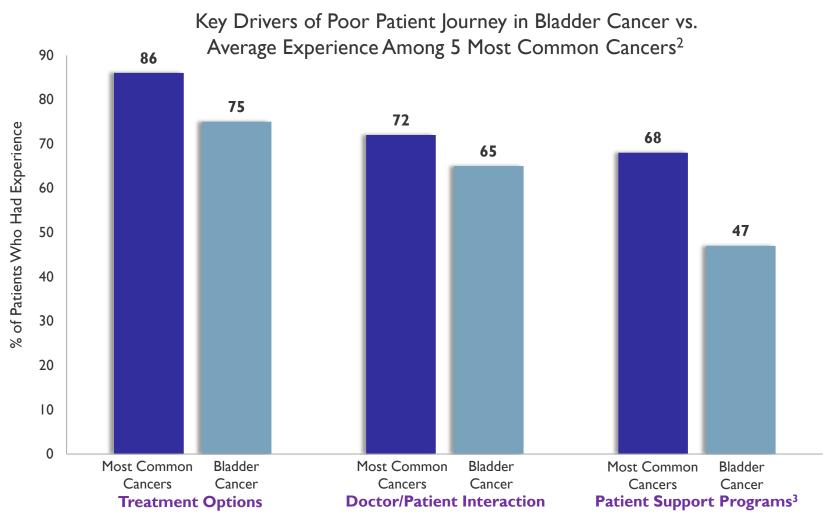
60-70% lifetime risk of cystectomy associated with NMIBC¹

- Complex, long 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 days³
 - ~35% of patients require ER visits and 26% require readmission³
 - Additional complications can occur as most patients with NMIBC are elderly and often have comorbidities
- Tremendous impacts to patient quality of life
 - Life following radical cystectomy requires catheterization and urinary diversion



Source:

Patient surveys have shown that the experience of those with bladder cancer is one of the $\ensuremath{\mathsf{poorest}}^1$

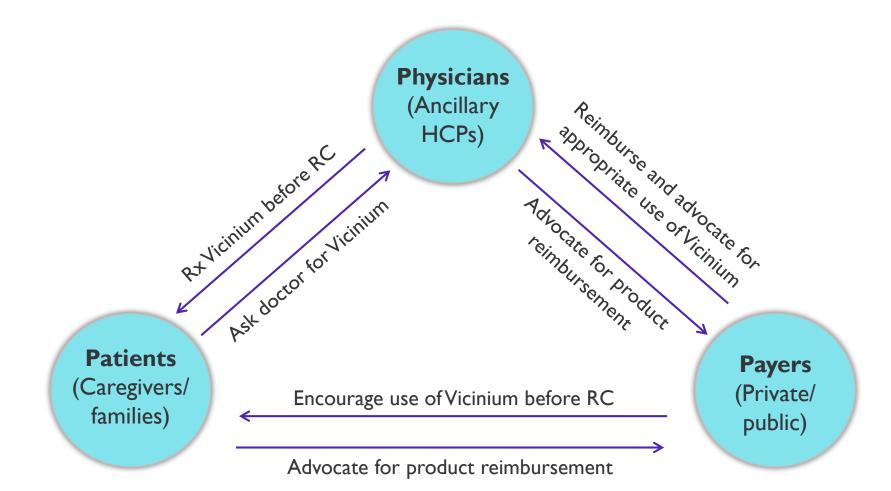


Sources: ¹Cancer Patient Experience Survey 2011/12. Department of Health. N=71,793. <u>https://www.quality-health.co.uk/resources/surveys/national-cancer-experience-survey/201112-national-cancer-patient-experience-survey-1/201112-national-cancer-patient-experience-survey-reports/495-cancer-patient-experience-survey-national-cancer-patient-experience-survey-1/201112-national-cancer-patient-experience-survey-reports/495-cancer-patient-experience-survey-1/201112-national-cancer-patient-experience-survey-reports/495-cancer-patient-experience-survey-national-cancer-patient-experience-survey-reports/495-cancer-patient-experience-survey-national-cancer-patient-experience-survey-reports/495-cancer-patient-experience-survey-national-cancer-patient-experience-survey-reports/495-cancer-patient-experience-survey-national-cancer-patient-experience-survey-national-cancer-patient-experience-survey-reports/495-cancer-patient-experience-survey-national-cancer-patient-experience-survey-reports/495-cancer-patient-experience-survey-national-cancer-patient-experience-survey-reports/495-cancer-patient-experience-survey-national-cancer-patient-experience-survey-national-cancer-patient-experience-survey-national-cancer-patient-experience-survey-reports/495-cancer-patient-experience-survey-national-cancer-patient-experience-survey-national-cancer-patient-experience-survey-national-cancer-patient-experience-survey-reports/495-cancer-patient-experience-survey-national-cancer-patient-experience-survey-national-cancer-patient-experience-survey-national-cancer-patient-experience-survey-reports/495-cancer-patient-experience-survey-national-cancer-patient-experience-survey-reports/495-cancer-patient-experience-survey-national-cancer-patient-experience-survey-reports/495-cancer-patient-experience-survey-national-cancer-patient-experience-survey-reports/495-cancer-patient-experience-survey-national-cancer-patient-experience-survey-national-cancer-patient-experience-survey-national-cancer-patient-experience-survey-national-cancer-patient-experie</u>

sese

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





Sources:

seser

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; ⁶Sesen Bio Qualitative Market Research Urologist/KOL IDIs February 2019, n=11.



Vicinium as potential to provide continuity of care for patients with NMIBC



BCG TREATMENT	VICINIUM TREATMENT
2-hour infusion, hold, and rotation	\checkmark
Administration through urinary catheter	\checkmark
Treated by Urologist	(same Urologist)
Medical support team throughout care	(same team)
Response assessment every 3 months	\checkmark

"I have been struck by the high patient tolerability of Vicinium which is instilled just like intravesical chemotherapy or BCG, making it easy for the treating Urologist."

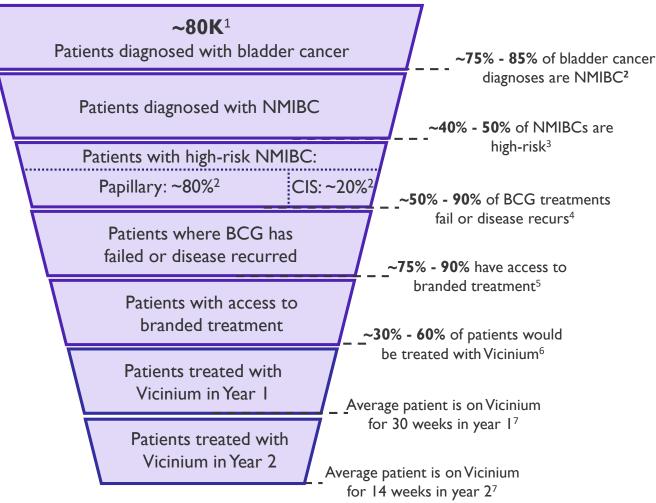
- Dr. Michael Jewett, Key Opinion Leader and Phase II clinical trial lead investigator



Addressable Market (US)



Annual Volume



Sources:

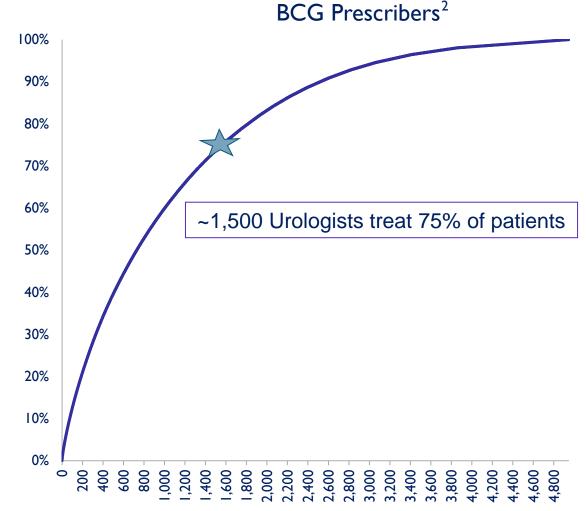


¹National Cancer Institute, SEER Cancer Stat Facts: Bladder Cancer, 2017. ²Therapeutic Advances in Urology. Best Practices in the Treatment of Non-muscle Invasive Bladder Cancer. 2012. ³Aldousari, S. et al (2010). Update on the management of non-muscle invasive bladder cancer. Can Urol Assoc J, 4(1), 56-64. ⁴Memorial Sloan Kettering Cancer Center. Bladder Cancer Management After BCG Failure. 2014. ⁵ClearView Analysis March 2019. ⁶Sesen Bio Qualitative Market Research Urologist/KOL IDIs February 2019, n=11. ⁷Phase III trial data. Only ~1,500 Urologists account for the bulk of NMIBC treatment and are concentrated in group practices allowing for a very efficient commercial model

% of Patients

~60% of Urology practices have \geq 5 Urologists¹

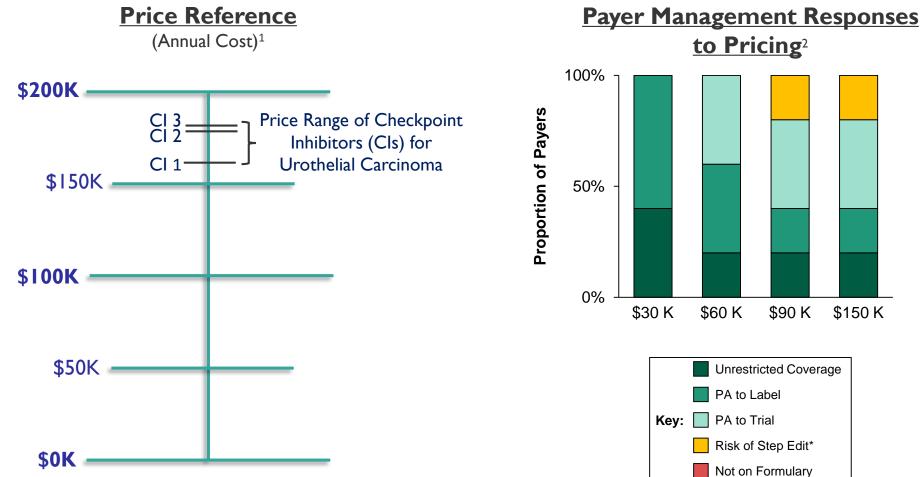






Pricing and Reimbursement (US)





Sources:

¹Center for Medicare and Medicaid Services (CMS) Average Selling Price (ASP) Price List. CI price benchmarks are based on Keytruda, Opdivo and Tecentriq. ²Payer 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



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. ¹Relative incidence is calculated from total bladder cancer, and does not account for differences in the distribution of patients between NMIBC and MIBC. ²Pricing 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. ³South Africa price multiplier was based on Keytruda only, as Opdivo has not yet been priced.



ADDENDUM TABLE OF CONTENTS

- Updated Phase III data further demonstrate a compelling benefit-risk profile
- 2. Strong regulatory and commercial rationale
- 3. Manufacturing process expected to be reliable and inexpensive

2000 L Production Centrifugation Bioreactor (bulk solids removal) Filtration (MF for fine solids removal and ЬК UF/DF for buffer exchange) Cell Bank Shake flask **5** Column Purification **DP Fill Finish** (7 mL @ 5mg/mL) I: Q-Sepharose FF 2: Ni²⁺ IMAC 3: Q-Sepharose HP 4: CHT 5: Q-Sepharose HP **BDS Formulation** (UF/DF for buffer exchange) (HMW aggregates (Crude capture) (Affinity capture, LMW (HCP removal) (Concentration step) removal) impurities)



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.

Manufacturing of Vicinium is expected to be reliable and inexpensive

Vicinium Comparability Strategy*

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."

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

- I. 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)

*As of May 20, 2019, the Type C CMC meeting has been completed and we have 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.



¹International 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

Baxter

Diesynth 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's BioPharma Solutions Business:

- I60 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





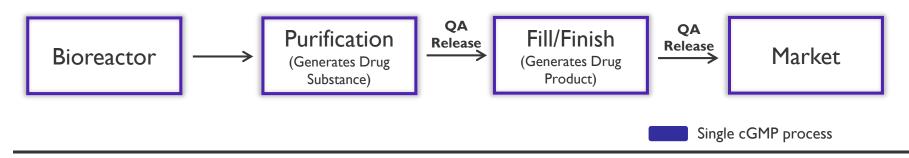




Vicinium: A single cGMP Manufacturing Process







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

