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): May 11, 2020

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 2.02 - Results of Operations and Financial Condition.

On May 11, 2020, Sesen Bio, Inc. (the "Company") announced its financial results for the quarter ended March 31, 2020. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information provided under this Item 2.02 of this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01 – Other Events.

On May 11, 2020, the Company posted a corporate presentation on its website www.sesenbio.com. A copy of the presentation is filed herewith as Exhibit 99.2 and is incorporated herein by reference.

Item 9.01 - Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description**
99.1	Press Release, dated May 11, 2020
99.2	Sesen Bio, Inc. Corporate Presentation dated May 11, 2020

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: May 11, 2020

Sesen Bio, Inc.

By: /s/ Thomas R. Cannell, D.V.M.

Thomas R. Cannell, D.V.M.

President and Chief Executive Officer

Sesen Bio Reports First Quarter 2020 Financial Results and Meaningful Progress towards Demonstrating Analytical Comparability

Manufacturing and release testing of the Fujifilm pre-PPQ batch completed successfully

Positive Interactions with EMA on Regulatory Pathway for Vicinium® in Europe

Market research conducted in 1Q 2020 supports Urologists prefer Vicinium to Keytruda®

CAMBRIDGE, Mass., May 11, 2020 – Sesen Bio (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, today reported operating results for the first quarter ended March 31, 2020. The Company also provided an update on the progress of manufacturing activities related to demonstrating analytical comparability between clinical batches of Vicinium and validation batches of Vicinium intended for potential future commercial use. The Company's lead program, Vicinium, also known as VB4-845, is currently in the follow-up stage of a Phase 3 registration trial for the treatment of high-risk, BCG-unresponsive non-muscle invasive bladder cancer (NMIBC). In December 2019, the Company initiated the BLA submission for Vicinium to the FDA under Rolling Review.

"In the first quarter of 2020, we successfully completed manufacturing of the pre-PPQ batch at Fujifilm," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "We believe the commercial-scale cGMP batches of Vicinium manufactured to date at our CMOs are comparable to Vicinium previously manufactured by Sesen for use in our clinical trials. This reinforces our confidence in the upcoming PPQ campaign and our ability to demonstrate analytical comparability between clinical and commercial drug supply. The Company's focus for 2020 remains the flawless execution of the PPQ campaign and the finalization of Module 3 to complete the Vicinium BLA submission."

Manufacturing Update

- In February 2020, manufacturing of the pre-PPQ bulk drug substance batch was completed at Fujifilm. In April, quality release testing of the bulk drug substance from this batch was completed and all quality acceptance criteria were met. The Company believes these data de-risk the PPQ campaign and increase the likelihood of demonstrating analytical comparability. In addition, in April 2020, this batch from Fujifilm was used to manufacture the first PPQ drug product batch at Baxter and release testing is currently underway. The Company remains on track to complete the Vicinium BLA submission in the second half of 2020 and anticipates potential approval in first half of 2021. At this time, the Company does not expect any impact to the manufacturing activities or regulatory processes related to Vicinium due to COVID-19.

CHMP Scientific Advice Update

- On May 7, 2020 the Company received clinical Scientific Advice from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA)

stating that the Committee agreed that the Company's nonclinical, clinical pharmacology and safety database are all sufficient to support a marketing authorization application (MAA). Furthermore, additional clinical trials were not requested by the CHMP in support of the MAA submission for Vicinium. Based on the guidance received, the Company expects to submit the MAA for Vicinium to the EMA in early 2021, with potential approval anticipated in early 2022.

Commercial Opportunity

- In the first quarter of 2020, the Company conducted 30-minute interviews with 34 randomly selected, high-prescribing Urologists to assess their views of a blinded clinical profile of Vicinium as well as an unblinded profile of Keytruda, which was recently approved by the FDA for BCG-unresponsive NMIBC patients with carcinoma in situ (CIS) with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy. The research revealed that, when prescribing a branded agent, Urologists would prescribe Vicinium to 83% of their patients compared to 17% for Keytruda. The overall preference for Vicinium was driven by comparable efficacy data to Keytruda with a favorable safety profile and mode of administration that would allow physicians to easily integrate Vicinium into their practices. We believe these data support the potential for a successful launch characterized by rapid uptake and growth of Vicinium.

First Quarter 2020 Financial Results

- Cash Position: Cash and cash equivalents were $42.5 million as of March 31, 2020, compared to $48.1 million as of December 31, 2019.
- R&D Expenses: Research and development expenses for the first quarter of 2020 were $8.9 million compared to $4.7 million for the same period in 2019. The first quarter increase was due primarily to costs related to the ongoing technology transfer process as we scale-up for commercial manufacturing, in addition to increased regulatory costs partially offset by lower employee compensation and lower clinical expenses related to the Phase 3 VISTA trial for Vicinium.
- G&A Expenses: General and administrative expenses for the first quarter of 2020 were $3.4 million compared to $3.1 million for the same period in 2019. The first quarter increase was due primarily to increases in professional fees and employee compensation, offset by reduced market research costs.
- Net Income (Loss): Net income was $41.6 million, or $0.31 per basic share and $0.31 per diluted share, for the three months ended March 31, 2020, compared to a net loss of $6.5 million, or $0.08 per basic and diluted share, for the same period in 2019. The change was primarily the result of the non-cash change in fair value of contingent consideration due to significantly higher discount rates associated with current market conditions related to the COVID-19 pandemic.

Conference Call and Webcast Information

Members of the Sesen Bio management team will host a conference call and webcast today at 8:00 AM ET to review the Company's financial results and provide a general business update. To

participate in the conference call, please dial (844) 831-3025 (domestic) or (315) 625-6887 (international) and refer to conference ID 3780957. The webcast can be accessed in the Investor Relations section of the company's website at www.sesenbio.com. The replay of the webcast will be available in the investor section of the company's website at www.sesenbio.com for 60 days following the call.

About the VISTA Clinical Trial

The VISTA trial is an open-label, multicenter, single-arm Phase 3 clinical trial evaluating the efficacy and tolerability of Vicinium® as a monotherapy in patients with high-risk, bacillus Calmette-Guérin (BCG) unresponsive non-muscle invasive bladder cancer (NMIBC). The primary endpoints of the trial are the complete response rate and the duration of response in patients with carcinoma in situ with or without papillary disease. Patients in the trial received locally administered Vicinium twice a week for six weeks, followed by once-weekly treatment for another six weeks, then treatment every other week for up to two years. To learn more about the Phase 3 VISTA trial, please visit www.clinicaltrials.gov and search the identifier NCT02449239.

About Vicinium®

Vicinium, a locally administered fusion protein, is Sesen Bio's lead product candidate being developed for the treatment of high-risk non-muscle invasive bladder cancer (NMIBC). Vicinium is comprised of a recombinant fusion protein that targets epithelial cell adhesion molecule (EpCAM) antigens on the surface of tumor cells to deliver a potent protein payload, Pseudomonas Exotoxin A. Vicinium is constructed with a stable, genetically engineered peptide tether to ensure the payload remains attached until it is internalized by the cancer cell, which is believed to decrease the risk of toxicity to healthy tissues, thereby improving its safety. In prior clinical trials conducted by Sesen Bio, EpCAM has been shown to be overexpressed in NMIBC cells with minimal to no EpCAM expression observed on normal bladder cells. Sesen Bio is currently conducting the Phase 3 VISTA trial, designed to support the registration of Vicinium for the treatment of high-risk NMIBC in patients who have previously received a minimum of two courses of bacillus Calmette-Guérin (BCG) and whose disease is now BCG-unresponsive. Additionally, Sesen Bio believes that cancer cell-killing properties of Vicinium promote an anti-tumor immune response that may potentially combine well with immuno-oncology drugs, such as checkpoint inhibitors. The activity of Vicinium in BCG-unresponsive NMIBC is also being explored at the US National Cancer Institute in combination with AstraZeneca's immune checkpoint inhibitor durvalumab.

About Sesen Bio

Sesen Bio, Inc. is a late-stage clinical company advancing targeted fusion protein therapeutics for the treatment of patients with cancer. The Company's lead program, Vicinium®, also known as VB4-845, is currently in a Phase 3 registration trial for the treatment of high-risk, BCG-unresponsive non-muscle invasive bladder cancer (NMIBC). In December 2019, the Company initiated the BLA submission for Vicinium to the FDA under Rolling Review. Vicinium is a locally administered targeted fusion protein composed of an anti-EpCAM antibody fragment tethered to a truncated form of Pseudomonas Exotoxin A for the treatment of high-risk NMIBC. For more information, please visit the company's website at www.sesenbio.com.

COVID-19 Pandemic Potential Impact

Sesen Bio continues to monitor the rapidly evolving environment regarding the potential impact of the COVID-19 pandemic on our Company. The Company has not yet experienced any disruptions to our operations as a result of COVID-19, however, we are not able to quantify or predict with certainty the overall scope of potential impacts to our business, including, but not limited to, our ability to raise capital and, if approved, commercialize Vicinium. Sesen Bio remains committed to the health and safety of patients, caregivers and employees.

Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, the Company's strategy, future operations, and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: our ability to successfully develop our product candidates and complete our planned clinical programs, expectations regarding the impact of the COVID-19 pandemic, expectations regarding our PPQ manufacturing runs, expectations regarding the timing of completion of our BLA submission for Vicinium, expectations regarding the timing of potential approval of our BLA submission by the FDA, expectations regarding the timing of the submission of our MAA for Vicinium to the EMA, expectations regarding the timing of potential approval of our MAA submission by the EMA, expectations regarding the potential successful launch of Vicinium, if approved, our ability to obtain marketing approvals for our product candidates, and other factors discussed in the "Risk Factors" section of the Company's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and other reports filed with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

Contact:
Erin Clark, Vice President, Corporate Strategy & Investor Relations
ir@sesenbio.com

SESEN BIO, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)
(In thousands, except per share data)
(Unaudited)

	Three Months ended March 31,	
	2020	2019
Operating expenses:		
Research and development	$ 8,867	$ 4,686
General and administrative	3,448	3,055
Change in change in fair value of contingent consideration	(53,700)	(1,000)
Total operating expenses	(41,385)	6,741
Income (Loss) from Operations	41,385	(6,741)
Other income (expense):		
Other income, net	179	261
Net Income (Loss) and Comprehensive Income (Loss)	$ 41,564	$ (6,480)
Net income (loss) attributable to common stockholders - basic	$ 34,407	$ (6,480)
Net income (loss) attributable to common stockholders - diluted	$ 34,408	$ (6,480)
Net income (loss) per common share - basic	$ 0.31	$ (0.08)
Weighted-average common shares outstanding - basic	109,808	77,458
Net income (loss) per common share - diluted	$ 0.31	$ (0.08)
Weighted-average common shares outstanding - diluted	109,823	77,458

SESEN BIO, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	March 31, 2020 (Unaudited)	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 42,463	$ 48,121
Prepaid expense and other current assets	2,420	6,326
Total current assets	44,883	54,447
Restricted cash	20	20
Property and equipment, net	207	238
Intangibles	46,400	46,400
Goodwill	13,064	13,064
Other assets	91	196
Total Assets	$ 104,665	$ 114,365
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 2,068	$ 1,902
Accrued expenses	4,893	6,169
Other current liabilities	405	446
Total current liabilities	7,366	8,517
Contingent consideration	66,320	120,020
Deferred tax liability	12,528	12,528
Total Liabilities	86,214	141,065
Commitments and contingencies		
Stockholders' Equity (Deficit):		
Preferred stock, $0.001 par value per share; 5,000,000 shares authorized at March 31, 2020 and December 31, 2019; no shares issued and outstanding at March 31, 2020 and December 31, 2019		
Common stock. $0.001 par value per share; 200,000,000 shares authorized at March 31, 2020 and December 31, 2019; 109,991,553 and 106,801,409 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	110	107
Additional paid-in capital	270,301	266,717
Accumulated deficit	(251,960)	(293,524)
Total Stockholders' Equity (Deficit)	18,451	(26,700)
Total Liabilities and Stockholders' Equity (Deficit)	$ 104,665	$ 114,365


sesen
bio
May 2020 Business Update
For Investor Purposes Only
May 11, 2020
NASDAQ:

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, 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: our projected financial position and estimated cash burn rate, expectations regarding the completion of our BLA filing, expectations regarding the impact of COVID-19 on our business, the possibility that the available preliminary data of the Phase III VISTA Trial are not indicative of final data from all patients in the Phase III VISTA Trial and/or that the final data may not be positive with regard to the safety or efficacy of Vicinium®, expectations regarding physicians' decisions to prescribe Vicinium, if approved, expectations regarding the timing of the submission of our MAA for Vicinium to the EMA, expectations regarding the timing of potential approval of our MAA submission by the EMA, expectations regarding future Scientific Advice from the CHMP on the CMC program for Vicinium, 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 and future post-marketing confirmatory 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, 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.

We are monitoring and mitigating potential risks across critical business areas
No business disruptions from COVID-19 at this time

Clinical
- Patient enrollment was completed in March 2018
- All patients have completed treatment in the VISTA trial
- Last data cut was done in May 2019
- All clinical and nonclinical data have been submitted to the FDA in December 2019

Regulatory
- 4 face-to-face meetings with the FDA in 2019 with alignment on BLA submission contents and timing
- No additional face-to-face meetings are expected to be needed before anticipated completion of BLA submission in 2H
- FDA interaction conducted via email and teleconference
- EMA Scientific Advice meetings completed via teleconference (pre-submission meeting and SAWP discussion meeting)

CMC
- All consumables and other raw materials for PPQ runs have been purchased and warehoused at CMOs
- Daily touchpoints with CMOs: Fuji and Baxter

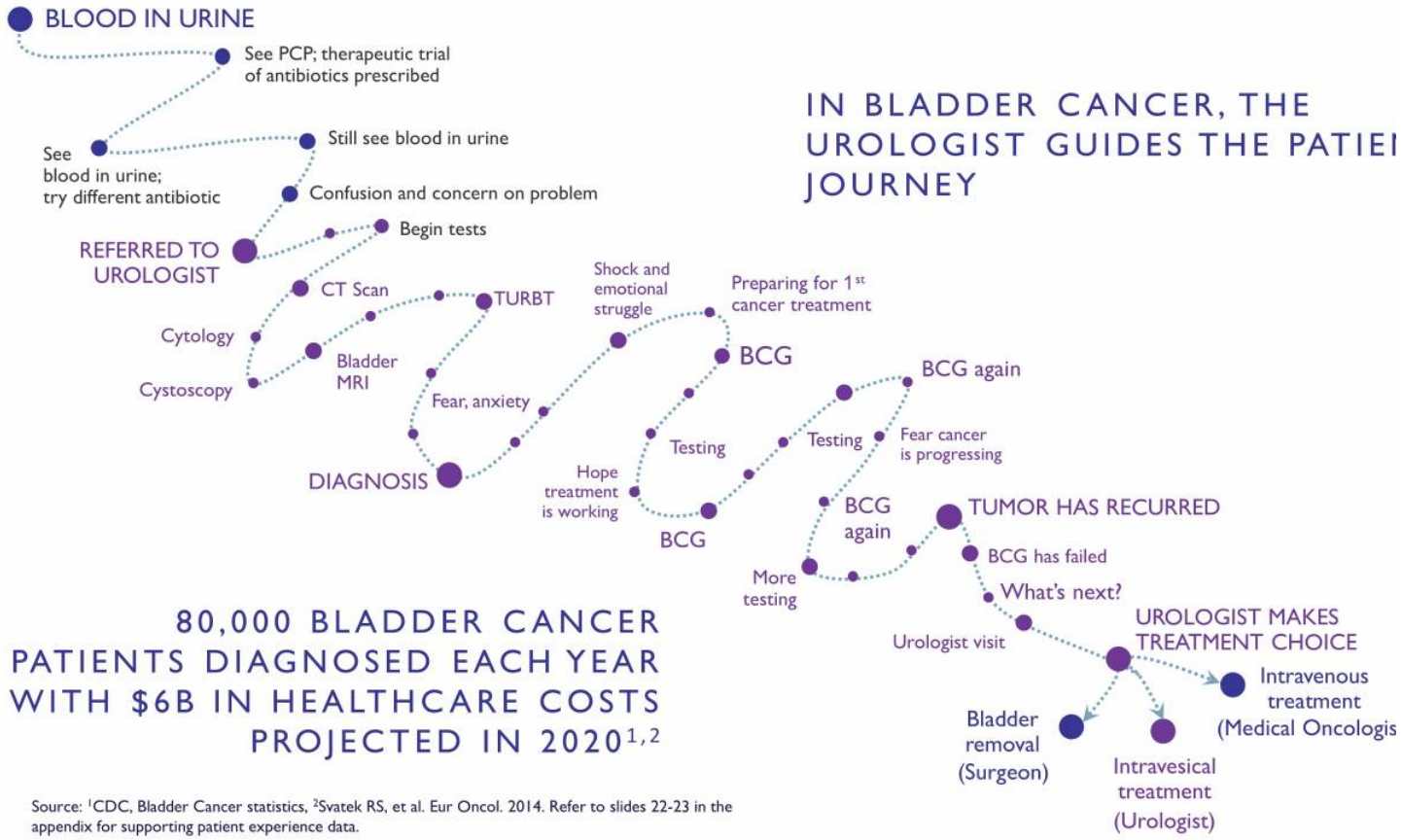
Operations
- Instituted a flexible work-from-home policy for employees
- All internal operations are continuing at normal levels

SAWP = Scientific Advice Working Party

MAY 2020 BUSINESS UPDA

- Highly differentiated mechanism o
  and clinical profile
- Market research supports large
  commercial opportunity
- Positive data demonstrates meanir
  progress for CMC comparability
- Clear regulatory path forward

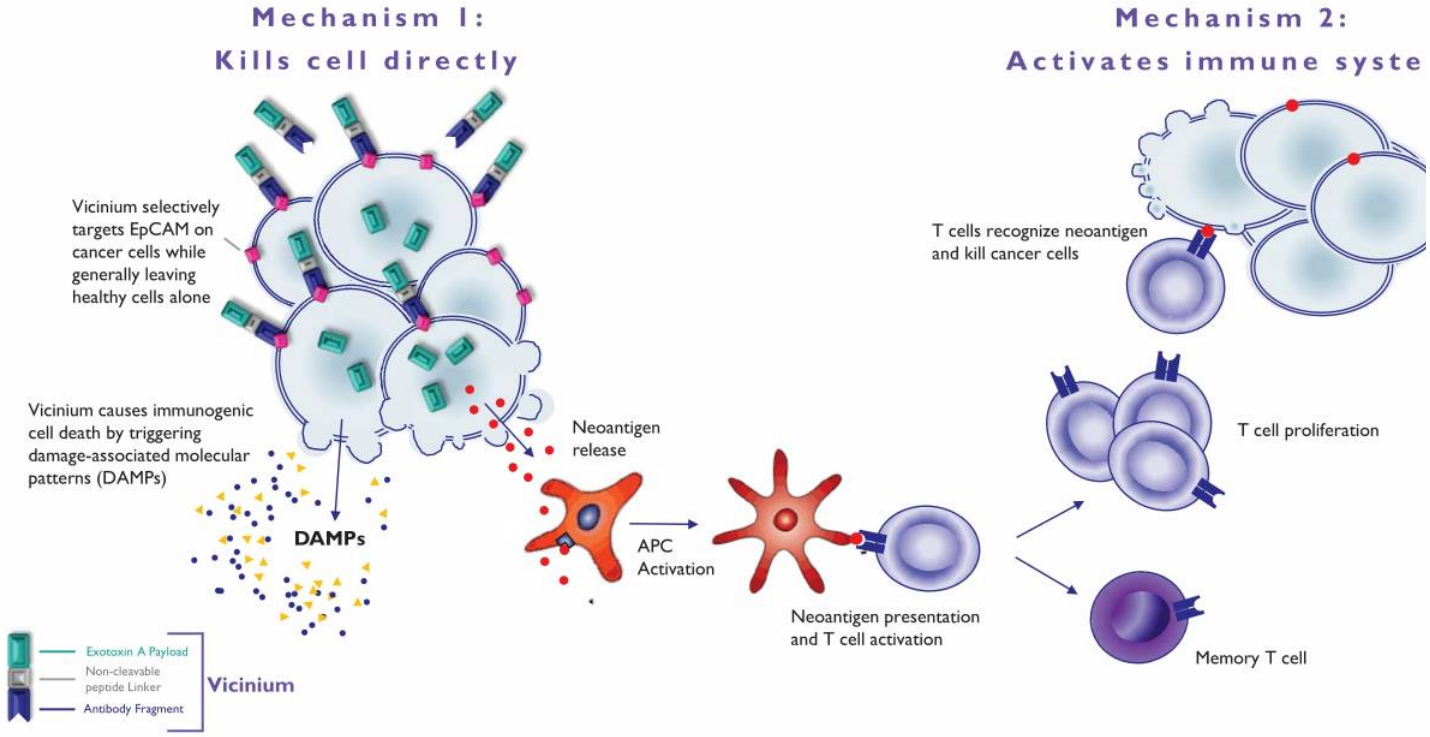
IN BLADDER CANCER, THE UROLOGIST GUIDES THE PATIEI JOURNEY



80,000 BLADDER CANCER PATIENTS DIAGNOSED EACH YEAR WITH $6B IN HEALTHCARE COSTS PROJECTED IN 2020[1,2]

Source: [1]CDC, Bladder Cancer statistics, [2]Svatek RS, et al. Eur Oncol. 2014. Refer to slides 22-23 in the appendix for supporting patient experience data.

Vicinium has a Highly Differentiated Mechanism of Action



For illustrative purposes only. Based on preclinical studies, we believe Vicinium works via a dual mechanism of action.

1Q 2020 Intent-to-Prescribe Market Research Results

We conducted 30-minute interviews with 34 high-prescribing Urologists to assess their views of the Vicinium profile vs. the Keytruda profile based on available clinical information

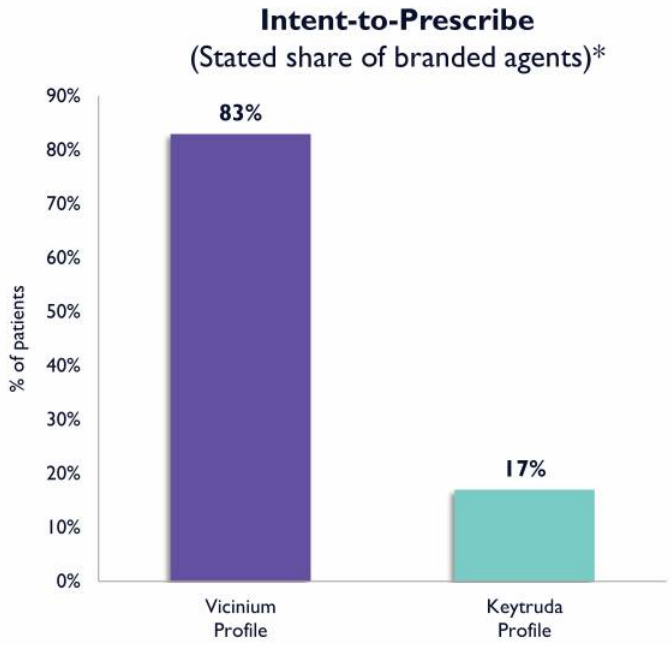
For investor purposes only

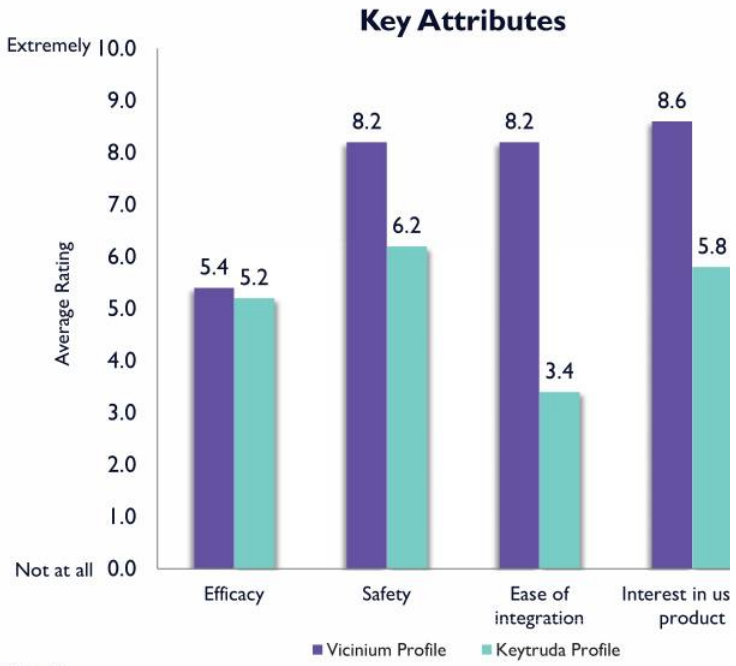
Market Research Input
Clinical Data from Emerging Treatments for NMIBC

	Vicinium Profile	Keytruda Profile
Efficacy	N=89	N=102
Complete Response Rate • **At 3 Months** • **At 12 Months** • **At 18 Months**	 40% (CI: 30-51) 17% 11%	 41% (CI: 32-51) 20% 13%
Time to Cystectomy	76% of patients were cystectomy-free at 36 months (n=133)	No data reported (not a clinical trial endpoint
Safety	N=133	N=102
Treatment-Related Grade 3-5 AEs	4%	13%
Discontinuation due to an AE	3%	10%
Mode of Administration	Intravesical	Intravenous

Source: Dec. 2019 FDA briefing book for Keytruda profile; Dec. 2019 BLA submission for Vicinium profile.
This slide is intended for market research purposes only and is not intended for marketing purposes.

1Q 2020 Market Research Results
High Prescribing Urologists Prefer Vicinium Profile





Source: Emerging treatment in-depth interviews (IDIs) with high BCG-treating Urologists, 1Q 2020, N=34
This slide is intended for market research purposes only and is not intended for marketing purposes.
*Urologists would use a branded agent in ~80% of their high-risk, BCG-unresponsive patients

1Q 2020 Market Research Results
Reasons Urologists Prefer Vicinium Profile

- **Urologists strongly prefer to retain ownership of patient journey**
  - High degree of reluctance to refer to Medical Oncologists
  - Fear of losing follow-up diagnostics with patient after treatment referral

- **Urologists perceive favorable product profile for Vicinium**
  - Comparable efficacy and favorable safety/tolerability relative to Keytruda profile
  - Compelling time-to-cystectomy data

- **Urologists perceive administration of Vicinium as highly consistent with office operations**
  - Vicinium administration protocol is identical to BCG
  - Many Urologists are less familiar with the side effects of intravenous chemotherapy

- **Urologists perceive negative psychological effects of intravenous chemotherapy on patients**
  - Stigma of seeing an Oncologist/going to large academic medical center
  - Patient perception of more advanced disease (e.g. terminal patients)

Source: Emerging treatment IDIs with high BCG-treating Urologists, 1Q 2020, N=34
This slide is intended for market research purposes only and is not intended for marketing purposes.

Meaningful Progress on Demonstrating Analytical Comparability

We have maintained high-quality manufacturing standards through tech transfer process to Fuji

	Sesen		Fuji	
Test	**Phase II**	**Phase III**	**GMP Run 2Q 2019**	**Pre-PPQ Run 1Q 2020**
Appearance	✓	✓	✓	✓
pH	✓	✓	✓	✓
Identity	✓	✓	✓	✓
Concentration	✓	✓	✓	✓
Polysorbate 80	✓	✓	✓	✓
Purity	✓	✓	✓	✓
Charge Variants	✓	✓	✓	✓
Potency	✓	✓	✓	✓
Binding	✓	✓	✓	✓
Host Cell Protein	✓	✓	✓	✓
Residual DNA	✓	✓	✓	✓
Endotoxin	✓	✓	✓	✓
Bioburden	✓	✓	✓	✓

✓ Indicates acceptance criteria met for batches used in clinical trials (Sesen manufactured) or technology transfer (Fujifilm manufactured)

Analytical Comparability Outlook

Clear FDA requirements for the PPQ Campaign

- Three manufacturing runs for both drug substance and drug product

Considerable in-house manufacturing process expertise from clinical manufacturing

- Successfully manufactured 10 drug substance and 12 drug product batches in support of Vicinium clinical tri

Completed two commercial-scale GMP runs at Fujifilm and Baxter

- All quality acceptance criteria met for drug substance from both batches, increasing the probability of succe for the PPQ campaign
- Bio-physical characterization testing of the first GMP batch demonstrated that material from Fujifilm is high similar to Sesen clinical trial material (testing of second batch ongoing)

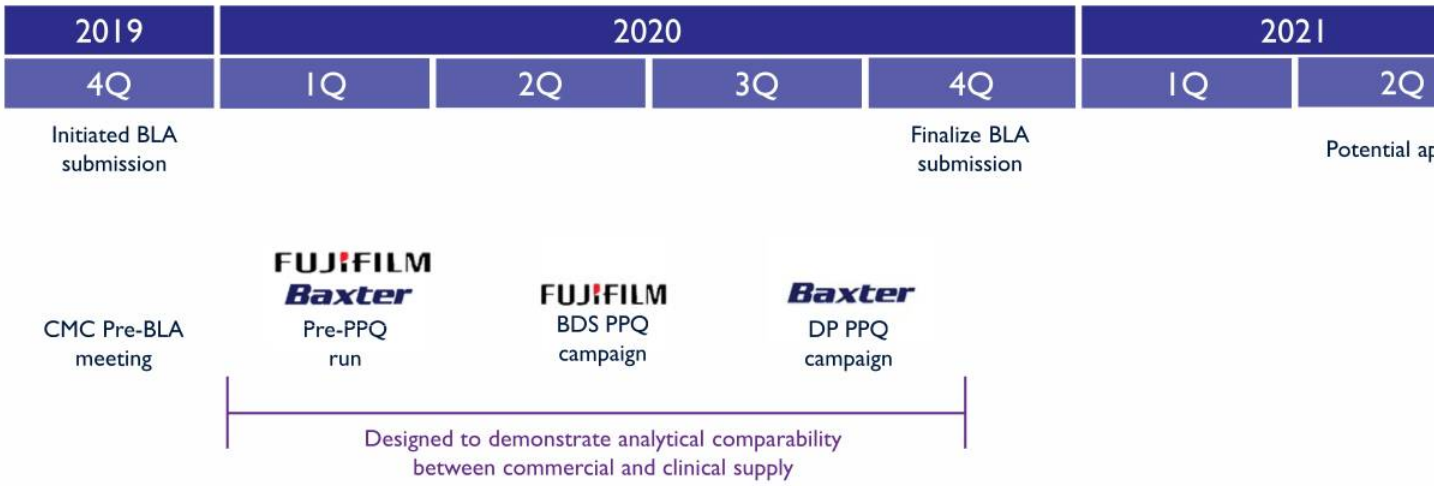
All consumables have been received and warehoused at CMOs for the entire 2020 PPQ Campaign

- Mitigates risk of supply chain disruptions due to COVID-19

*Includes both the Phase III VISTA trial and the Phase I NCI combination trial with durvalumab

US Regulatory Path Forward

Key CMC activities in 2020 are designed to demonstrate analytical comparability between commercial and clinical supply for the finalization of the BLA submission



CMC = chemistry, manufacturing and controls; BLA = Biologics License Application; PPQ = process performance qualification; BDS = bulk drug substance; DP = drug product

Positive Interactions with EMA on Regulatory Pathway for Vicinium

The CHMP issued guidance on the regulatory pathway for Vicinium:

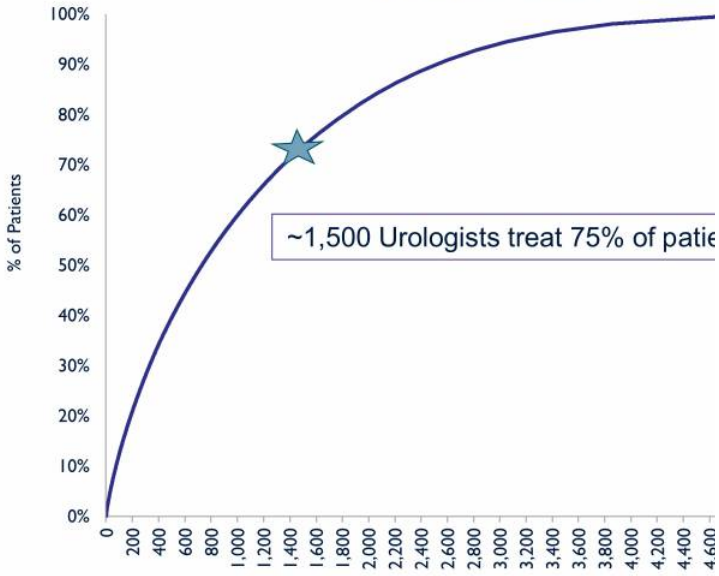
- The nonclinical and clinical pharmacology studies, and safety database are all sufficient to support a M submission for Vicinium and additional clinical trials were not requested in support of the MAA
- It was acknowledged that due to the well-known impact of cystectomy on morbidity and quality of lif patients, a new local treatment that enables patients to avoid radical cystectomy would be meaningful especially for patients who are contraindicated for cystectomy
- Additional data analyses were requested for inclusion in the MAA, and we believe these can be fully addressed with the Phase 3 dataset
- Based on the guidance received, we expect to submit the MAA for Vicinium to the EMA in early 2021 with potential approval anticipated in early 2022
- We expect to receive Scientific Advice from the CHMP on the CMC program for Vicinium at a later d

CHMP = Committee for Medicinal Products for Human Use
EMA = European Medicines Agency
MAA = marketing authorization application
CMC = Chemistry, Manufacturing and Controls

Highly Concentrated Prescriber Base Allows for Efficient Commercial Model

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

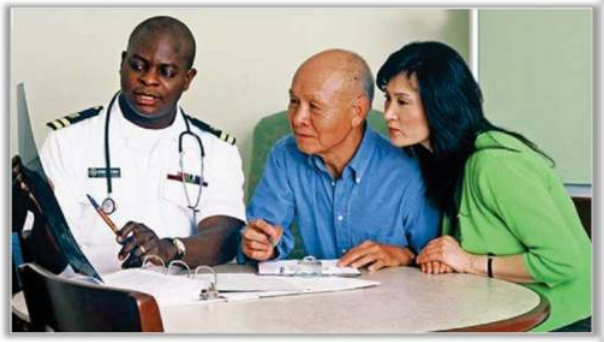
BCG Prescribers[2]



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

At treatment decision points, caregivers often play an influential role

Our strategy is to educate and inform caregivers via a wide range of digital and social channels



Digital

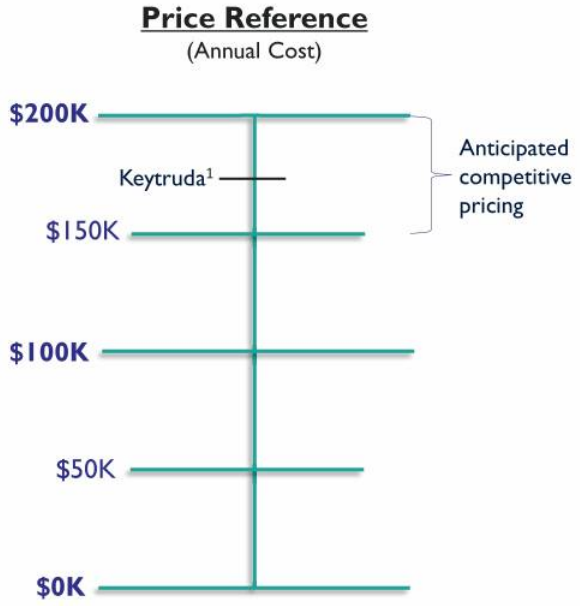
- Paid search
- Organic search
- Videos
- Banners
- Website (branded or unbranded)

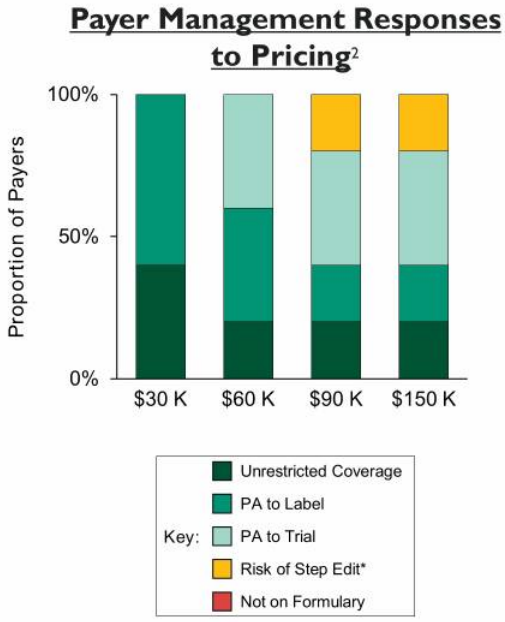
Social

- Facebook community groups
- Twitter
- Lead gen/CRM

Lead gen = lead generation
CRM = customer relationship management

Pricing and Reimbursement US Benchmarks





Sources: [1]Center for Medicare and Medicaid Services (CMS) Average Selling Price (ASP) Price List as of 1Q 2020.
[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

Financial Overview as of March 31, 2020

Cash position

- Ending cash and cash equivalents of $42.5M
- Sufficient cash to fund key strategic priorities into 2021

ATM

- 4Q 2019: net proceeds of $1.9M (2.1M shares)
- 1Q 2020: net proceeds of $3.2M (3.2M shares)

Capital structure

- 110 M shares of common stock outstanding
  - No preferred stock
  - 143 M fully diluted[1]
- No Debt

[1]Fully diluted shares include outstanding warrants and stock options as of March 31, 2020.

MAY 2020 SUMMARY

- Highly differentiated mechanism o
  and clinical profile
- Market research supports large
  commercial opportunity
- Positive data demonstrates meanir
  progress for CMC comparability
- Clear regulatory path forward

Talented and Experienced Leadership Team Prepared for Commercial Launch

Senior Management

Thomas Cannell, DVM
President, CEO and Director

Monica Forbes
Chief Financial Officer

Glen MacDonald, Ph.D.
Chief Technology Officer

Erin Clark
Vice President, Corporate Strategy and Investor Relations

Mark Sullivan
General Counsel and Corporate Secretary

Omar Rifi
Vice President, Business Development and Alliance Management

Louise Stejbach
Commercial Advisor

Jeannick Cizeau, Ph.D.
Head of Research

Jeanette Kohlbrenner
Human Resources Advisor

Board of Directors

Jay Duker, M.D.
Chair of the Board of Directors

Carrie L. Bourdow
Director

Thomas Cannell, DVM
President, CEO and Director

Jane V. Henderson
Director

Jason Keyes
Director

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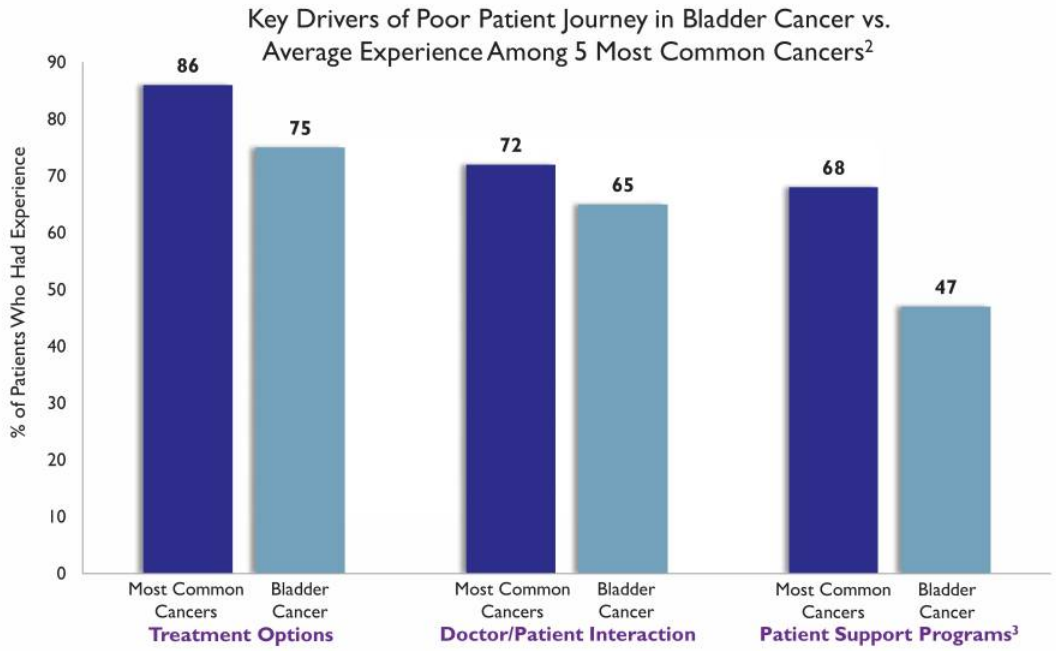
Appendix

Patient Journey

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



[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.

Appendix

Unmet Medical Need

Significant Unmet Medical Need in NMIBC

ses
b

Bladder cancer is the 6th most prevalent cancer in the US, of which 75%-85% is N

Bladder cancer is the most expensive cancer to treat in the US with projected c
~$6B by 2020[4]

One of the worst patient experiences among common cancers

Survival rates for bladder cancer have decreased in recent years in the UK, durin
time there was also a BCG shortage[5]

[1]Bray F et al. CA Cancer J Clin, 2018. [2]Anastasiadis et al. Therapeutic Advances in Urology, 2012. [3]Siegel et al. CA Cancer J Clin, 2019. [4]Svatek RS, et al. Eur Oncol. 2014. [5]Office of National Statistics, Aug 2019 Report.

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

Your Bladder: An Essential 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

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

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

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

Latest global BCG shortage expected to last through 2020

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 2020.
- 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.
- Two clinical trials are underway to examine if a BCG vaccine protects people against infection with COVID-19 virus.

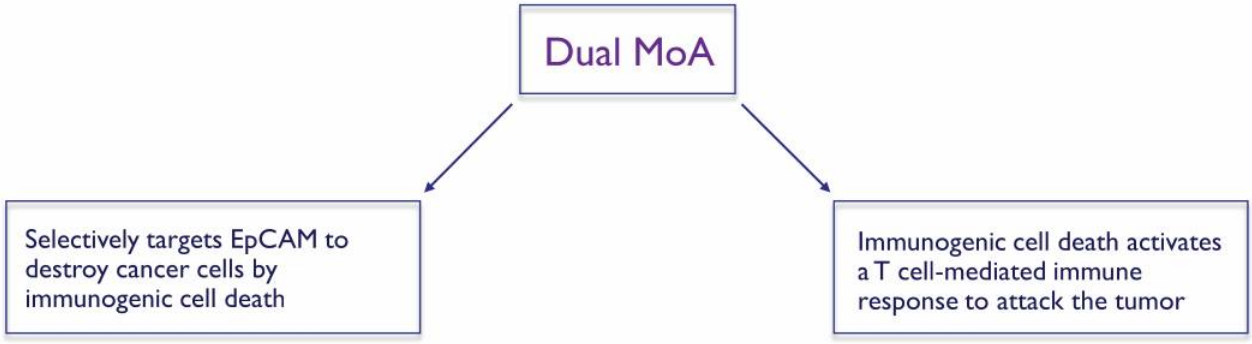
Sources and Additional Information:
Wall Street Journal. *Sanofi to Stop Production of Bladder Cancer Drug BCG.* Peter Loftus. 2016. https://www.auanet.org/practice-resources/bcg-info/bcg-shortage-notice
https://www.bcan.org/2019-bcg-shortage-bladder-cancer/. https://www.who.int/news-room/commentaries/detail/bacille-calmette-gu%C3%A9rin-(bcg)-vaccination-and-covid-19

Appendix

Dual Mechanism of Action

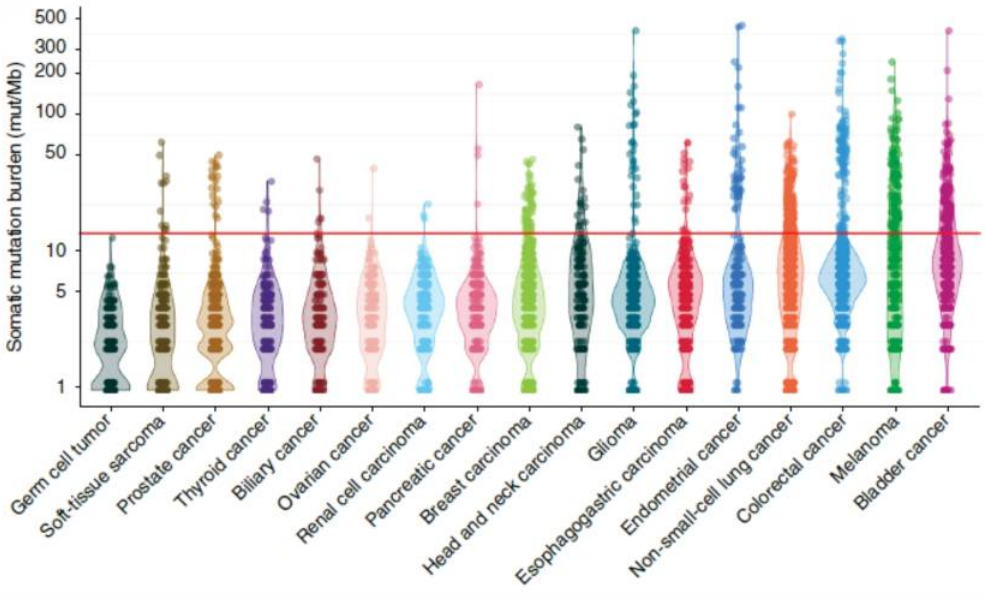
Vicinium is Highly Differentiated and has a Dual Mechanism of Action

- Fusion protein consisting of an antibody fragment and a cytotoxic payload
- Small size facilitates tumor penetration and greater drug delivery
- Selectively targets cancer cells while generally sparing healthy cells
- Inhibits protein synthesis and kills both rapidly proliferating and slow-growing cancer cells
- Effective against multi-drug resistant cancer cells



Based on preclinical studies, we believe Vicinium works via dual mechanism of action.

The high somatic mutation rate in bladder cancer may lead to a better response to agents such as Vicinium that may stimulate T cell-mediated immune activation driven by neoantigens



Adapted from Zahir et al. Nature Medicine, 2017

Appendix

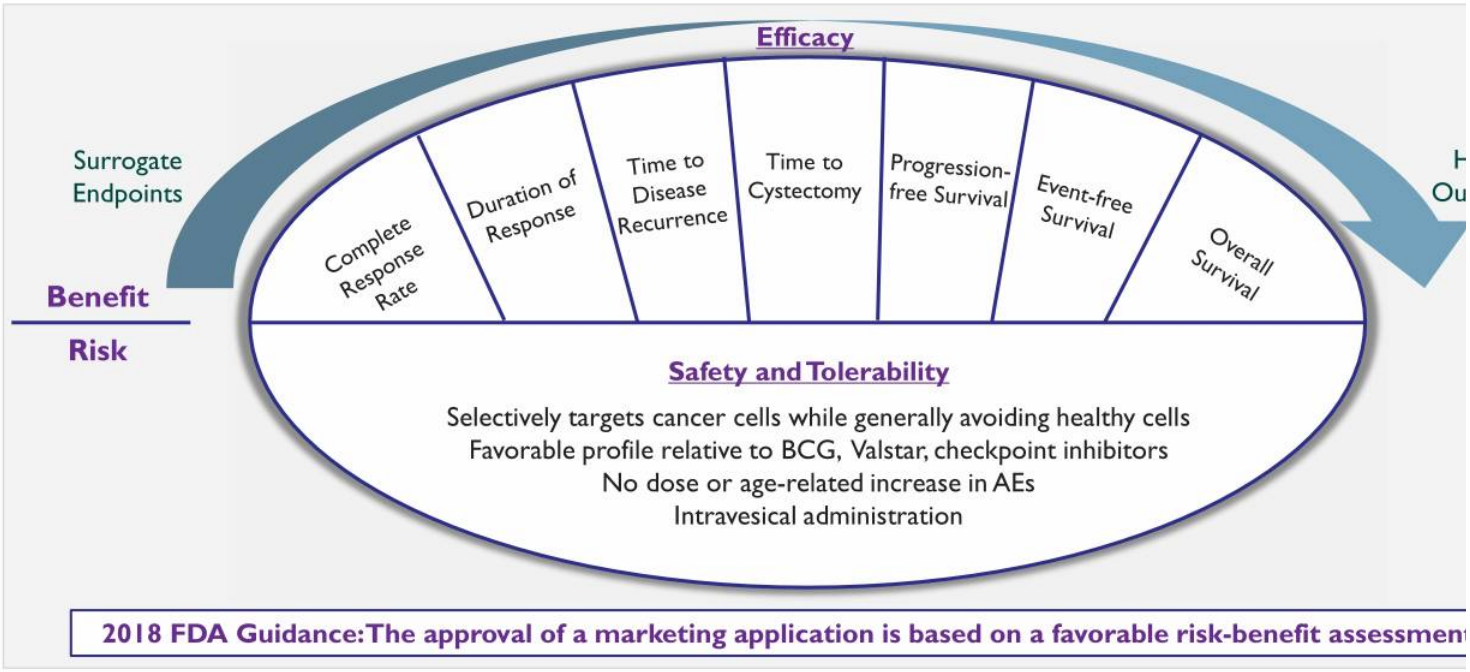
Regulatory

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	✓

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.

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



Phase III clinical trial is an open-label, multicenter, single-arm 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.

Initiation of Vicinium BLA submission under Rolling Review on December 6, 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.

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

Significant Progress in 2019

4 Pivotal Face-to-Face Meetings Led to BLA Submission of Clinical/Nonclinical Data

✓ **May 2019:** FDA Accepts CMC Analytical Comparability Plan
- No additional clinical trials deemed necessary at this time, subject to final review of comparability data in the BLA

✓ **June 2019:** FDA Recommends Accelerated Approval Pathway and Rolling Review
- Nonclinical data, clinical pharmacology data, and the safety database are sufficient to support a BLA submission

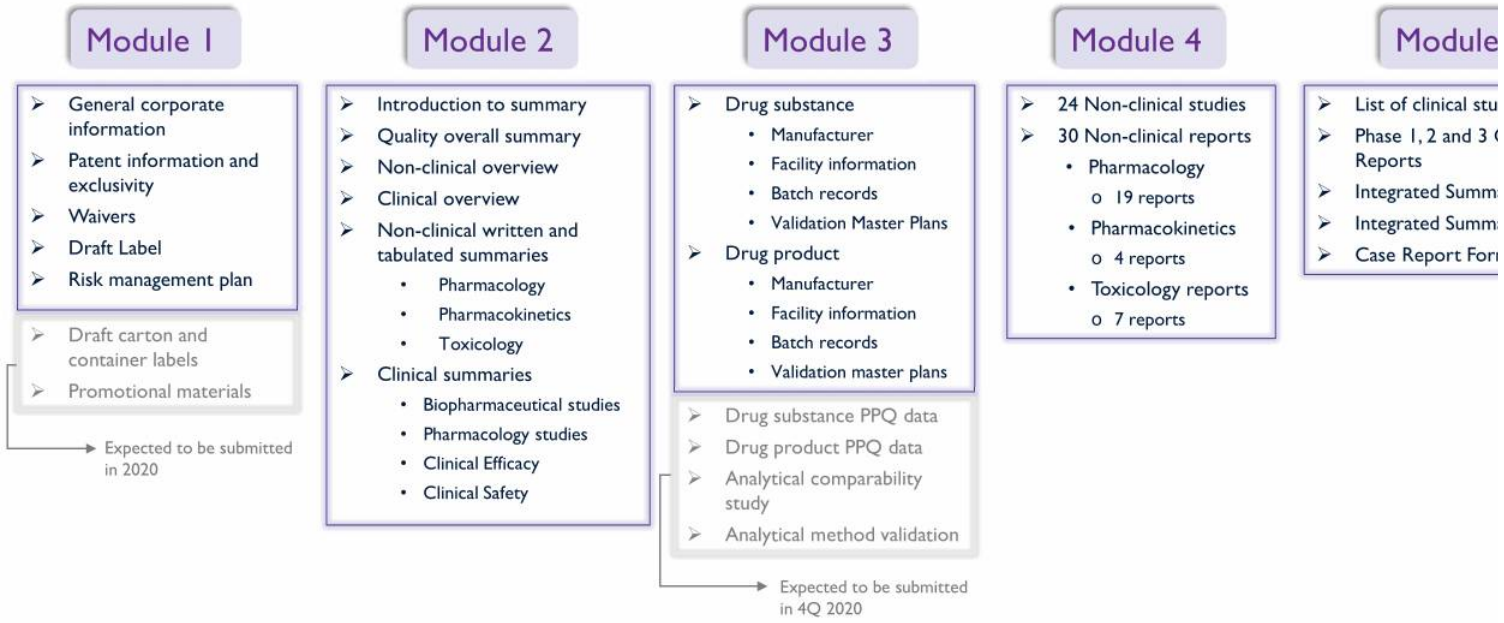
✓ **November 2019:** Gained alignment with FDA on post-marketing confirmatory trial
- Creates opportunity for future label expansion in broader population

✓ **December 2019:** Gained alignment with the FDA on the final content of the BLA
- Shared commitment to accelerate the timing of the pre-license inspection

December 2019: Initiated BLA submission for Vicinium under Rolling Review

Key Elements of BLA Submission for Vicinium

We initiated our BLA submission under Rolling Review on December 6th 2019 and believe this significantly de-risks the regulatory path to



Appendix

Clinical Data

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 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	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

Vicinium has a Highly Differentiated Clinical Profile

Efficacy Data

3 month response data
- CIS: 40% complete response rate
- Papillary: 71% recurrence-free rate

Durability of response
- CIS: 52% duration of 9 months (12 months of therapy)
- Papillary: Median time to recurrence of 402 days

Positive time to cystectomy data
- 76% of patients are cystectomy-free for 3 years
- Meaningful data for patients and payers

Encouraging survival data
- Overall survival is 98% at 12 months

Safety Data

Intravesical administration
- Bladder wall serves protective function
- Preference of FDA* and most Urologists

Clinical experience
- 243 patients exposed to Vicinium for periods up to 782 days across all clinical trials
- Average patient received 15 instillations of BCG

Differentiated safety profile
- 95% of all AEs were Grade 1 or 2
- Only 4% of patients experienced a treatment-related Grade 3-5 AE

Favorable tolerability
- Low discontinuation rate due to AEs (3%)
- No age-related increase in AEs

*As referenced in FDA NMIBC Guidance for Industry, February 2018.
Source: Phase III data as of the May 29, 2019 data cut.

Compelling Clinical Data Set

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.	• 76% of patients are cystectomy-free for 3 years • Responders have an 88% probability of remaining cystectomy-free at 3 y • Average responder remains cystectomy-free for 1,035 days vs 631 days f 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 are 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 or requency of AE
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 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 is achieved, proceed to maintenance dosing consisting of three cycles of 3 weekly doses, followed by 9 weeks off; 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 is achieved, proceed to maintenance dosing consisting of three cycles of 3 weekly doses, follov by 9 weeks off.

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

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

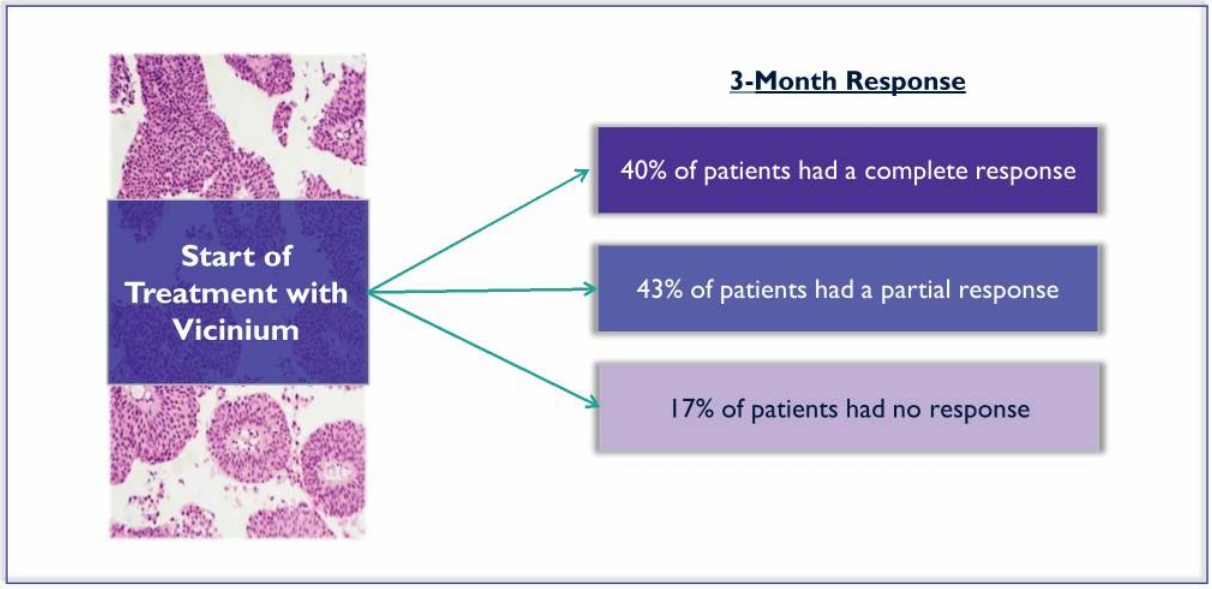
Phase III Trial: Evaluable Patient Data Tables by Cohort for Carcinoma *in situ*

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%)

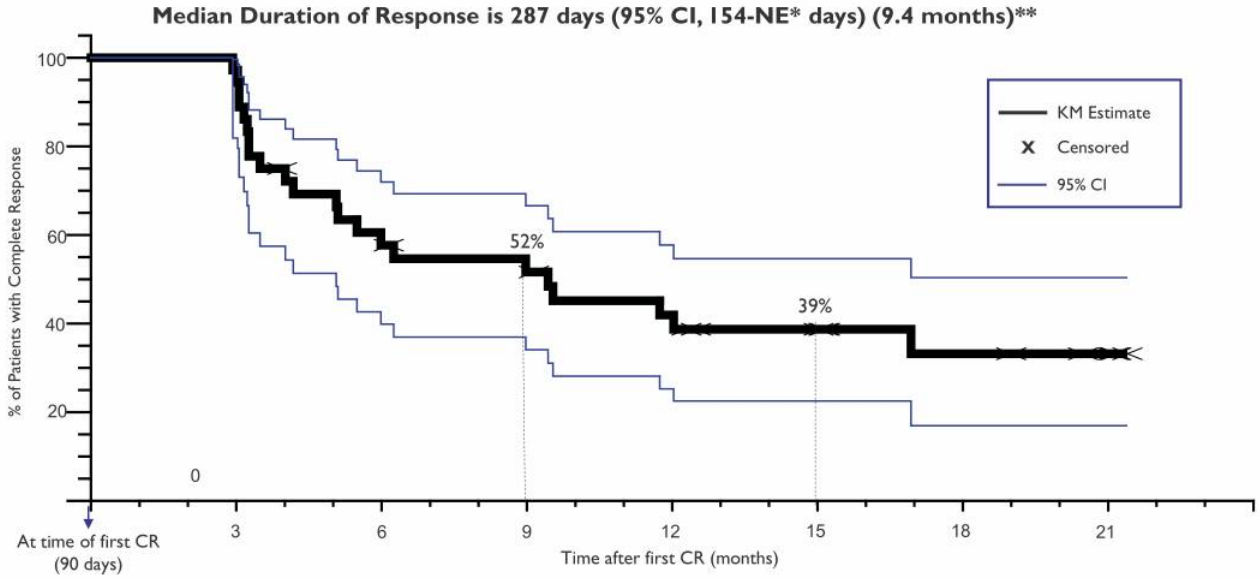
Response-evaluable population includes any modified intention-to-treat (mITT) subject who completed the induction phase
Note: Data are as of May 29, 2019 data cut

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.

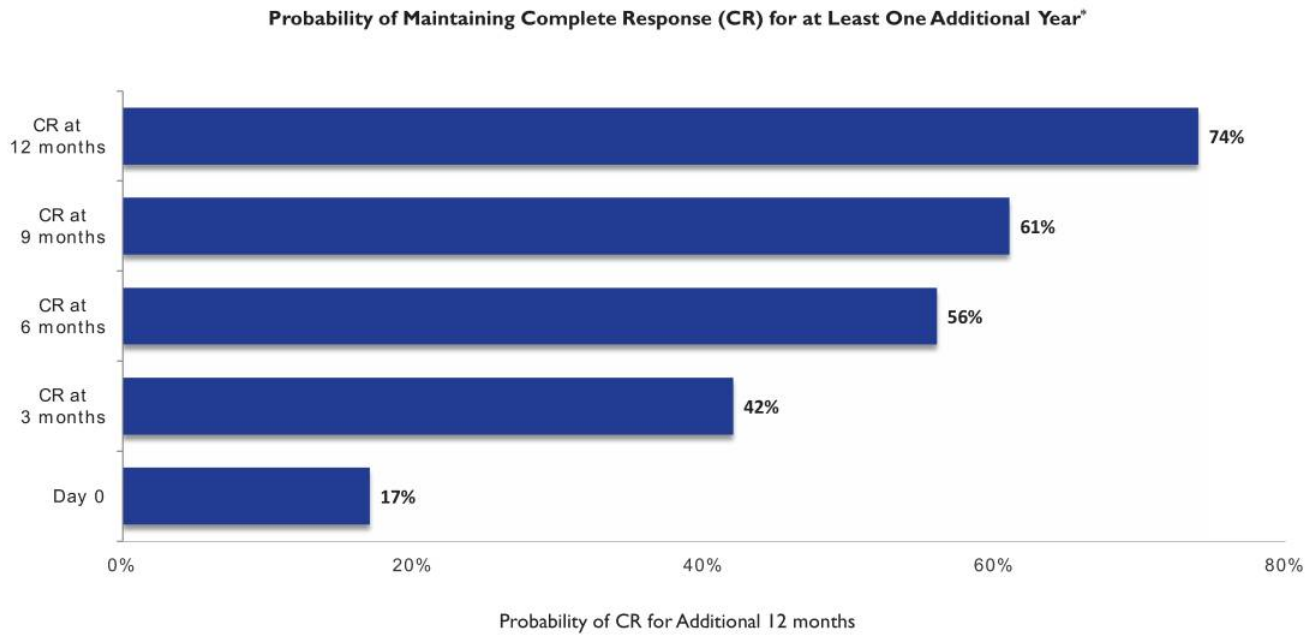
Duration of Response: 52% of CIS patients who had a complete response at 3 months remained disease-free for a total of 12 months after starting treatment



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

Duration of response: 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.

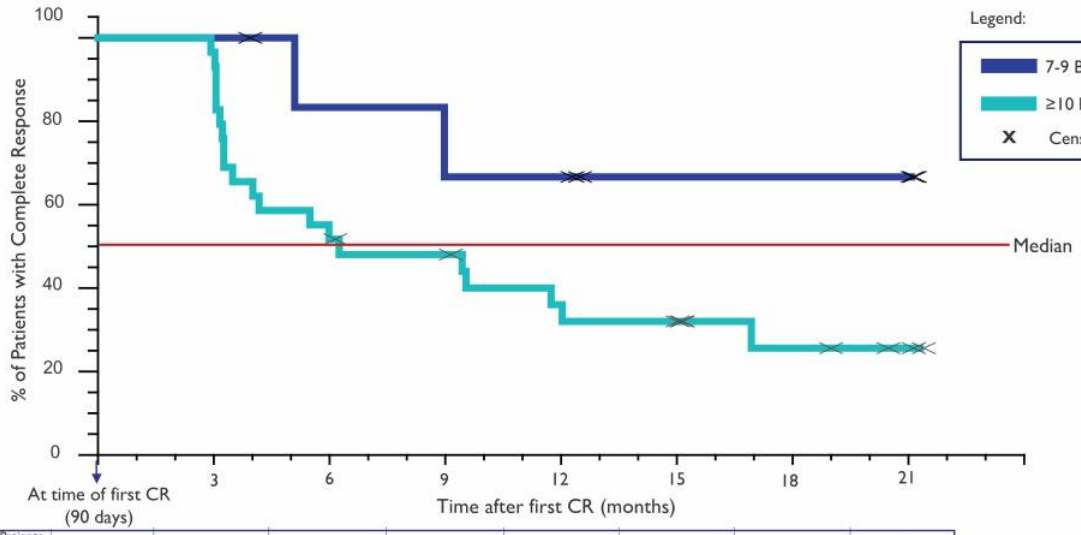
Duration of Response: The longer you have a complete response, the higher the probability of remaining cancer-free



Duration of response: 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.

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

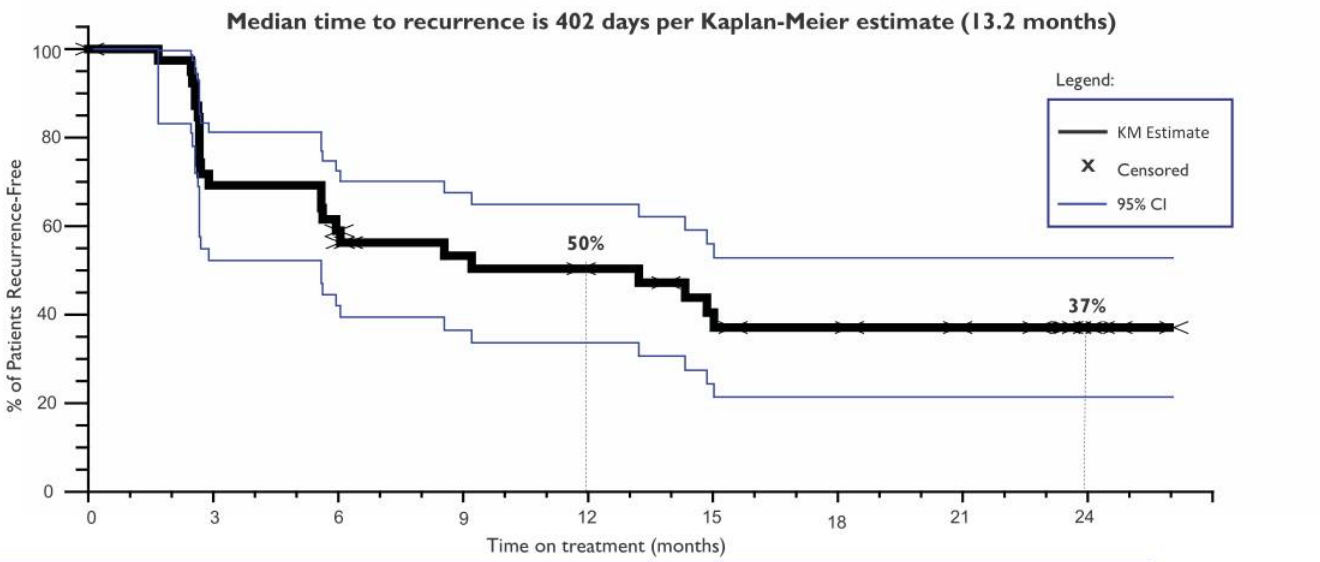
The BCG shortage may cause a new normal wherein patients receive less BCG



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: 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.

Time to Disease Recurrence: Time to Disease-Recurrence: 50% of high-risk papillary patients who were treated with Vicinium 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.

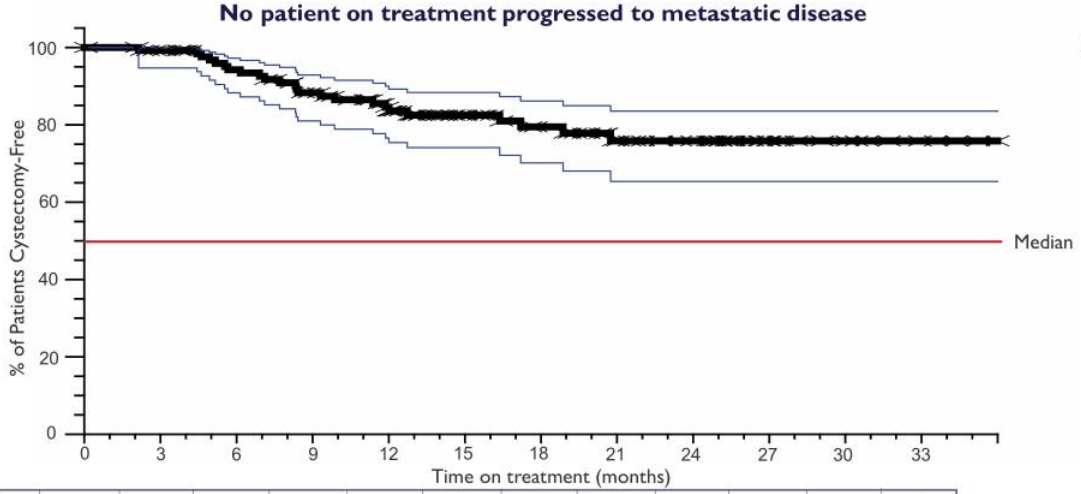
Recurrence-free Rate: 42% of high-risk papillary patients remain disease-free after one year

Recurrence-free Rate (Papillary patients)		
Time Point	**Evaluable Patients**	**RF Rate (95% Confidence Interval)**
3-months	n=38	71% (54%-85%)
6-months	n=38	58% (41%-74%)
9-months	n=38	45% (29%-62%)
12-months	n=38	42% (26%-59%)

Recurrence-free rate: defined as the percentage of patients that are recurrence-free at the given assessment time point.
Response-evaluable population includes any modified intention-to-treat (mITT) subject who completed the induction phase
Note: Data are as of May 29, 2019 data cut

Highly Differentiated Time-to-Cystectomy Data vs. Currently Available Agents

76% of patients are cystectomy-free for 3 years



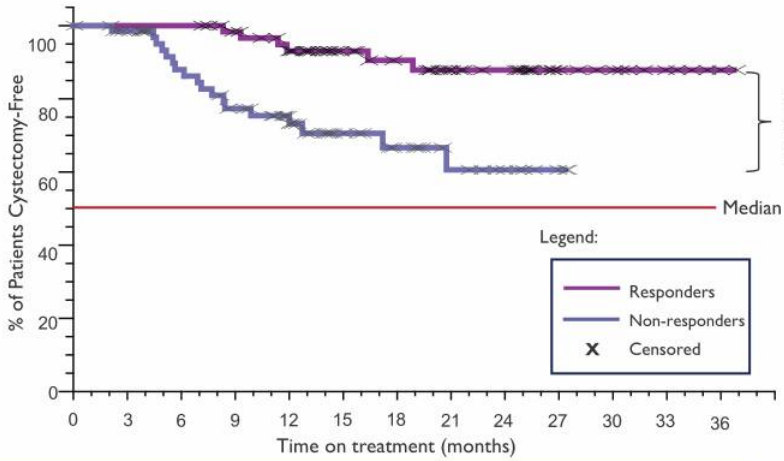
KM Evaluable Patients:	133	127	113	100	86	60	49	37	29	15	10	5

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.

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).

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 Patients (%)	Phase III Patients (%)
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%)

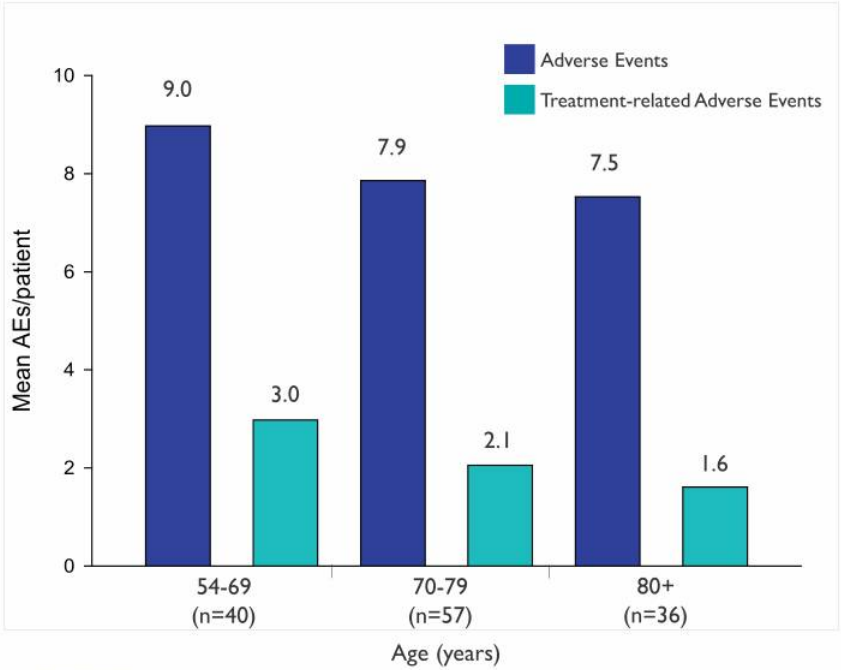
Vicinium Treatment Exposure:

Average Instillations per Patient	12	27
Average Duration of Exposure (days)	147	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 June 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).

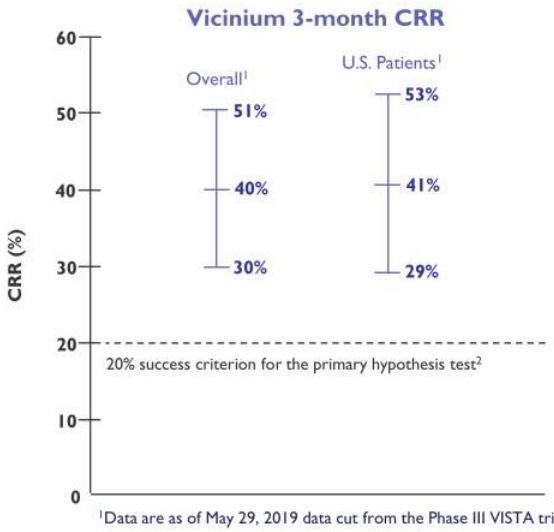
Market Research Input
Profile of Emerging Treatments for NMIBC

	Keytruda Profile	Vicinium Profile
Mechanism of Action	Binds to the PD-1 receptor, blocking both PD-L1 and PD-L2 from interacting with PD-1 to help restore T cell-mediated immune responses to attack the tumor	Selectively targets and kills bladder cancer cells whil sparing healthy cells, while also activating the immur system to attack the tumor
Indication	• Carcinoma *in situ*	• Carcinoma *in situ* • High-risk papillary (Ta/T1)
	2nd line use for patients who have failed following at least 2 courses of BCG (minimum 7 doses), and still have evidence of disease	2nd line use for patients who have failed following at courses of BCG (minimum 7 doses), and still have e of disease
	Limitations: Only patients ineligible for or refusing cystectomy	Limitations: None (anticipated upon FDA revie
Mode of Administration	Intravenous	Intravesical
Dosing Regimen	Every 3 weeks	Induction Weeks 1-6: twice weekly Weeks 7-12: once weekly Maintenance Every 2 weeks
Generally Administered By	Medical Oncologist	Urologist

Source: Dec. 2019 FDA briefing book for Keytruda profile; Dec. 2019 BLA submission for Vicinium profile.
This slide is intended for market research purposes only and is not intended for marketing purposes.

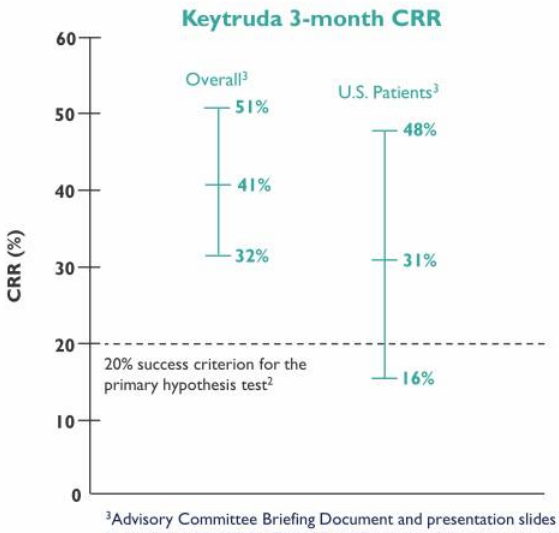
3-month complete response rate data from different clinical trials

Please use caution when drawing comparisons across different clinical trials



[1]Data are as of May 29, 2019 data cut from the Phase III VISTA trial

[2]To demonstrate a clinically meaningful response, per Keytruda ODAC panel discussion on Dec. 17, 2019 and based on the 18% CRR of Valstar



[3]Advisory Committee Briefing Document and presentation slides for pembrolizum for NMIBC (PEMBROLIZUMAB-P057V01MK3475). December 17, 2019.

CRR: complete response rate
CRR data from each trial are for CIS patients only
95% confidence intervals determined using exact binomial method (Clopper Pearson)

Pipeline of Targeted Therapies

We believe there is strong scientific rationale for Vicinium in combination with checkpoint inhibitors. Vicinium in combination with AstraZeneca's anti-PD-L1, Imfinzi (durvalumab), is being evaluated in a Phase 1 trial run by the National Cancer Institute.

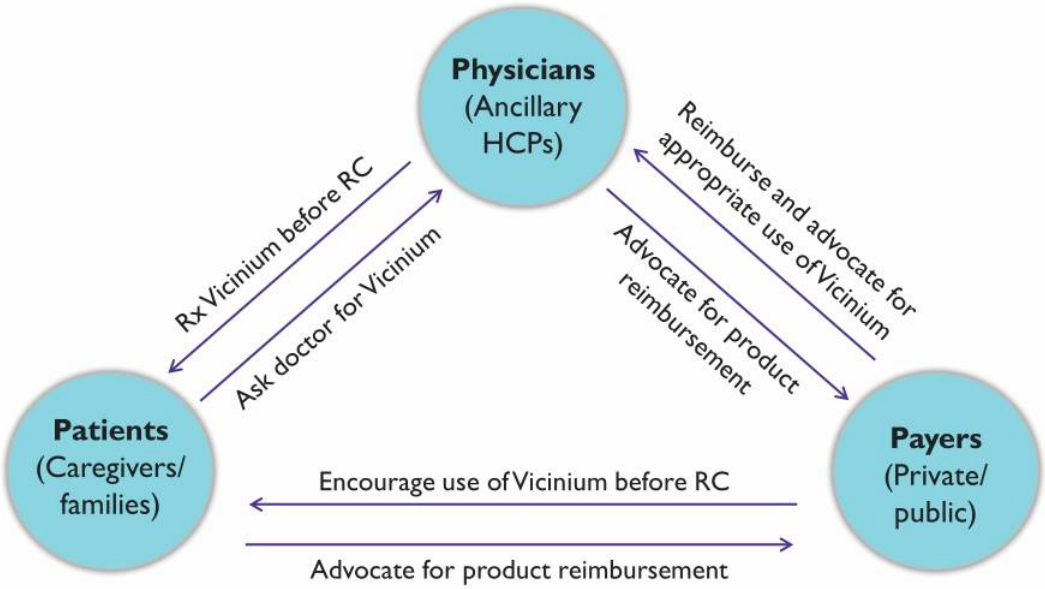
PRODUCT CANDIDATE	PAYLOAD	INDICATION	PRECLINICAL	Ph I	Ph II	Ph III	BLA
Locally administered TPTs							
Vicinium	**ETA**	BCG-unresponsive high-risk NMIBC	Submission Initiated				
Vicinium	**ETA**	SCCHN	Complete				
Locally administered TPT + Systemic Checkpoint Inhibitor							
Vicinium + Durvalumab	**ETA & IO**	BCG-unresponsive high-risk NMIBC	Ongoing				
Vicinium (Combination with checkpoint inhibitor)	**ETA & IO**	SCCHN	Deferred				

We have deferred further development of Vicinium, for the treatment of squamous cell carcinoma of the head and neck (SCCHN), and VB6-845d in order to focus our efforts and our resources on our ongoing development of Vicinium for the treatment of high-risk NMIBC. We are also exploring collaborations for Vicinium, for the treatment of SCCHN, and VB6-845d.
ETA, exotoxin A; IO, immuno-oncology agent

Appendix

Commercial Opportunity

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

Large Global Commercial Opportunity

Substantial US opportunity and OUS potential of 2-3 times the US

- We have CMO partners capable of reliably meeting that demand

Anticipated virtuous cycle of advocacy across physicians, patients/caregivers, and payers to driv
rapid uptake and strong growth after approval and launch

Compelling intent to prescribe research

Highly concentrated market of ~1,500 Urologists treating ~75% of BCG patients allows for effi
targeting

- Estimated 40-50 sales representatives required
- Allows for efficient digital/social strategies to activate patients/caregivers

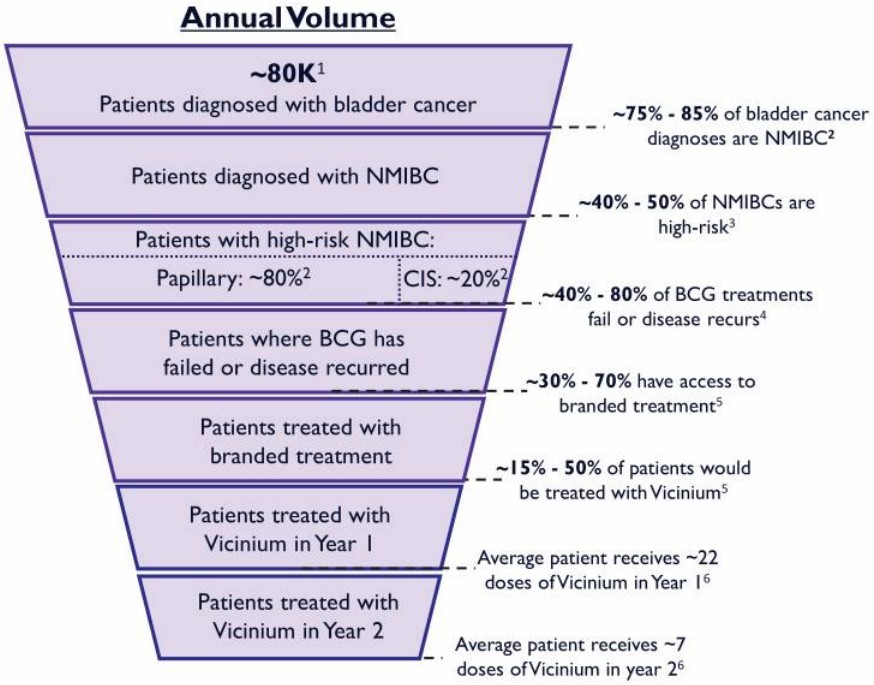
Source: Sesen Bio Qualitative market research, Urologist IDIs June 2019, n = 30.

Vicinium has the Potential to Provide Continuity of Care for Patients with NMIBC

Treatment Protocol	BCG	Vicinium	Checkpoint Inhibitors
Treatment at Urology office	✓	✓	X
Directed by Urologist	✓	✓	X
Administration by Urology nurse	✓	✓	X
Bladder infusion via urinary catheter	✓	✓	X
2-hour infusion, hold, and rotation	✓	✓	X

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

Addressable Market (US)



Sources: [1]National Cancer Institute, SEER Cancer Stat Facts: Bladder Cancer, 2019. [2]Anastasiadis et al. Therapeutic Advances in Urology, 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] Emerging Treatment In-Depth-Interviews (IDIs) with High BCG-Treating UROs, 1Q 2020, N=34. [6]Phase III trial data as of May 29, 2019 data cut. 80%

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.

Appendix

Manufacturing & Supply Chain

Reliable and Inexpensive Manufacturing Process

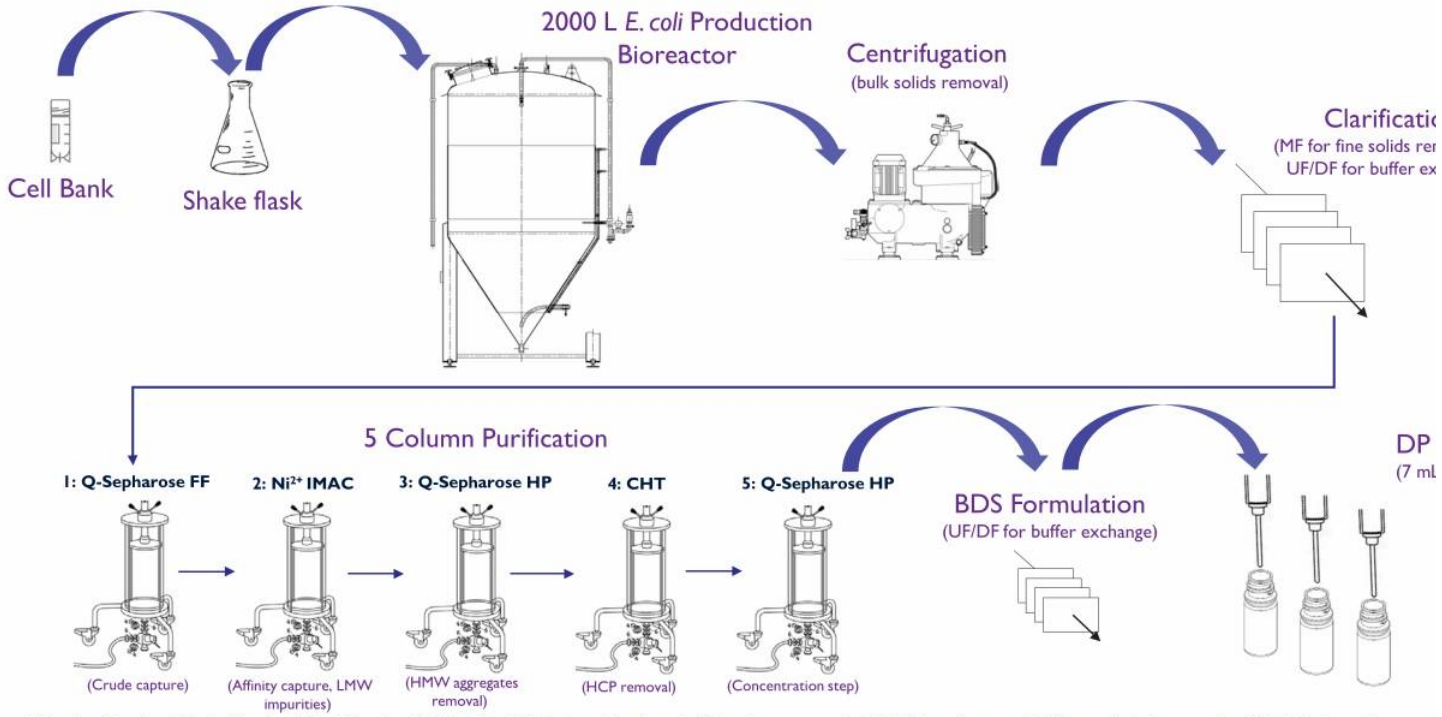
Vicinium is manufactured using a robust, industry-standard microbial expression system

The manufacturing process is highly reliable, reducing the risk of supply shortages

The manufacturing process is inexpensive, leading to a relatively low cost-of-goods

For manufacturing, we have partnered with Fujifilm and Baxter, both world-class contract manufactur

Reliable and Inexpensive Manufacturing Process



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.

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

Vicinium Commercial Manufacturing Strategy

	Clinical Supply	Commercial Supply
Drug Substance	Sesen	Fuji (CMO)
Drug Product	Sesen	Baxter (CMO)

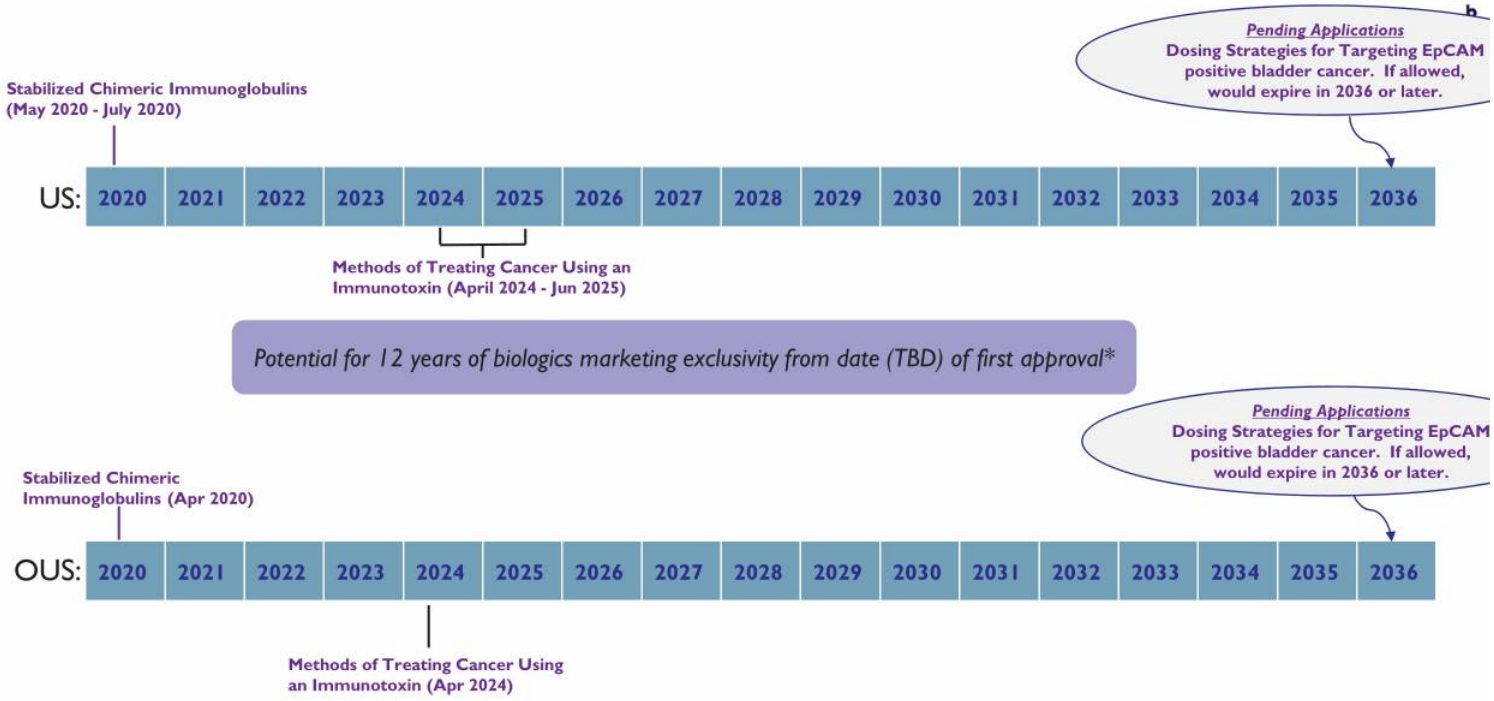
The analytical comparability plan is comprised of 4 key elements:

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 ex
4. Stability Studies
   - Assesses the stability of the protein under long-term storage conditions (e.g. purity by HPLC after storage at -20°)

Appendix

Intellectual Property

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))