
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): March 16, 2020

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

Delaware
(State or other jurisdiction
of incorporation)

001-36296
(Commission
File Number)

26-2025616
(I.R.S. Employer
Identification No.)

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

02142
(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 March 16, 2020, Sesen Bio, Inc. (the "Company") announced its financial results for the quarter and year ended December 31, 2019. 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 March 16, 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated March 16, 2020
99.2	Sesen Bio, Inc. Corporate Presentation dated March 16, 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: March 16, 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 Fourth Quarter and Full-Year 2019 Financial Results

Company on track to complete Vicinium® BLA submission in the second half of 2020 with potential approval in first half of 2021

New market research supports large commercial opportunity

CAMBRIDGE, Mass., March 16, 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 fourth quarter and full-year ended December 31, 2019. The Company also provided an update highlighting regulatory progress and the commercial opportunity of Vicinium for the treatment of patients with high-risk non-muscle invasive bladder cancer (NMIBC).

“2019 was a year of tremendous progress for Sesen Bio in every way, but especially in terms of our regulatory progress,” said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. “After four pivotal meetings with the FDA and the initiation of our BLA submission in 2019, we now turn our focus to finalizing the BLA for Vicinium and transforming into a commercial-ready organization in 2020. We believe Vicinium is a highly differentiated product candidate with a unique mechanism of action and clinical profile. We look forward to continuing our collaborative relationship with the FDA as we work to bring this important product to patients.”

Regulatory Update

- Initiation of Vicinium BLA Submission of clinical and non-clinical data
 - On December 6, 2019, the Company initiated the BLA submission for Vicinium under Rolling Review to the FDA. The initial submission included the completed non-clinical and clinical modules, and a partially completed Module 3 which details Chemistry, Manufacturing and Controls (CMC).
 - Anticipated completion of BLA submission in second half of 2020 with potential approval in first half of 2021. As part of finalizing Module 3, the Company anticipates completing three commercial-scale process performance qualification manufacturing runs for both bulk drug substance and drug product in the summer of 2020. The associated quality release testing results and master validation report will then be incorporated into Module 3, along with additional characterization testing and stability data to support the demonstration of analytical comparability between clinical and commercial drug supply. The Company anticipates submitting this information to the FDA in the second half of 2020 to complete the BLA submission. If the FDA accepts the BLA filing, the Company plans to request a Priority Review.

Commercial Opportunity

- Early commercial launch planning underway
-

- New market research supports large commercial opportunity. In the first quarter of 2020, the Company conducted 30-minute interviews with 34 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). Overall, these urologists indicated that Vicinium would be the preferred treatment modality in the majority of their patients in comparison to Keytruda and radical cystectomy. We believe this favorable response from urologists is due not only to the distinct mechanism of action and strong efficacy and safety profile of Vicinium, but also to its mode of administration and ease of adoption into clinical practice, which may provide continuity of care for patients and urologists.

Fourth Quarter and Full-Year 2019 Financial Results

- Cash Position: Cash and cash equivalents were \$48.1 million as of December 31, 2019, compared to \$50.4 million as of December 31, 2018.
- R&D Expenses: Research and development expenses for the fourth quarter of 2019 were \$5.4 million compared to \$4.7 million for the same period in 2018. For the year ended December 31, 2019, research and development expenses were \$24.7 million compared to \$14.1 million for the same period in 2018. The fourth quarter and annual increases were due primarily to costs related to the ongoing technology transfer process as we scale-up for commercial manufacturing and increased regulatory, internal and external staffing costs, partially offset by reduced expenses related to the Phase 3 VISTA trial for Vicinium.
- G&A Expenses: General and administrative expenses for the fourth quarter of 2019 were \$3.3 million compared to \$3.5 million for the same period in 2018. For the year ended December 31, 2019, general and administrative expenses were \$12.2 million compared to \$11.6 million for the same period in 2018. The fourth quarter decrease was due primarily to decreases in market research expense, public relations expense and external legal fees, partially offset by increases in internal staffing costs and professional and audit fees. The annual increase was due primarily to increases in internal staffing costs, professional and audit fees, partially offset by lower external legal fees and commercial expenses.
- Net Loss: Net loss was \$33.6 million, or \$0.32 per share, for the fourth quarter of 2019, compared to \$6.8 million, or \$0.09 per share, for the same period in 2018. For the year ended December 31, 2019, net loss was \$107.5 million, or \$1.18 per share, compared to \$33.7 million, or \$0.55 per share, for the same period in 2018. The fourth quarter and annual increases were due primarily to a higher non-cash change in the fair value of contingent consideration and the higher research and development expenses described above.

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.

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 timing of our process performance qualification manufacturing runs, expectations regarding the timing of completion of our BLA submission for Vicinium, our expectation to request a Priority Review in the event our BLA submission is accepted by the FDA, expectations

regarding the timing of potential approval of our BLA submission by the FDA, 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.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except per share data)

	(unaudited)		(unaudited)	
	Three Months ended December 31,		Twelve Months ended December 31,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	\$ 5,420	\$ 4,671	\$ 24,663	\$ 14,077
General and administrative	3,298	3,495	12,208	11,623
Change in fair value of contingent consideration	25,020	(1,100)	71,620	8,800
Total operating expenses	<u>33,738</u>	<u>7,066</u>	<u>108,491</u>	<u>34,500</u>
Loss from Operations	<u>(33,738)</u>	<u>(7,066)</u>	<u>(108,491)</u>	<u>(34,500)</u>
Other income (expense):				
Other income, net	185	309	991	807
Net Loss and Comprehensive Loss	<u>\$ (33,553)</u>	<u>\$ (6,757)</u>	<u>\$ (107,500)</u>	<u>\$ (33,693)</u>
Net loss per common share - basic and diluted	<u>\$ (0.32)</u>	<u>\$ (0.09)</u>	<u>\$ (1.18)</u>	<u>\$ (0.55)</u>
Weighted-average common shares outstanding - basic and diluted	<u>103,848</u>	<u>77,345</u>	<u>90,929</u>	<u>61,774</u>

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

	(unaudited) December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 48,121	\$ 50,422
Prepaid expense and other current assets	6,326	1,334
Total current assets	54,447	51,756
Restricted cash	20	20
Property and equipment, net	238	321
Intangibles	46,400	46,400
Goodwill	13,064	13,064
Other assets	196	-
Total Assets	\$ 114,365	\$ 111,561
Liabilities and Stockholders' (Deficit) Equity		
Current liabilities:		
Accounts payable	\$ 1,902	\$ 1,367
Accrued expenses	6,169	4,746
Other current liabilities	446	-
Total current liabilities	8,517	6,113
Contingent consideration	120,020	48,400
Deferred tax liability	12,528	12,528
Other liabilities	-	313
Total Liabilities	141,065	67,354
Commitments and contingencies		
Stockholders' (Deficit) Equity:		
Preferred stock, \$0.001 par value per share; 5,000,000 shares authorized at December 31, 2019 and 2018; no shares issued and outstanding at December 31, 2019 and 2018		
Common stock, \$0.001 par value per share; 200,000,000 shares authorized at December 31, 2019 and 2018; 106,801,409 and 77,456,180 shares issued and outstanding at December 31, 2019 and 2018, respectively	107	77
Additional paid-in capital	266,717	230,154
Accumulated deficit	(293,524)	(186,024)
Total Stockholders' (Deficit) Equity	(26,700)	44,207
Total Liabilities and Stockholders' (Deficit) Equity	\$ 114,365	\$ 111,561



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March 2020 Business Update



March 16, 2020

NASDAQ

For investor purposes only

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.

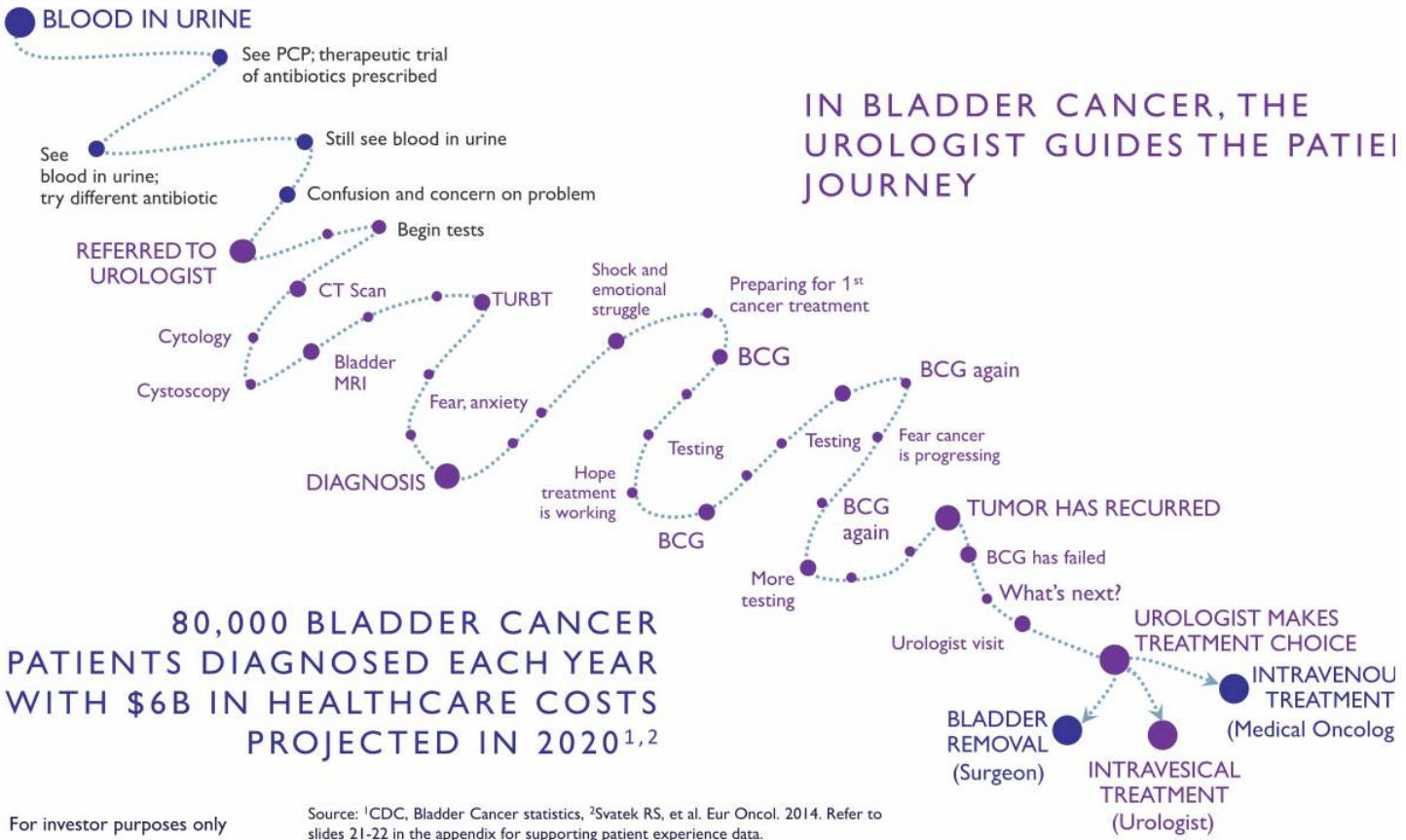
We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking 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, 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®, expectations regarding physicians’ decisions to prescribe Vicinium, if approved, 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.

For investor purposes only

MARCH 2020 BUSINESS UPD



- Significant unmet medical need for patients, caregivers and payers
- Highly differentiated mechanism of action and clinical profile
- New market research supports large commercial opportunity
- Clear regulatory path forward



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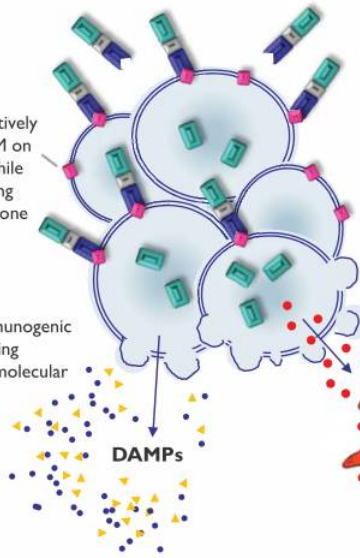
Source: ¹CDC, Bladder Cancer statistics, ²Svatek RS, et al. Eur Oncol. 2014. Refer to slides 21-22 in the appendix for supporting patient experience data.

Highly Differentiated Mechanism of Action

Mechanism 1: Kills cell directly

Vicinium selectively targets EpCAM on cancer cells while generally leaving healthy cells alone

Vicinium causes immunogenic cell death by triggering damage-associated molecular patterns (DAMPs)



Neoantigen release

APC Activation

Neoantigen presentation and T cell activation

Mechanism 2: Activates immune system

T cells recognize neoantigen and kill cancer cells

T cell proliferation

Memory T cell



Vicinium

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

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
- Significant cost savings to healthcare system

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

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

IQ 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

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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 while sparing healthy cells, while also activating the immune system to attack the tumor
Indication	<ul style="list-style-type: none"> • Carcinoma <i>in situ</i> 	<ul style="list-style-type: none"> • Carcinoma <i>in situ</i> • High-risk papillary (Ta/T1)
	2 nd line use for patients who have failed following at least 2 courses of BCG (minimum 7 doses), and still have evidence of disease	2 nd line use for patients who have failed following at least 2 courses of BCG (minimum 7 doses), and still have evidence of disease
	Limitations: Only patients ineligible for or refusing cystectomy	Limitations: None (anticipated upon FDA review)
Mode of Administration	Intravenous	Intravesical
Dosing Regimen	Every 3 weeks	<u>Induction</u> Weeks 1-6: twice weekly Weeks 7-12: once weekly <u>Maintenance</u> 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.

Market Research Input

Clinical Data from Emerging Treatments for NMIBC

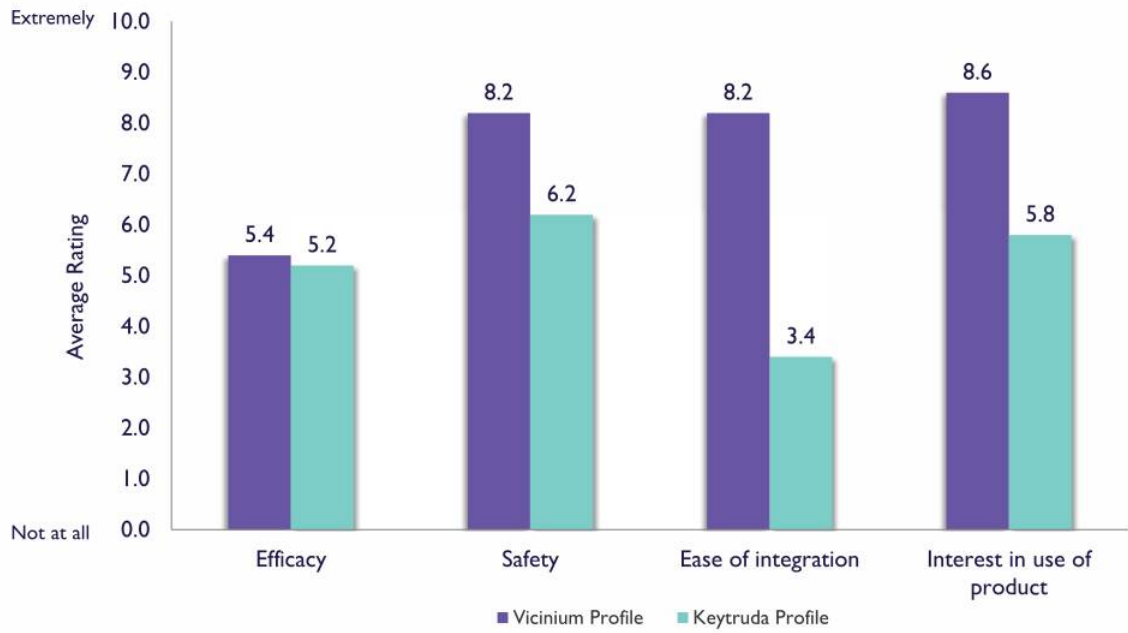


	Keytruda Profile	Vicinium Profile
Efficacy	N=102	N=89
Complete Response Rate		
• At 3 Months	41% (CI: 32-51)	40% (CI: 30-51)
• At 12 Months	20%	17%
• At 18 Months	13%	11%
Time to Cystectomy	No data reported (not a clinical trial endpoint)	76% of patients were cystectomy-free at 36 months (n=133)
Safety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

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.

Market Research Results

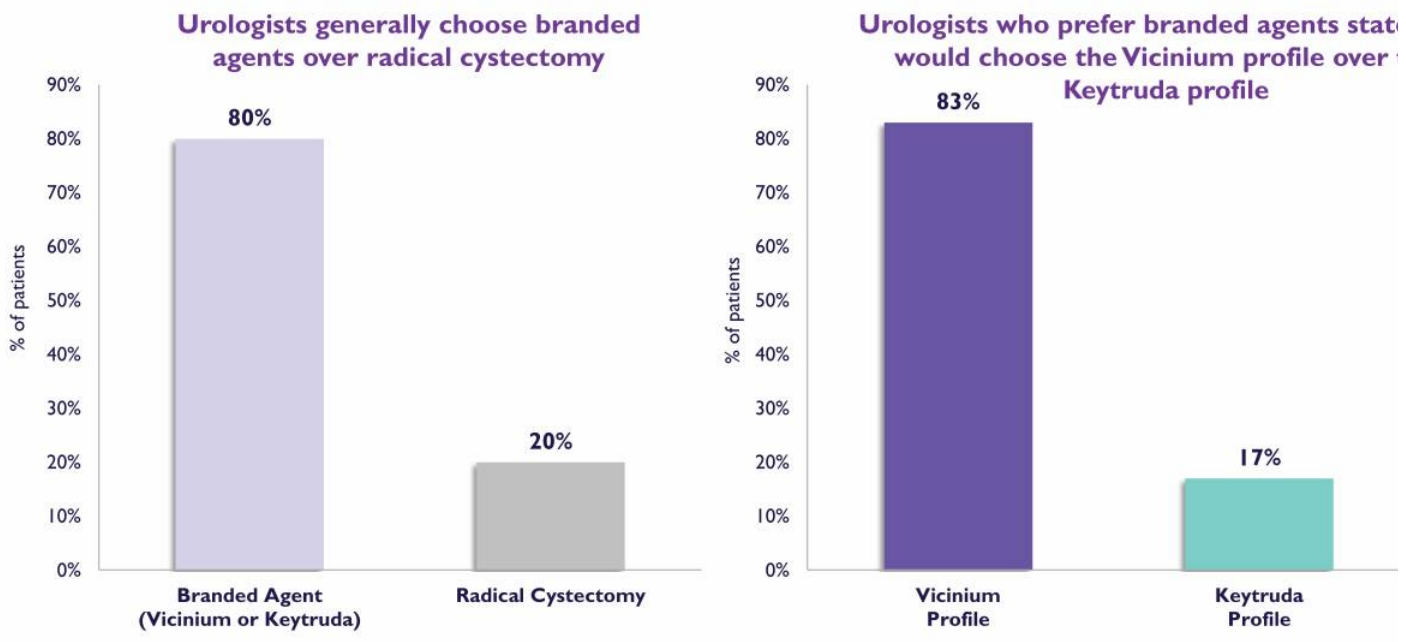
High Prescribing Urologists Prefer Vicinium Profile: Key Attributes



Source: Emerging Treatment In-Depth-Interviews (IDIs) with High BCG-Treating UROs, 1Q 2020, N=34
This slide is intended for market research purposes only and is not intended for marketing purposes.

Market Research Results

High Prescribing Urologists Prefer Vicinium Profile: Intent to Prescribe



Source: Emerging Treatment In-Depth-Interviews (IDIs) with High BCG-Treating UROs, 1Q 2020, N=34
This slide is intended for market research purposes only and is not intended for marketing purposes.

Market Research Results

Reasons Urologists Prefer Vicinium Profile



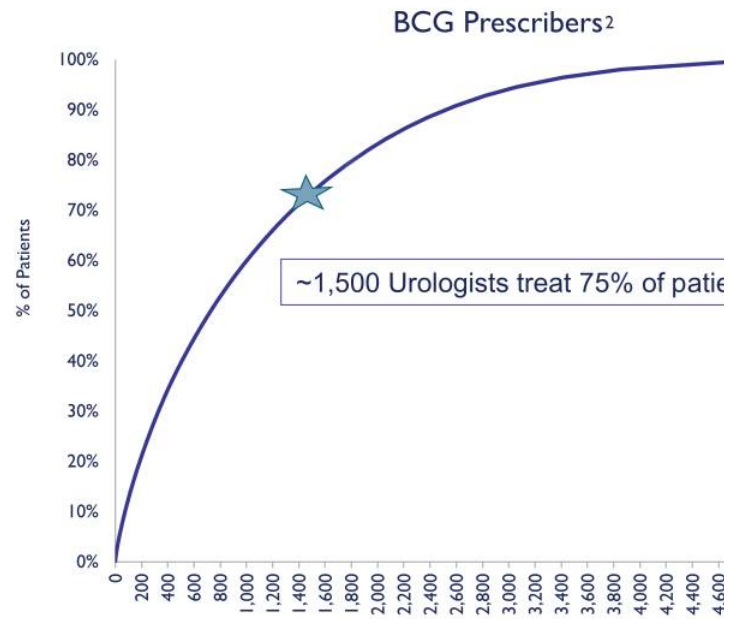
- **Urologists strongly prefer to retain ownership of patient journey**
 - High degree of reluctance to refer to Medical Oncologists
 - Fear of losing follow-up diagnostics with patient after treatment referral
- **Urologists perceive favorable product profile for Vicinium**
 - Comparable efficacy and favorable safety/tolerability relative to Keytruda profile
 - Compelling time-to-cystectomy data
- **Urologists perceive administration of Vicinium as highly consistent with office operations**
 - Treatment protocol for Vicinium identical to BCG
 - Many Urologists are less familiar with intravenous chemotherapy side effects
- **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 UROs, IQ 2020, N=34
This slide is intended for market research purposes only and is not intended for marketing purposes.

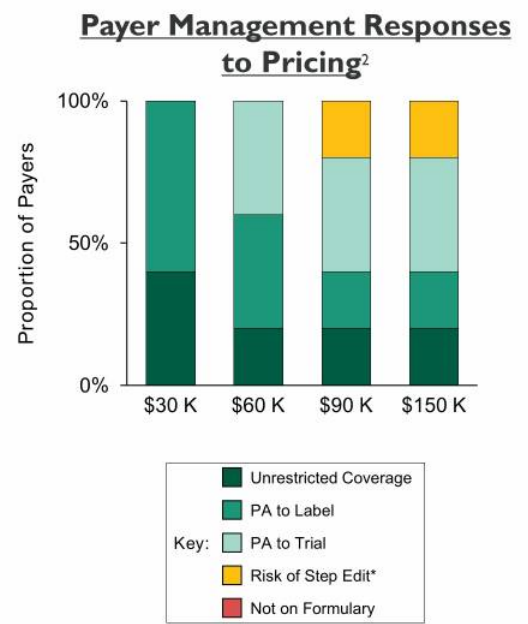
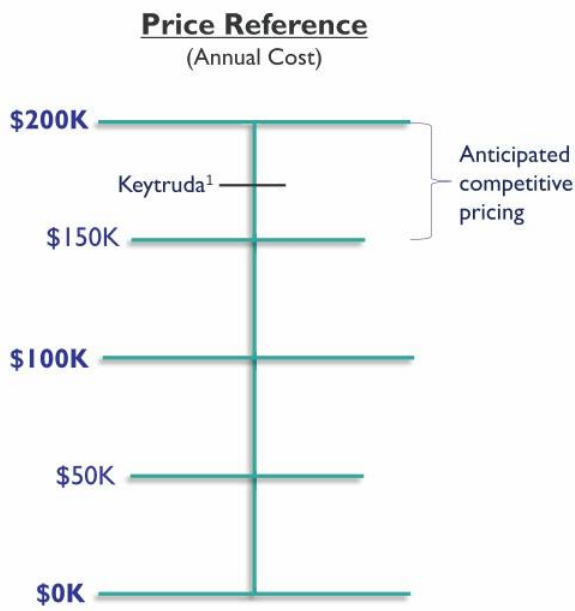
Highly Concentrated Prescriber Base Allows for Efficient Commercial Model



~60% of Urology practices have ≥ 5 Urologists¹



For investor purposes only ¹AUA State of the Urology Workforce and Practice in the United States. 2017. ²Health Verity 2019.



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

²Payer Interviews, ClearView Analysis, n=10, March 2019.

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*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

4 Pivotal Face-to-Face Meetings Lead 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

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Cash position

- Ending cash and cash equivalents of \$48.1M
- Sufficient cash to fund key strategic priorities into 2021

Capital structure

- 106.8 M shares of common stock outstanding
 - No preferred stock
 - 136 M fully diluted¹
- No Debt

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¹Fully diluted shares include outstanding warrants and stock options as of December 31, 2019.



2019 KEY HIGHLIGHTS

- Significant unmet medical need for patients, caregivers and payers
- Highly differentiated mechanism of action and clinical profile
- New market research supports large commercial opportunity
- Clear regulatory path forward

Senior Management		Board of Directors	
 Thomas Cannell, DVM President, CEO and Director	 Omar Rifi Vice President, Business Development and Alliance Management	 Jay Duker, M.D. Chair of the Board of Directors	 Carrie L. Bourdow Director
 Monica Forbes Chief Financial Officer	 Louise Stejbach Commercial Advisor	 Thomas Cannell, DVM President, CEO and Director	 Jane V. Henderson Director
 Glen MacDonald, Ph.D. Chief Technology Officer	 Jeannick Cizeau, Ph.D. Head of Research	 Jason Keyes Director	 Daniel S. Lynch Director
 Erin Clark Vice President, Corporate Strategy and Investor Relations	 Jeanette Kohlbrenner Human Resources Advisor		
 Mark Sullivan General Counsel and Corporate Secretary			

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Appendix - Table of Contents

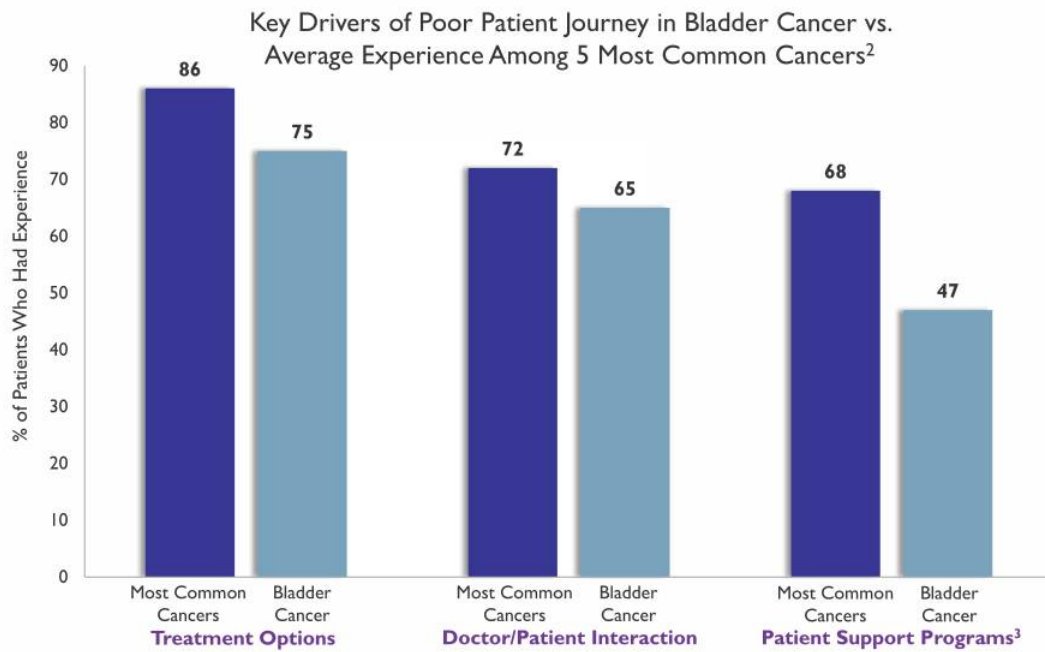
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For investor purposes only

Patient Journey

For investor purposes only

Patient surveys have shown that the experience of those with bladder cancer is one of the poorest¹



¹Cancer 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>. ²Most common cancers include breast, lung, prostate, colorectal, and skin cancers. SEER Database. <https://seer.cancer.gov/statfacts/html/urinb.html>. ³Includes self-help groups and financial assistance.

For investor purposes only

Unmet Medical Need

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Significant Unmet Medical Need in NMIBC

ses
b

~440,000

new cases each year globally¹

BCG
SHORTAGE

is complicating patient care

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

Bladder cancer is the most expensive cancer to treat in the US with projected costs of ~\$6B by 2020⁴

One of the worst patient experiences among common cancers

Survival rates for bladder cancer have decreased in recent years in the UK, during this time there was also a BCG shortage⁵

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

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

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.

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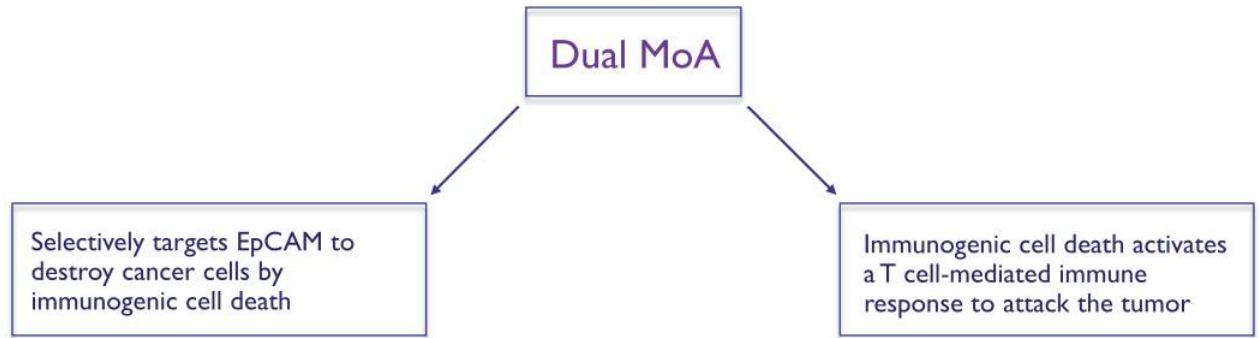
Sources and Additional Information:
Wall Street Journal. *Sanofi to Stop Production of Bladder Cancer Drug BCG*. Peter Loftus. 2016.
<https://www.auanet.org/practice-resources/bcg-info/bcg-shortage-notice>
<https://www.bcan.org/2019-bcg-shortage-bladder-cancer/>

Dual Mechanism of Action

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Vicinium is Highly Differentiated and has a Dual Mechanism of Action

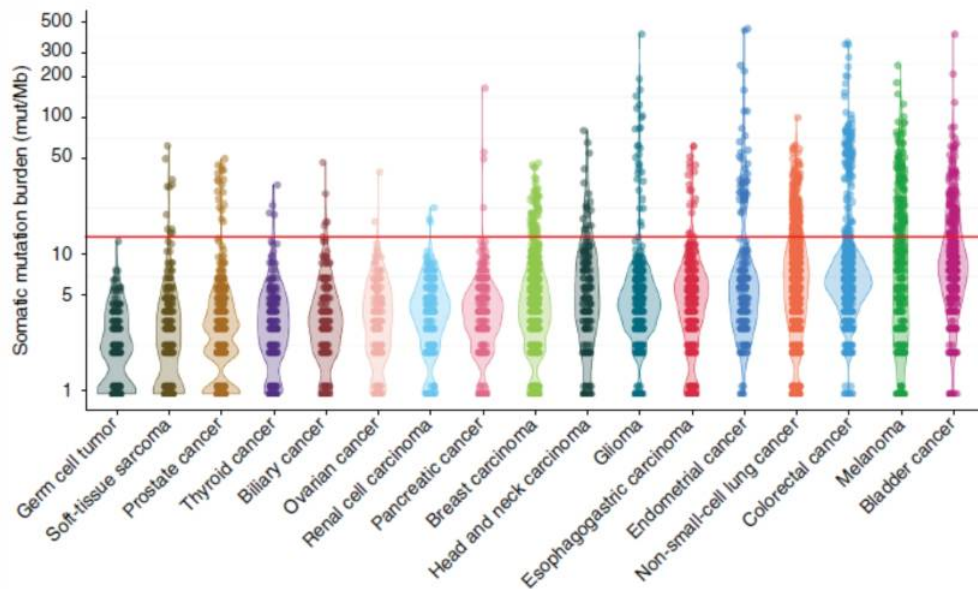
- Fusion protein consisting of an antibody fragment and a cytotoxic payload
- Small size facilitates tumor penetration and greater drug delivery
- Selectively targets cancer cells while generally sparing healthy cells
- Inhibits protein synthesis and kills both rapidly proliferating and slow-growing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



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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



For investor purposes only

Adapted from Zahir et al. Nature Medicine, 2017

Regulatory

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



2018 FDA Guidance

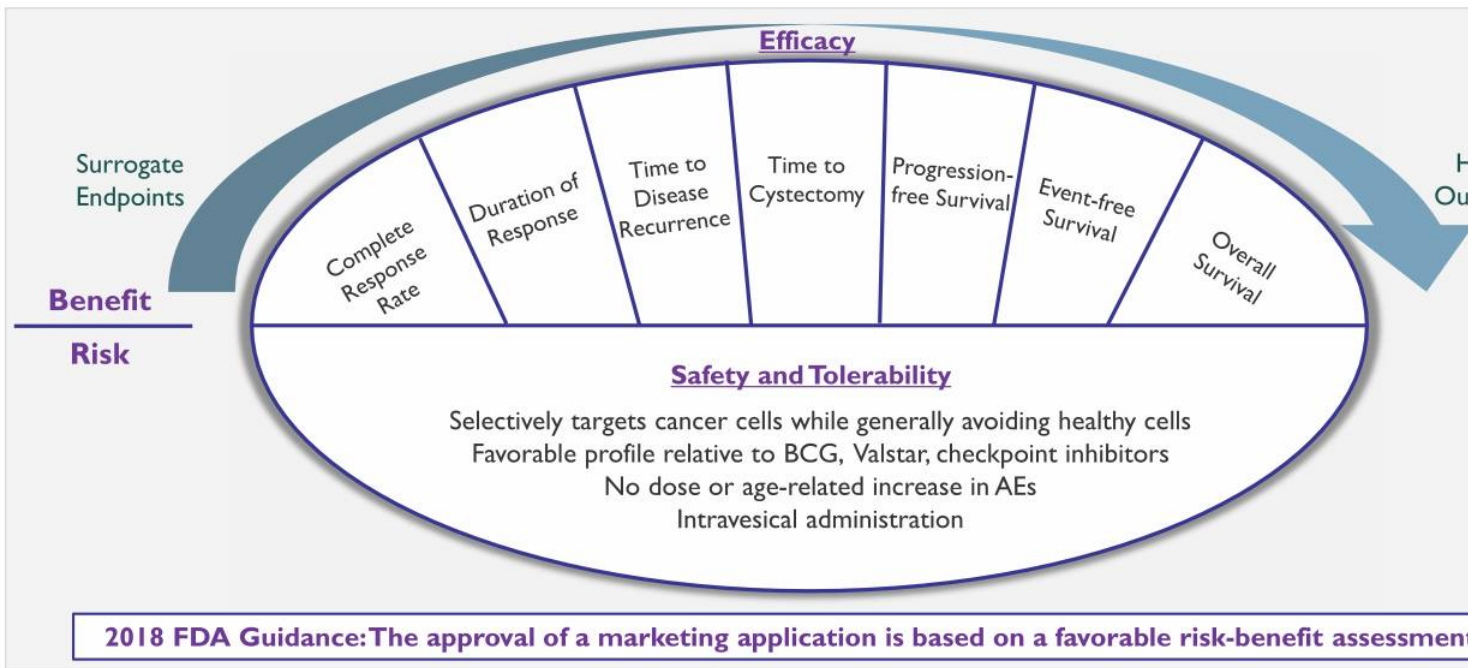
Vicinium Clinical Program

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



For investor purposes only 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



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

Oncology Products Reviewed by FDA 2006 - 2015

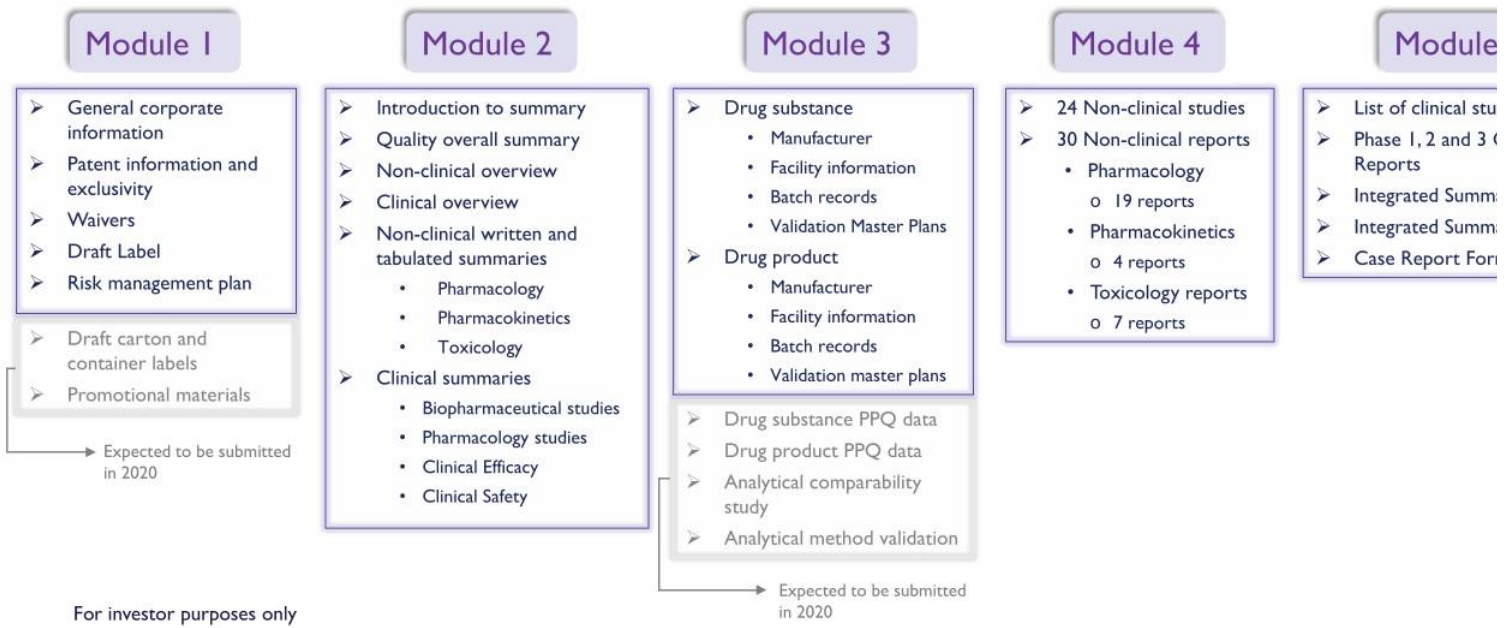
Phase	Probability of Approval
Products at end of Phase I	5%
Products at end of Phase II	8%
Products at end of Phase III	33%
Products with BLA Submission	82%

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.

Key Elements of BLA Submission for Vicinium



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



Clinical Data

For investor purposes only

Phase III Trial: Patient Demographics

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

For investor purposes only

TURBT: transurethral resection of bladder tumor
 Note: Data are as of 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).	<ul style="list-style-type: none"> 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.	<ul style="list-style-type: none"> 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.	<ul style="list-style-type: none"> 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.	<ul style="list-style-type: none"> 76% of patients are cystectomy-free for 3 years Responders have an 88% probability of remaining cystectomy-free at 3 years Average responder remains cystectomy-free for 1,035 days vs 631 days for 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.	<ul style="list-style-type: none"> 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.	<ul style="list-style-type: none"> 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.	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 2% treatment-related SAEs 4% treatment-related Grade 3-5 AEs Increased dosing in Phase III did not increase severity of AEs
Tolerability Secondary Endpoint All Cohorts	Full review of all tolerability data from Phase III	<ul style="list-style-type: none"> AEs generally low grade Low rate of discontinuations for AEs No age-related increase in AEs

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%)

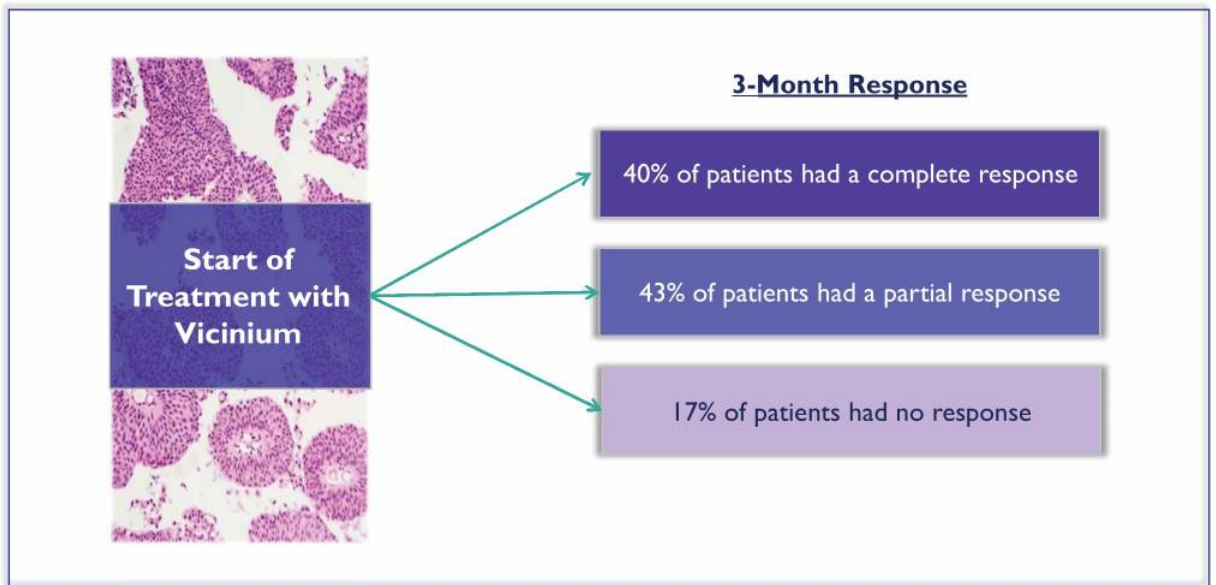
Cohort 2 (n=7) Complete Response Rate

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%)

For investor purposes only

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



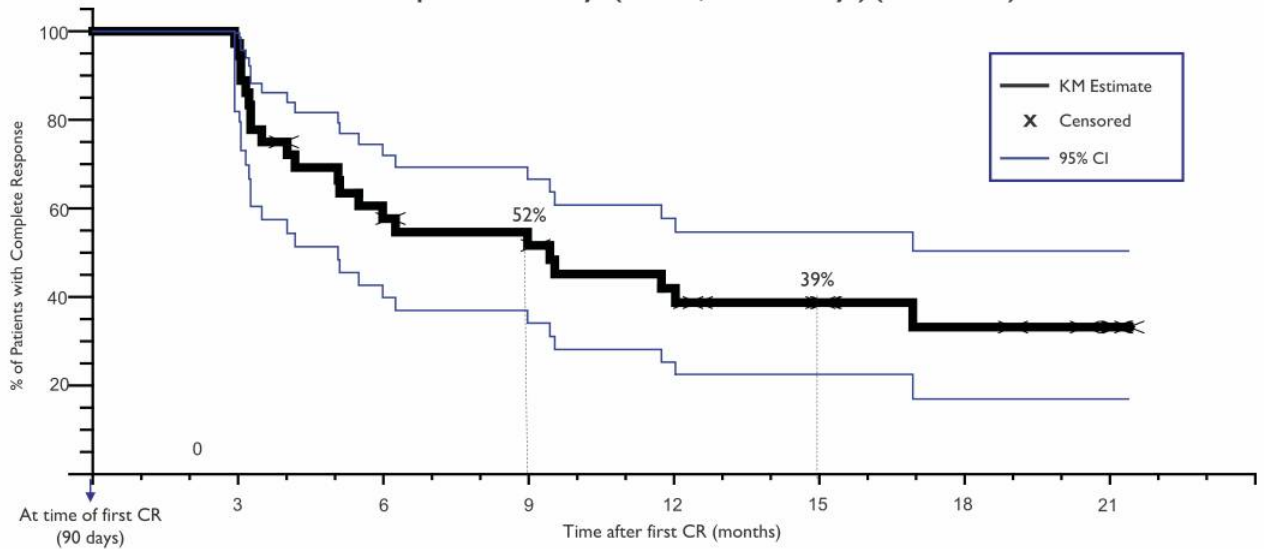
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*Note: Data are from Phase II clinical trial, n=45 (40% of patient had a complete response at 3 months; 60% of patients did not have a complete response and, of those, 71% of patients had a partial response). Partial response, as measured by bladder 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



Median Duration of Response is 287 days (95% CI, 154-NE* days) (9.4 months)**



KM Evaluable Patients:	36	35	21	16	13	10	6	4
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Duration of response: defined as the time of complete response to treatment failure.

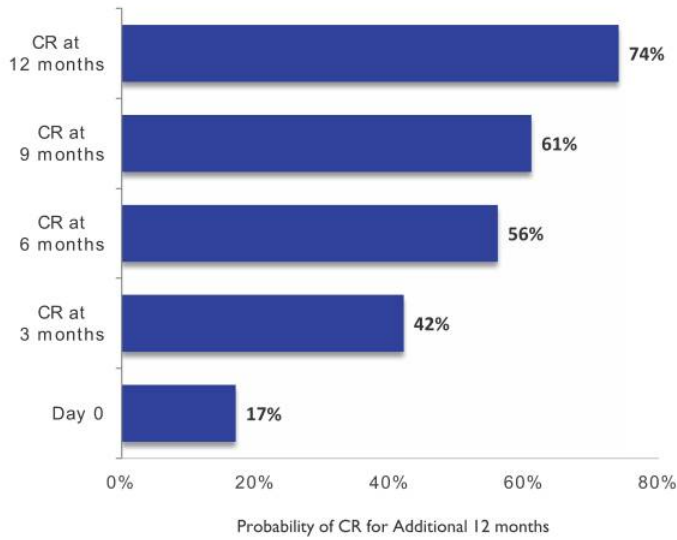
*Not Estimable, the upper bound for the 95% confidence interval has not reached the median.

**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 (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.

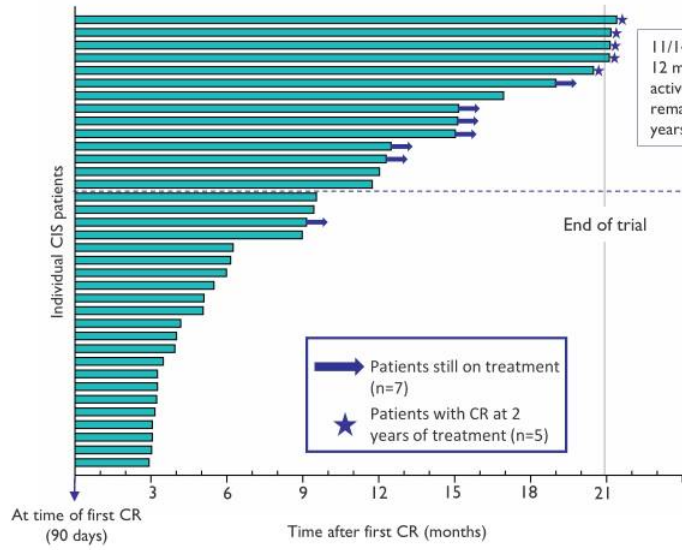
For investor purposes only

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

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



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



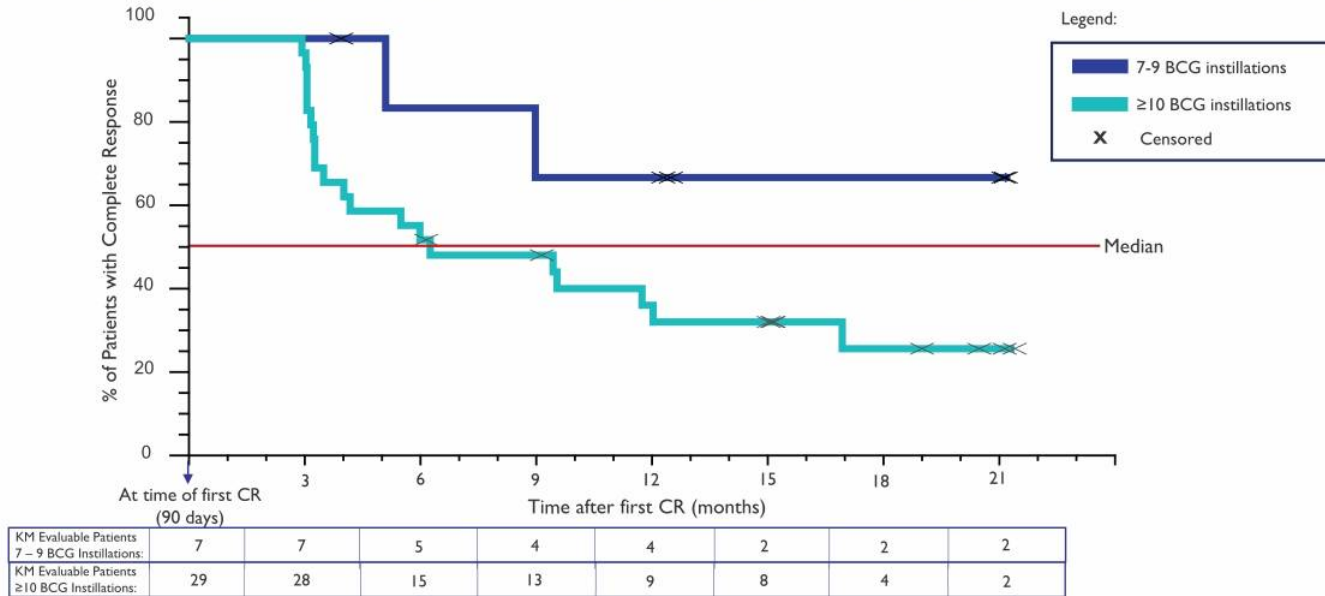
For investor purposes only

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



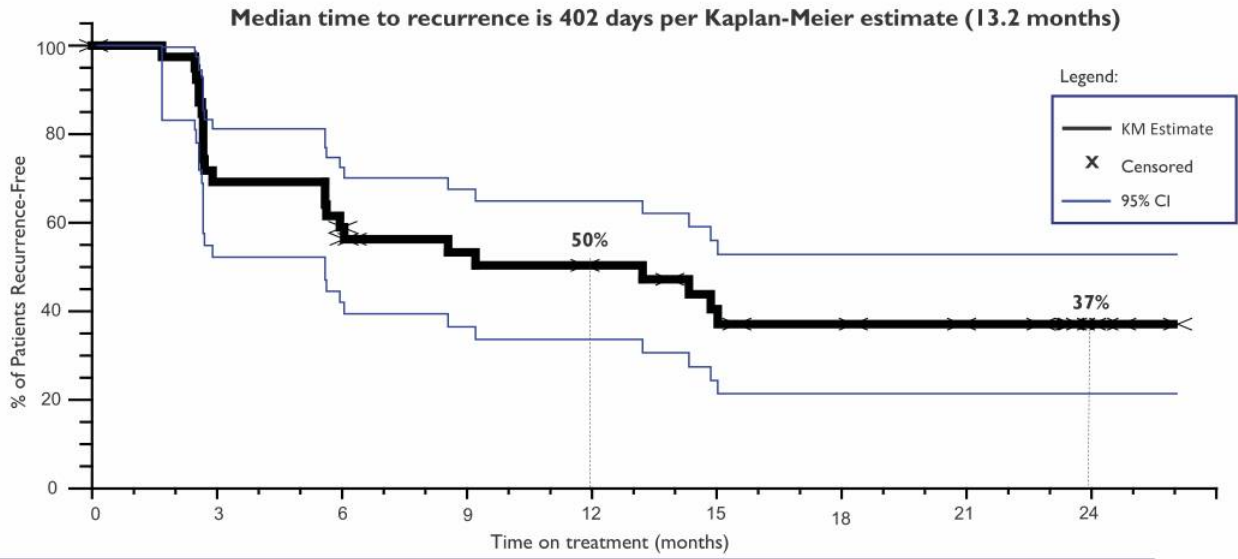
The BCG shortage may cause a new normal wherein patients receive less BCG



For investor purposes only

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



KM Evaluable Patients:	40	27	23	18	16	12	10	8	4
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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 reached the median.

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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

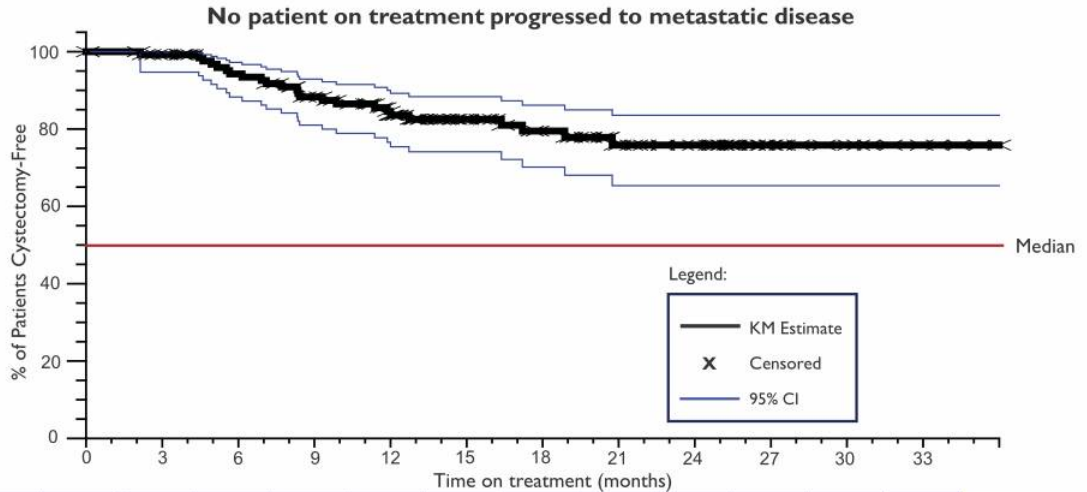


Recurrence-free Rate (Papillary patients)		
Time Point	Evaluable Patients	RF Rate (95% Confidence Interval)
3-months	n=38	71% (54%-85%)
6-months	n=38	58% (41%-74%)
9-months	n=38	45% (29%-62%)
12-months	n=38	42% (26%-59%)

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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

Time to Cystectomy: 76% of patients remain cystectomy-free for at least 3 years



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

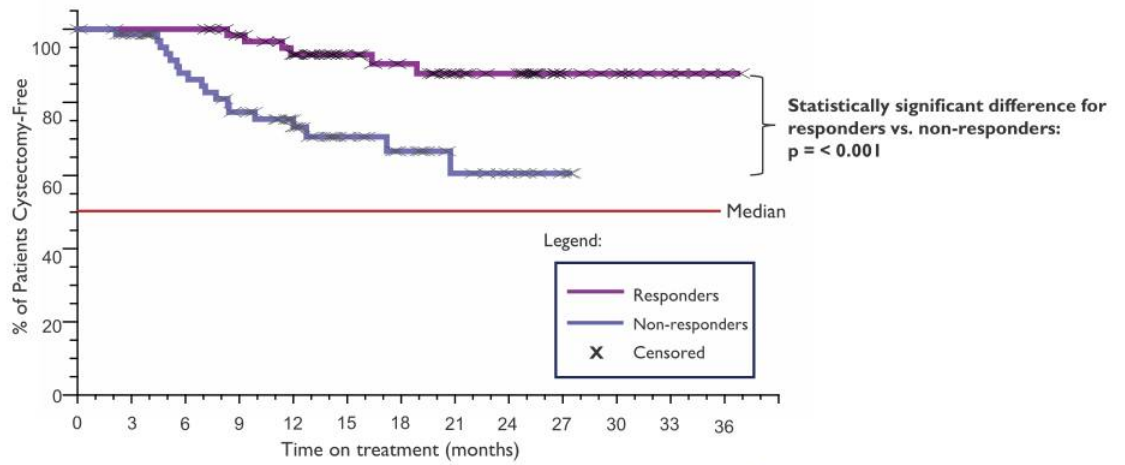
Note: Average time to cystectomy from transurethral resection of bladder tumor (TURBT) for NMIBC patients with high-risk papillary disease in Europe is ~105 days (National Institute of Health, *Timing of radical cystectomy in Central Europe - multicenter study on factors influencing the time from diagnosis to radical treatment of bladder cancer patients*, Poletajew S, et al., 2015.)

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

For investor purposes only 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 failure¹, grade 3 acute kidney injury², 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:

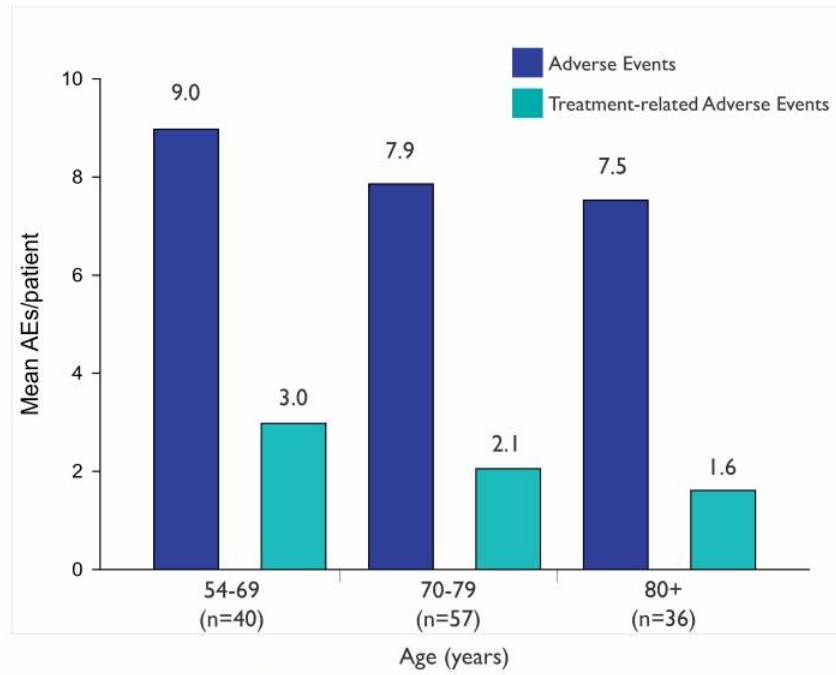
Average Instillations per Patient	12	27
Average Duration of Exposure (days)	189	240

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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 June 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 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



For investor purposes only 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).

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 I study 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	Anticipated				

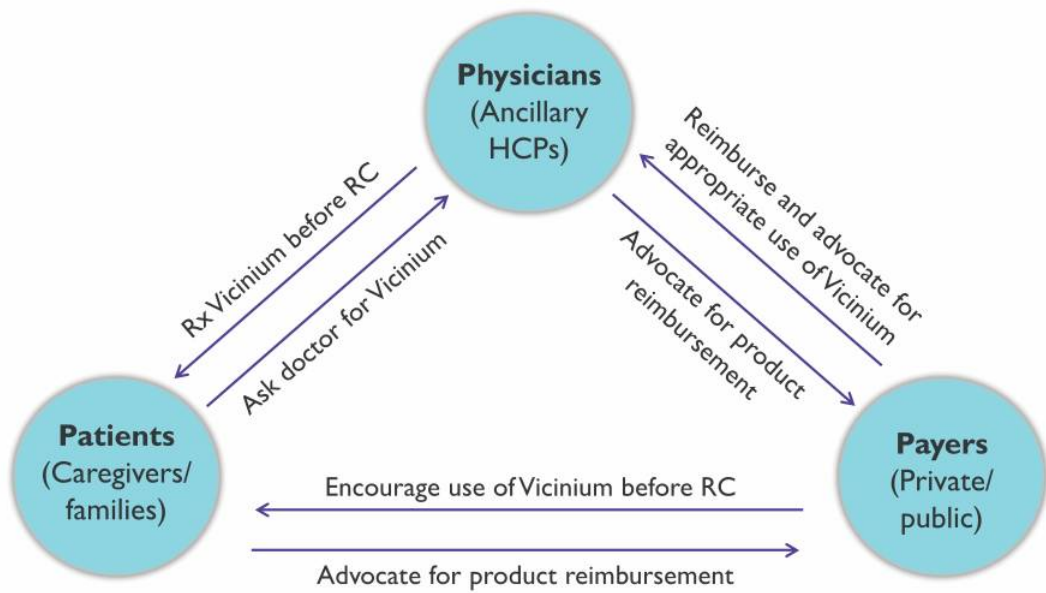
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We have deferred further development of Vicinium for the treatment of SCCHN and VB6-845d in order to focus our efforts and our resources on our ongoing development of Vicinium for the treatment of high-risk NMIBC. We are also exploring collaborations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

Commercial Opportunity

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



Sources:

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

For investor purposes only

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 drive 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 efficient targeting

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

For investor purposes only

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

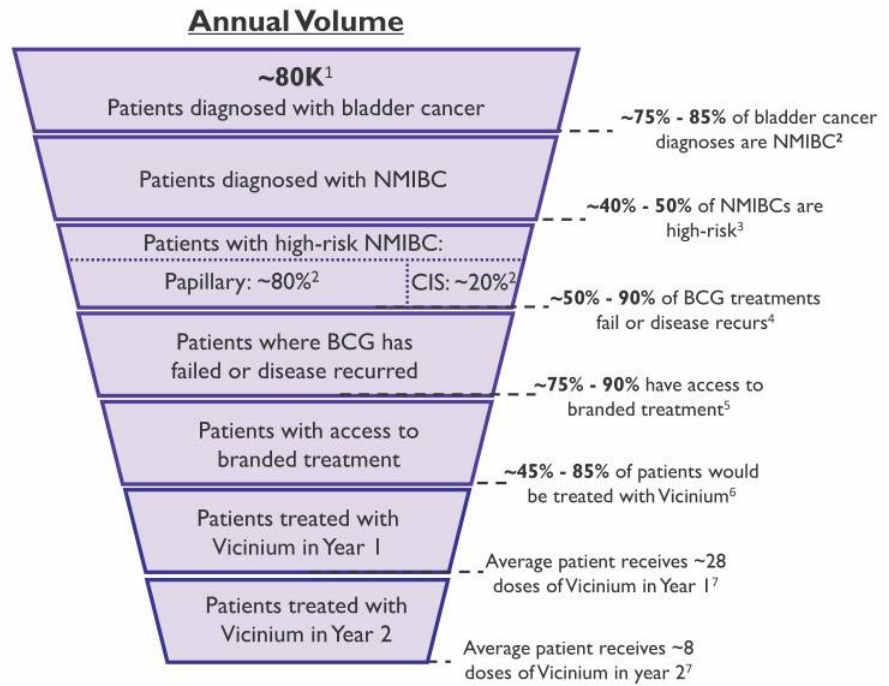
Vicinium has the Potential to Provide Continuity of Care for Patients with NMIBC



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

For investor purposes only

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



For investor purposes only Sources: ¹National Cancer Institute, SEER Cancer Stat Facts: Bladder Cancer, 2019. ²Anastasiadis et al. Therapeutic Advances in Urology, 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 Failure*. 2014. ⁵ClearView Analysis March 2019. ⁶ Emerging Treatment IDIs with High BCG-Treating UROs, IQ 2020, N=34. ⁷Phase III trial data as of May 29, 2019 data cut.

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. 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.

For investor purposes only

Manufacturing & Supply Chain

For investor purposes only

Reliable and Inexpensive Manufacturing Process



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

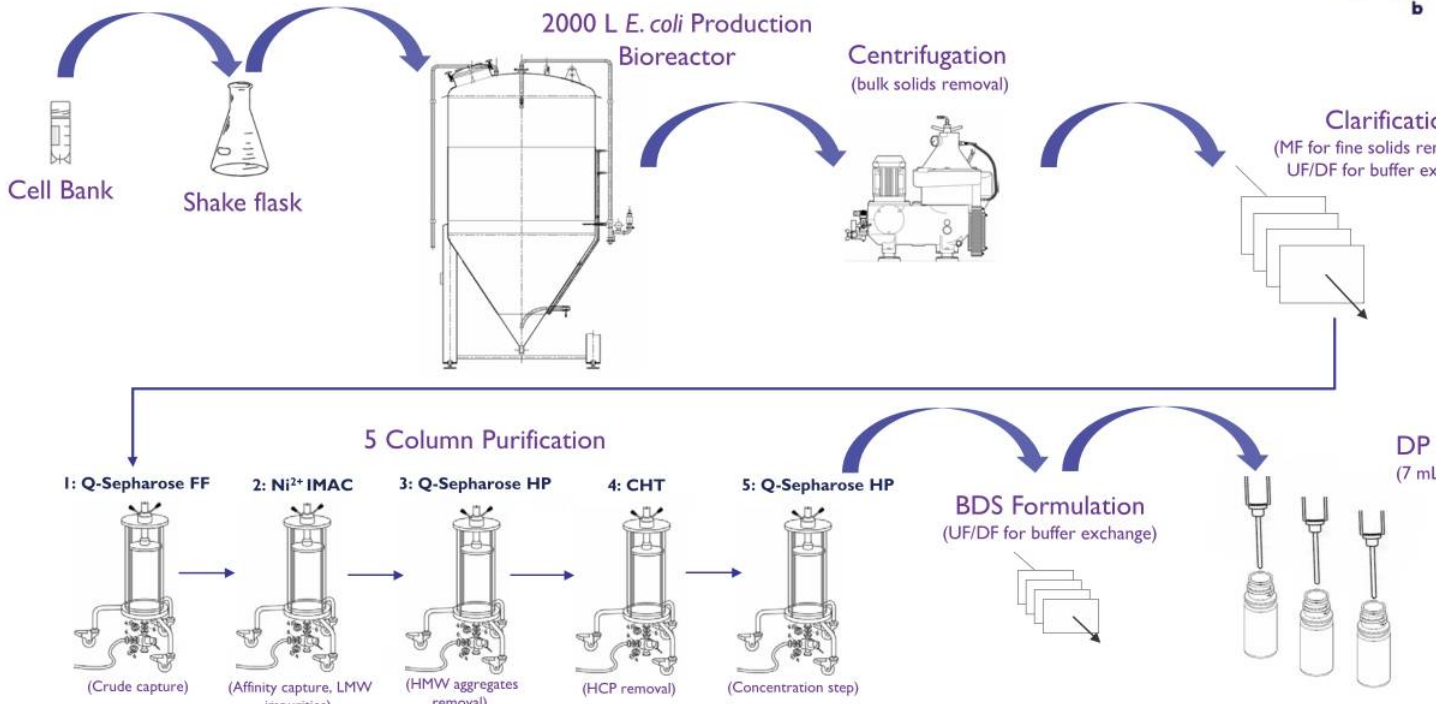
The manufacturing process is highly reliable, reducing the risk of supply shortages

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 manufacturer

For investor purposes only

Reliable and Inexpensive Manufacturing Process



For investor purposes only

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

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- 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:
- 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



For investor purposes only

	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°)

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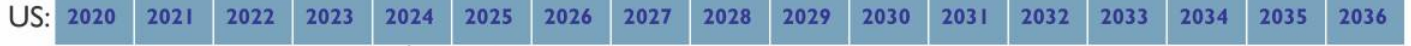
Intellectual Property

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Vicinium Patent Life

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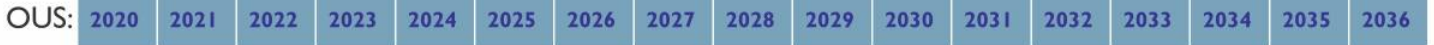
Stabilized Chimeric Immunoglobulins
(April 2020 - July 2020)



Methods of Treating Cancer Using an
Immunotoxin (April 2024 - Jun 2025)

Potential for 12 years of biologics marketing exclusivity from date (TBD) of first approval^{†*}

Stabilized Chimeric
Immunoglobulins (Apr 2020)



Methods of Treating Cancer Using
an Immunotoxin (Apr 2024)

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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))

