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

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**FORM 8-K**

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

Date of Report (Date of earliest event reported): November 9, 2020

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

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**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.)

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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:

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- 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 November 9, 2020, Sesen Bio, Inc. (the "Company") announced its financial results for the quarter ended September 30, 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 November 9, 2020, the Company posted a corporate presentation on its website [www.sesenbio.com](http://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	<a href="#">Press Release dated November 9, 2020</a>
99.2	<a href="#">Sesen Bio, Inc. Corporate Presentation dated November 9, 2020</a>

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**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: November 9, 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 Third Quarter 2020 Financial Results and Positive Progress Towards Completing the BLA Submission for Vicineum™ in December 2020

Manufacturing of Vicineum drug substance and drug product PPQ batches has been completed

Emerging manufacturing data provides strong support for analytical comparability between clinical and commercial material

On track to complete BLA submission to the FDA in December 2020

CAMBRIDGE, Mass., Nov 9, 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 third quarter ended September 30, 2020. The Company's lead program, Vicineum™, 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 Vicineum to the FDA under Rolling Review.

"We are rapidly advancing toward the finalization of our BLA in December as well as a potential MAA submission in Europe in early 2021," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "We believe the probability of regulatory success is high in both the US and Europe due to the strong clinical profile of Vicineum enabled by the unique dual mechanism of action. Once approved, we think Vicineum has the potential to be the best-in-class therapeutic in BCG-unresponsive NMIBC with a significant global commercial opportunity. We remain laser-focused towards executing on upcoming key milestones to the benefit of both patients and shareholders."

#### Manufacturing Update

Manufacturing and release testing of the three drug substance PPQ batches has been completed and all quality acceptance criteria were met. Manufacturing of the three drug product batches has also been completed and release testing has been completed for the first and second batch, with all quality acceptance criteria met. Testing of the third drug product PPQ batch is expected to be completed in November 2020. Based on the results obtained thus far, the Company is confident that the remaining batch will also meet the required acceptance criteria in support analytical comparability.

As part of the analytical comparability plan submitted to the FDA, the Company also committed to conduct extensive biophysical characterization and forced degradation testing on Vicineum manufactured using the proposed commercial process. These studies were completed in October 2020, and the Company believes the data demonstrates that clinical and commercial material are highly similar, providing strong support for analytical comparability.

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## EMA Regulatory Process

On October 23, 2020, the Company completed a successful Pre-Submission meeting with the European Medicines Agency (EMA) for Vicineum. During the meeting, the EMA provided updated guidance on various administrative topics, which help to clarify the regulatory path forward. In addition, earlier in 2020, the EMA provided written notice of the Company's eligibility to file a MAA under the EMA's centralized procedure. These interactions with the EMA in 2020 confirm the Company's pathway to a MAA submission for Vicineum in early 2021 with anticipated approval in early 2022.

## Supply Chain

The Company recently announced an exclusive agreement with Cardinal Health for third-party logistics and specialty pharmaceutical distribution services related to the commercial distribution of Vicineum in the United States. The addition of Cardinal Health completes the selection of major supply chain partners in support of the commercial distribution of Vicineum in the United States. All of Sesen Bio's major supply chain partners, including Fujifilm, Baxter and Cardinal Health, are recognized leaders within the industry, which the Company believes will help to ensure manufacturing and distribution excellence.

## OUS Partnership

On July 31, 2020, the Company announced an exclusive license agreement with Qilu Pharmaceutical for the development and commercialization of Vicineum in Greater China. On September 29, 2020, the Company received \$10.0 million in net proceeds associated with the \$12 million upfront payment due under the license agreement. Under the terms of the agreement, the Company is also eligible to receive (i) a 12% royalty, subject to certain reductions, based upon annual net sales of Vicineum in Greater China, and (ii) payments totaling up to \$23 million upon the achievement of certain technology transfer, development and regulatory milestones, the first of which the Company expects to receive in early 2021.

## Third Quarter 2020 Financial Results

- **Cash Position:** Cash and cash equivalents were \$42.0 million as of September 30, 2020, compared to \$48.1 million as of December 31, 2019. This change includes \$8.2 million of net proceeds received during the third quarter of 2020 provided by our ATM offering.
  - **Revenue:** Revenue for the third quarter of 2020 was \$11.2 million, which was due to the recognition of revenue from the Company's license agreement with Qilu. The Company did not record any revenue for the third quarter of 2019.
  - **R&D Expenses:** Research and development expenses for the third quarter of 2020 were \$10.2 million compared to \$6.6 million for the same period in 2019. The third quarter increase was due primarily to costs related to the ongoing technology transfer process
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with Fujifilm and Baxter as the Company scales-up for commercial manufacturing, partially offset by lower clinical expenses related to the Phase 3 VISTA trial for Vicineum and lower regulatory consulting fees in support of the Company's ongoing BLA submission with the FDA.

- G&A Expenses: General and administrative expenses for the third quarter of 2020 were \$4.1 million compared to \$3.2 million for the same period in 2019. The third quarter increase was due primarily to increases in investment banking and legal fees related to the Company's license agreement with Qilu.
- Net Loss: Net loss was \$22.6 million, or \$0.19 per basic share and diluted share, for the three months ended September 30, 2020, compared to a net loss of \$13.1 million, or \$0.13 per basic and diluted share, for the same period in 2019. The change was due primarily to revenue recognized in the third quarter of 2020 related to the Company's license agreement with Qilu, offset by higher technology transfer costs and a non-cash change in fair value of contingent consideration due to changes in discount rates.

#### 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 9360749. The webcast can be accessed in the Investor Relations section of the Company's website at [www.sesenbio.com](http://www.sesenbio.com). The replay of the webcast will be available in the investor section of the Company's website at [www.sesenbio.com](http://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 Vicineum<sup>TM</sup> 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 Vicineum 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](http://www.clinicaltrials.gov) and search the identifier NCT02449239.

#### About Vicineum<sup>TM</sup>

Vicineum, 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). Vicineum 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. Vicineum 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

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currently conducting the Phase 3 VISTA trial, designed to support the registration of Vicineum 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 Vicineum promote an anti-tumor immune response that may potentially combine well with immuno-oncology drugs, such as checkpoint inhibitors. The activity of Vicineum 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, Vicineum™, 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 Vicineum to the FDA under Rolling Review. Sesen Bio retains worldwide rights to Vicineum with the exception of Greater China, for which the Company has partnered with Qilu Pharmaceutical for commercialization. Vicineum 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](http://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 Vicineum. 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: the Company's ability to successfully develop its product candidates and complete its planned clinical programs, expectations regarding the completion of the Company's PPQ runs; expectations that the Company's remaining PPQ batches will meet the required acceptance criteria in support analytical comparability, expectations that the Company will complete its BLA submission for Vicineum in December 2020, the Company's expectations to submit its MAA for Vicineum in early 2021 with anticipated approval in early 2022, expectations regarding the timing and amounts of any payments due under the Company's license agreement with Qilu, 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

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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](mailto:ir@sesenbio.com)

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

	Three Months ended September 30,		Nine Months ended September 30,	
	2020	2019	2020	2019
License revenue	\$ 11,236	\$ -	\$ 11,236	\$ -
Operating expenses:				
Research and development	10,196	6,613	23,625	19,243
General and administrative	4,115	3,238	10,882	8,910
Change in change in fair value of contingent consideration	18,400	3,600	(16,820)	46,600
Total operating expenses	32,711	13,451	17,687	74,753
Loss from operations	(21,475)	(13,451)	(6,451)	(74,753)
Other income (expense):				
Other income (expense), net	(1)	319	195	806
Net Loss and Comprehensive Loss Before Taxes	\$ (21,476)	\$ (13,132)	\$ (6,256)	\$ (73,947)
Provision for income taxes	(1,132)	-	(1,132)	-
Net Loss and Comprehensive Loss After Taxes	\$ (22,608)	\$ (13,132)	\$ (7,388)	\$ (73,947)
Deemed dividend	-	-	(147)	-
Net Loss and Comprehensive Loss Available to Common Stockholders	\$ (22,608)	\$ (13,132)	\$ (7,535)	\$ (73,947)
Net loss per common share - basic and diluted	\$ (0.19)	\$ (0.13)	\$ (0.07)	\$ (0.85)
Weighted-average common shares outstanding - basic and diluted	117,886	101,266	113,437	86,575

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

	September 30, 2020	December 31, 2019
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 41,969	\$ 48,121
Prepaid expense and other current assets	7,072	6,326
<b>Total current assets</b>	<b>49,041</b>	<b>54,447</b>
Restricted cash	20	20
Property and equipment, net	154	238
Intangibles	46,400	46,400
Goodwill	13,064	13,064
Other assets	349	196
<b>Total Assets</b>	<b>\$ 109,028</b>	<b>\$ 114,365</b>
<b>Liabilities and Stockholders' Deficit</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 1,524	\$ 1,902
Accrued expenses	7,703	6,169
Other current liabilities	481	446
<b>Total current liabilities</b>	<b>9,708</b>	<b>8,517</b>
Contingent consideration	103,200	120,020
Deferred tax liability	12,528	12,528
Other liabilities	145	-
<b>Total Liabilities</b>	<b>125,581</b>	<b>141,065</b>
<b>Commitments and contingencies</b>		
<b>Stockholders' Deficit:</b>		
Preferred stock, \$0.001 par value per share; 5,000,000 shares authorized at September 30, 2020 and December 31, 2019; no shares issued and outstanding at September 30, 2020 and December 31, 2019		
Common stock, \$0.001 par value per share; 200,000,000 shares authorized at September 30, 2020 and December 31, 2019; 123,645,007 and 106,801,409 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	123	107
Additional paid-in capital	284,236	266,717
Accumulated deficit	(300,912)	(293,524)
<b>Total Stockholders' Deficit</b>	<b>(16,553)</b>	<b>(26,700)</b>
<b>Total Liabilities and Stockholders' Deficit</b>	<b>\$ 109,028</b>	<b>\$ 114,365</b>





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3Q 2020 Business Update

November 9, 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 timing and amounts of any payments from Qilu under our license agreement, expectations regarding Qilu's ability to manufacture, develop and commercialize Vicineum in Greater China, expectations regarding potential OUS partnerships, expectations regarding the completion of our BLA filing, expectations regarding the impact of COVID-19 on our business, expectations regarding the timing of our PPQ campaign, expectations regarding the timing of the submission of our MAA for Vicineum™ to the EMA, expectations regarding the timing of potential approval of our MAA submission by the EMA, expectations regarding the timing of potential commercialization of Vicineum, expectations regarding physicians' decisions to prescribe Vicineum, expectations regarding potential revenue opportunities, 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, 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.

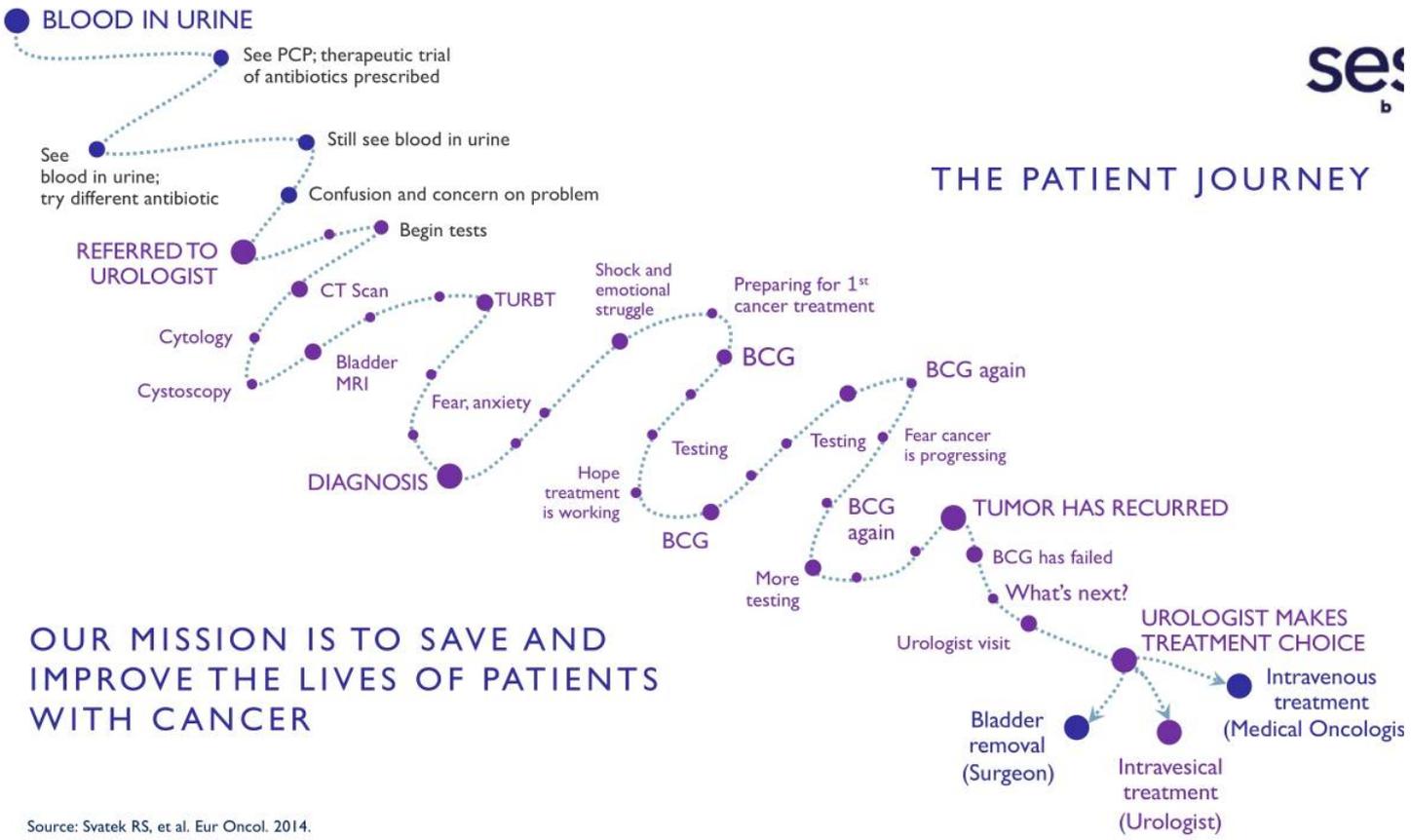
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## NOVEMBER 2020 BUSINESS UPD



1. Differentiated MOA and clinical profile creates opportunity for best-in-class profile for Vicineum
  2. Clear regulatory path forward for potential approval in US in 2021 and Europe in 2022
  3. Significant global commercial opportunity; projected \$1B - \$3B revenue for Vicineum
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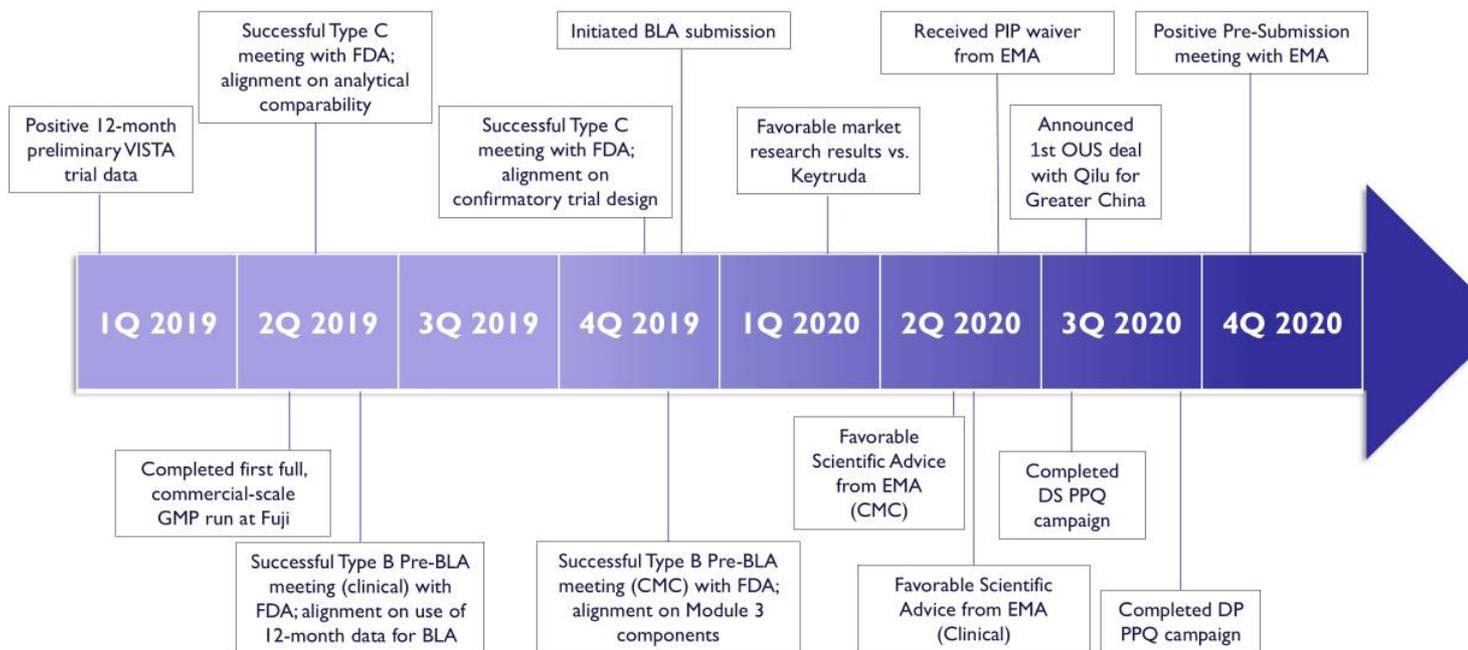
# THE PATIENT JOURNEY



OUR MISSION IS TO SAVE AND IMPROVE THE LIVES OF PATIENTS WITH CANCER

Source: Svatek RS, et al. Eur Oncol. 2014.

# Corporate Highlights: Two Years of Execution Excellence



GMP=Good Manufacturing Practice; FDA=Food and Drug Administration; BLA=Biologic License Application; CMC=Chemistry, manufacturing and controls; EMA=European Medicines Agency; PIP=Paediatric Investigation Plan; DS=Drug Substance; PPQ=Process Performance Qualification; OUS=Outside of the United States; DP=Drug Product

## Vicineum has a Highly Differentiated Clinical Profile



### Efficacy Data

#### 3-month response data

- CIS: 40% complete response rate (CRR)
- 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 (OS) is 98% at 12 months
- 2-year OS is 96% vs. 94% for the general population at 2 years (matched for age/gender)

### Safety Data

#### Intravesical administration

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

#### Clinical experience

- 243 patients exposed to Vicineum 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.  
For additional information regarding Phase III clinical trial data please refer to slides 43-63.

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

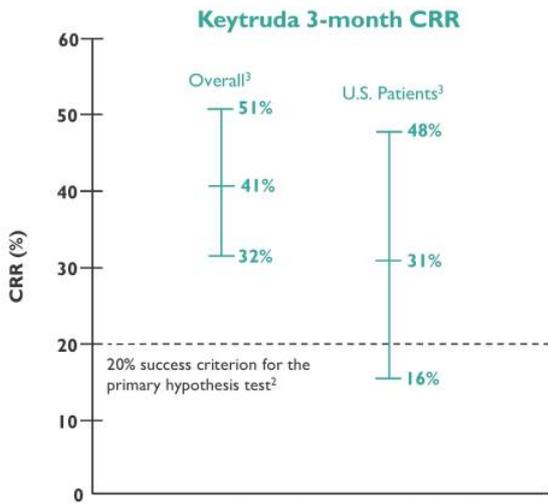
2018 FDA Guidance

Vicineum Clinical Program

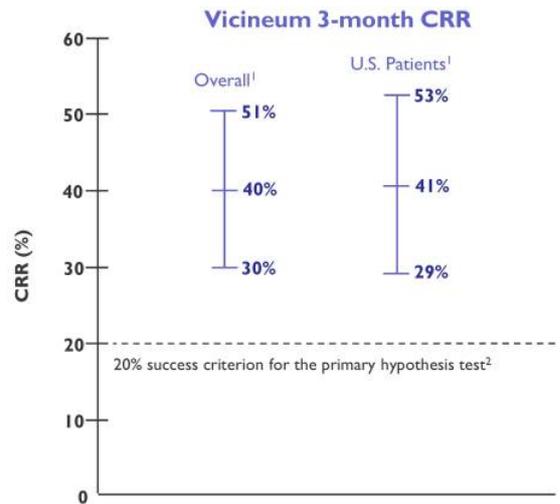
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|---|---|
| • Conduct nonclinical studies to assess toxicity in animal models                     | ✓ |
| • Conduct nonclinical studies to demonstrate anti-tumor activity                      | ✓ |
| • Conduct nonclinical studies to determine optimal 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 administration                                     | ✓ |
| • 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.

Vicineum confidence interval above FDA success criteria based upon complete response of other agents in patients with Carcinoma in situ



<sup>3</sup>Advisory Committee Briefing Document and presentation slides for pembrolizumab for NMIBC (PEMBROLIZUMAB-P057V01MK3475), December 17, 2019.

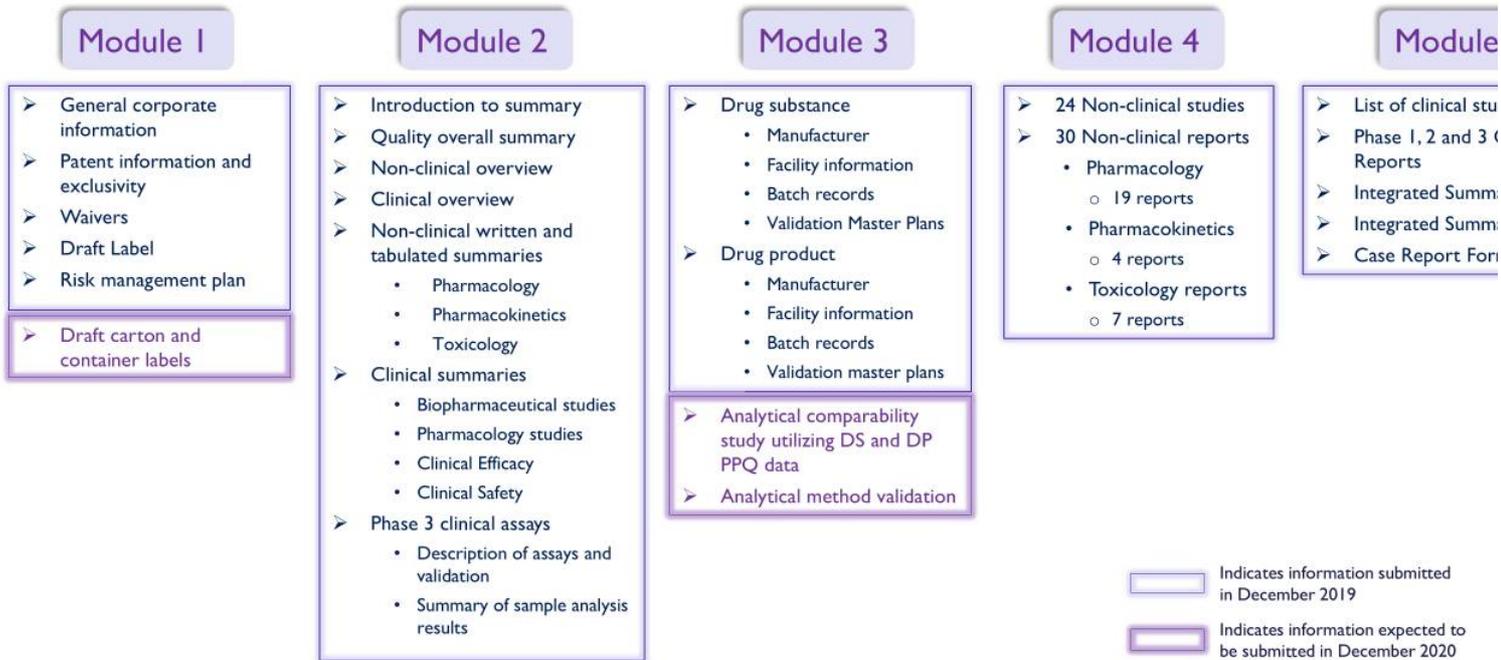


<sup>1</sup>Data are as of May 29, 2019 data cut from the Phase III VISTA trial

<sup>2</sup>To demonstrate a clinically meaningful response, per ODAC panel discussion on Dec. 17, 2019, and based on a meta-analysis of commonly used chemotherapy agents and the 18% CRR of Valstar.

Please use caution when drawing comparisons across different clinical trials

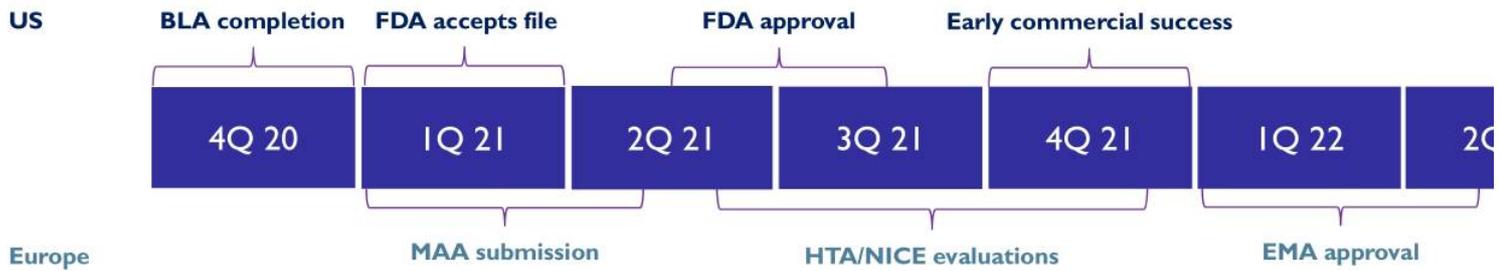
# Positive progress in CMC comparability enables anticipated completion of BLA in December 2020



# Forward-looking Timeline for Vicineum



Positive progress in the US and Europe enables a clear regulatory path forward with the following anticipated milestones:



BLA=Biologics License Application; MAA=Marketing Authorization Application; HTA=Health Technology Assessment; NICE=National Institute for Clinical Excellence

## Completion of Vicineum BLA submission anticipated in December 2020



### 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.

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## Large Global Commercial Opportunity



Substantial US opportunity and OUS potential of roughly two times the US

- Projected peak revenue opportunity of \$1B - \$3B

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

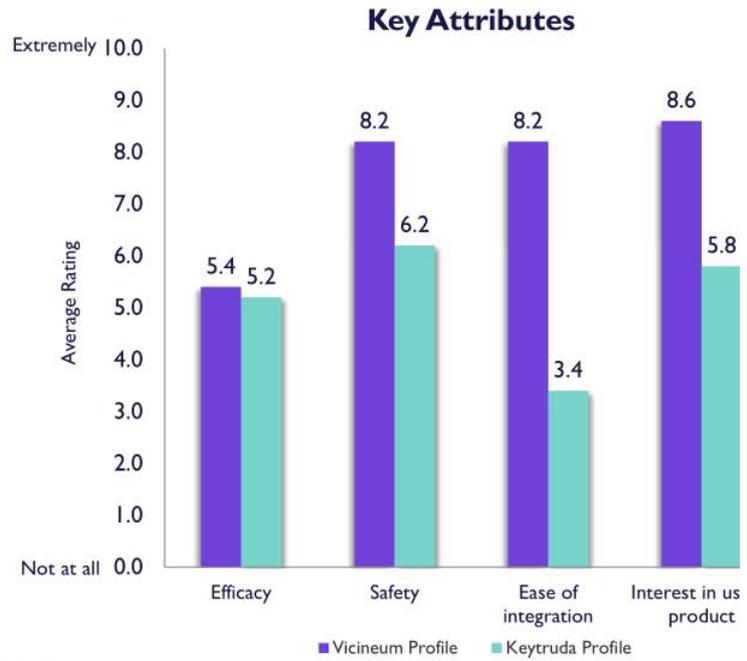
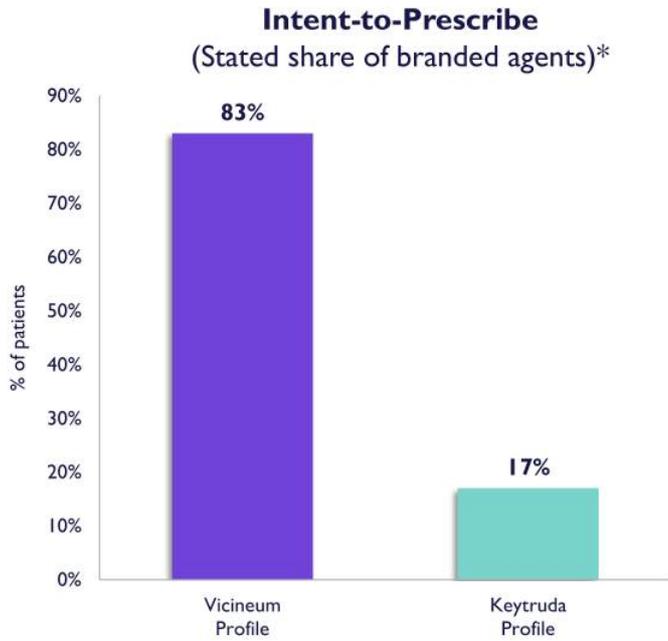
- Estimated 40-50 sales representatives required
- Allows for efficient digital/social strategies to activate patients/caregivers

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

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# 2020 Market Research Results

## High Prescribing Urologists Prefer Vicineum Profile



Source: Emerging treatment in-depth interviews (IDIs) with high BCG-treating Urologists, IQ 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

# NMIBC Therapeutics Have Been Plagued by Manufacturing Issues



## No clear near-term resolution of the BCG shortage or the CMC issues for Adstiladrin

Valstar was pulled from the market in 2002 due to impurities in the formulation. FDA approval to re-introduce Valstar to the market was not received until 2009

Merck is constructing a new facility that may expand BCG production. Anticipated completion in 2021



Sources and Additional Information:

Valera Pharmaceuticals IOK 2006. Wall Street Journal. *Sanofi to Stop Production of Bladder Cancer Drug BCG*. Peter Loftus, 2016. <https://www.aunet.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](https://www.who.int/news-room/commentaries/detail/bacille-calmette-gu%C3%A9rin-(bcg)-vaccination-and-covid-19). <https://fergene.com/media/fergene-provides-update-on-bla-for-nadofaragene-firadenovec/>. <https://www.merck.com/news/merck-announces-plans-to-construct-new-facility-in-the-united-states-to-expand-manufacturing-capacity-for-tice-bcg/>.

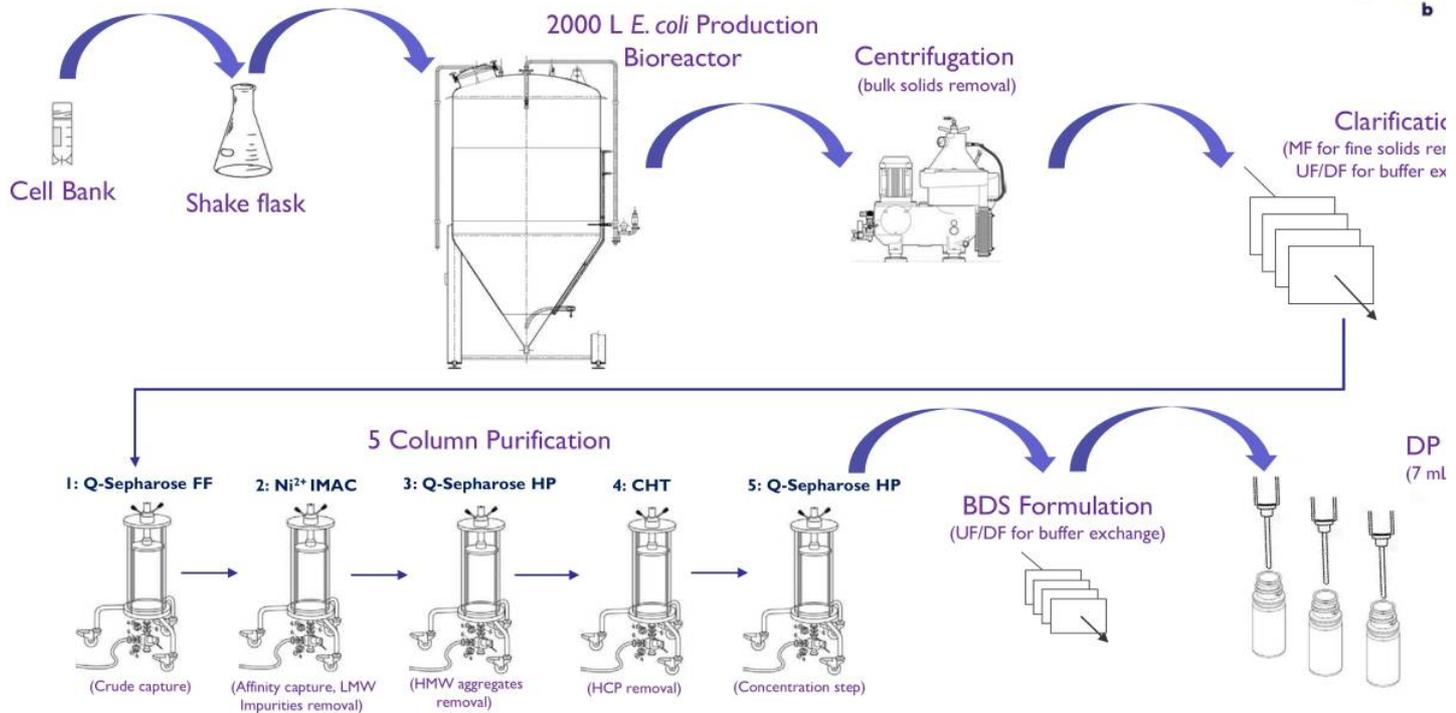
# Vicineum End-to-End Supply Chain



World-class manufacturing and distribution capabilities ensure execution excellence



# Highly Reliable Manufacturing Process for Vicineum



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.

## Positive US and European Regulatory CMC Feedback



**Our analytical comparability plan is aligned with global standards issued by the ICH and feedback from the FDA and EMA**

### FDA Feedback

May 2019 Type C and December 2019 Type B pre-BLA meeting: FDA Accepts Analytical Comparability Plan

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

### EMA Feedback

May 2020: CHMP Issues CMC Advice for Vicineum

- CHMP agreed that the CMC comparability plan provides a strong analytical package, and no additional clinical trials to establish comparability are deemed necessary at this time
- CHMP agreed to accept the GMP inspections conducted by the FDA

ICH=The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use; CHMP=Committee for Medicinal Products for Human Use

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# Commercial Manufacturing Strategy Based on Demonstrating Comparability



We aligned with the FDA on assessing analytical comparability in support of approval for commercial manufacturing at our CMOs

	Clinical Supply	Commercial Supply
<b>Drug Substance</b>	Sesen	FUJIFILM Diosynth Biotechnologies (CMO)
<b>Drug Product</b>	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 Vicineum
  2. Biophysical Characterization
    - Assesses the structural characteristics of Vicineum
  3. Forced Degradation Studies
    - Assesses the degradation pathway of Vicineum when exposed to stress conditions
  4. Stability Studies
    - Assesses the stability of Vicineum at accelerated and long-term storage temperatures
-

## Meaningful Progress on Demonstrating Comparability



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

Test	Sesen	FUJIFILM Diosynth Biotechnologies		
	Phase III	PPQ1	PPQ2	PPQ3
Appearance	✓	✓	✓	✓
pH	✓	✓	✓	✓
Identity	✓	✓	✓	✓
Concentration	✓	✓	✓	✓
Polysorbate 80	✓	✓	✓	✓
Purity	✓	✓	✓	✓
Charge Variants	✓	✓	✓	✓
Potency	✓	✓	✓	✓
Binding	✓	✓	✓	✓
Host Cell Protein	✓	✓	✓	✓
Residual DNA	✓	✓	✓	✓
Endotoxin	✓	✓	✓	✓

✓ Indicates acceptance criteria met for batches used in clinical trials (Sesen) or technology transfer (FUJIFILM Diosynth Biotechnologies)

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## Extensive Biophysical Characterization Supports Comparability



### Structural characteristics of biologics impart biological function

Test	Sesen (Phase III Average)	FUJIFILM Diosynth Biotechnologies (PPQ Average)	Highly Comparable
Analytical Ultracentrifugation (S-value)	4.25	4.24	✓
Circular Dichroism (Near UV emission maxima)	272.9 nm 281.7 nm 289.4 nm	272.5 nm 281.5 nm 289.3 nm	✓
Differential Scanning Calorimetry (Thermal Transition Temperature)	Tm1 39.7°C Tm2 42.1°C Tm3 51.4°C	Tm1 39.6°C Tm 2 41.8°C Tm3 51.4°C	✓
Fourier-transform infrared spectroscopy	α-helix: 13.3% β-sheet: 41.8%	α-helix: 13.5% β-sheet: 41.7%	✓
Free Sulfhydryl Analysis	None detected	None detected	✓
Intact Mass (Native Mass)	69555.8 Da (Native) 69564.5 Da (Reduced)	69555.5 Da (Native) 69565.3 (Reduced)	✓
Intrinsic Tryptophan Fluorescence (Emission Maxima)	345 nm (Native) 357 nm (Denatured)	344 nm (Native) 356 nm (Denatured)	✓
Peptide Mapping	100% match to theoretical sequence	100% match to theoretical sequence	✓
SEC-MALS (Monomer molecular weight)	70.4 kDa	70.0 kDa	✓

\*Data shown is a representative sampling of all available biophysical characterization data.

Averages reflect three clinical lots used in the Phase 3 trial manufactured by Sesen vs. the three PPQ lots manufactured by Fuji.

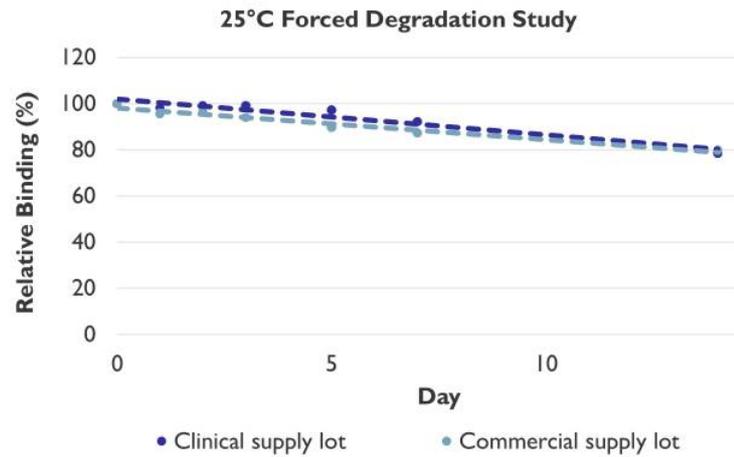
## Forced Degradation Studies in Support of Comparability



**Clinical and commercial material display highly similar degradation profiles, providing strong support for comparability**

The Comparability plan includes:

1. High temperature (25°C)
2. pH 7.5 and pH 10
3. Oxidative stress
4. Freeze-thaw stress
5. Photostability



Normalized to T = 0 of 100% for ANCOVA analysis, P = 0.47

P > 0.05 = The rate of change between the two processes is not significantly c

ANCOVA=Analysis of covariance. The analysis combines the methods used in ANOVA with linear regression on a number of different levels.

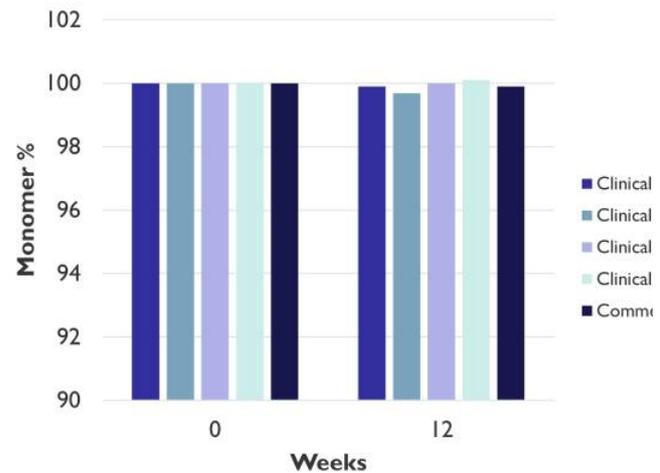
## Long-term Stability in Support of Comparability



**Based on available stability data, clinical and commercial material display comparable stability profiles at -20°C, providing strong support for comparability and justification for a robust commercial shelf**

At our CMC pre-BLA meeting, we reached agreement with the FDA:

1. To submit stability data throughout the BLA review period
2. That if analytical comparability is demonstrated, the stability data from clinical lots can be leveraged



Normalized to T = 0 of 100% for ANCOVA analysis, P = 0.8423  
P > 0.05 = The rate of change between the two processes is not significantly different

## Key Activities to Complete Module 3



Finalize the statistical analysis of in-process and release testing data from the PPQ campaigns

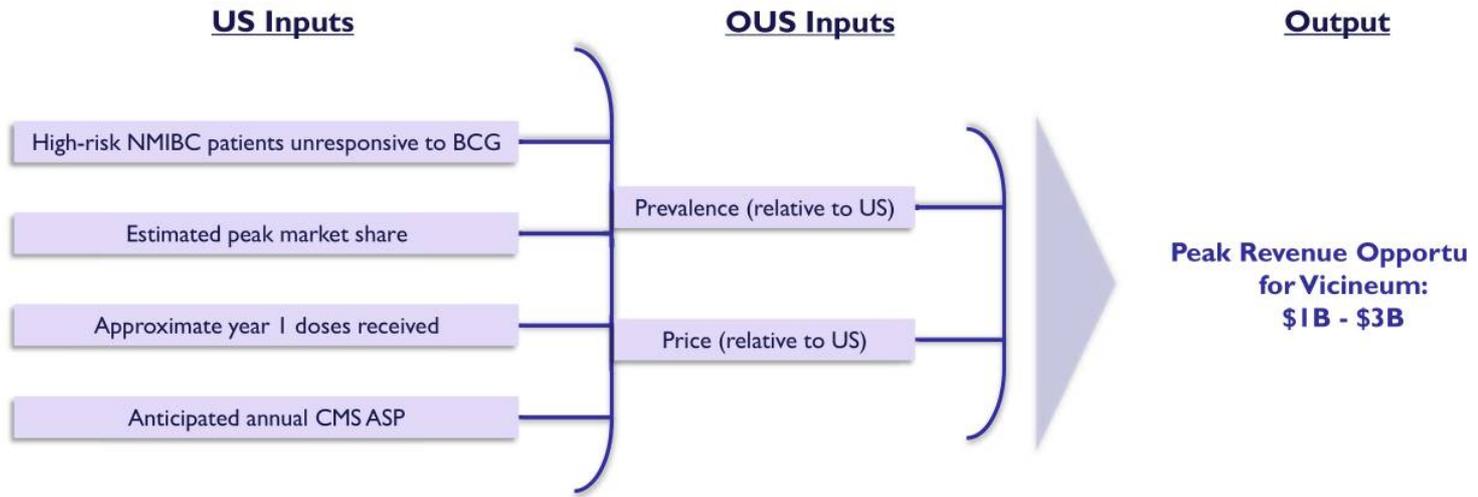
Finalize the writing of all validation documents required for Module 3

Perform quality control review of Module 3 and publish into FDA submission format

**We anticipate Module 3 will be submitted to the FDA in December 2020**

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# Forecast Simulation Model Key Assumptions US and OUS



CMS=Centers for Medicare and Medicaid Services; ASP=Average Selling Price  
For detailed model assumptions please refer to backup slides 79-80

We estimate the OUS opportunity for Vicineum is roughly double the US



Geography	Peak Revenue Opportunity for Vicineum (captures 80% of variance)
Europe	\$450M - \$1,125M
US	\$423M - \$942M
China	\$155M - \$418M
MENA	\$158M - \$420M
Rest of Asia (incl. Japan)	\$109M - \$282M
Latin America	\$51M - \$150M
Canada	\$28M - \$81M
Oceania*	\$17M - \$53M

\*Australia, New Zealand, Melanesia, Micronesia, Polynesia

Note: The peak sales ranges above were calculated using a Monte Carlo revenue simulation model; using the inputs listed on backup slides 79-80, the model calculated a range of alternative futures and possibilities. Peak sales presented capture 80% of uncertainty (10th-90th percentiles)

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## 3Q 2020 Financial Highlights



### 3Q 2020 Net Proceeds

Qilu upfront	\$10.0M
ATM	\$ 8.2M
<b>Total</b>	<b>\$18.2M</b>

### \$14M Cash Used in Operations in 3Q

- Tech transfer/manufacturing scale-up
- Regulatory support of BLA in US
- Regulatory support of MAA in Europe

### \$42M in cash and cash equivalents

- No outstanding debt

### ATM Utilization

1Q 2020	\$3.2M
2Q 2020	\$4.8M
3Q 2020	\$8.2M

**\$58.5M available on ATM facility**

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## 3Q 2020 Flux Analysis

Strengthening the Balance Sheet while Minimizing Dilution



	<u>June 30</u>	<u>Sept 30</u>	<u>Change</u>
Cash and cash equivalents	\$38M	\$42M	+10%
Shares outstanding	117M	124M	+6%
Market cap	\$84M	\$173M	+106%

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## SESEN BIO HIGHLIGHTS

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1. Differentiated MOA and clinical profile creates opportunity for best-in-class profile for Vicineum
  2. Clear regulatory path forward for potential approval in US in 2021 and Europe in 2022
  3. Significant global commercial opportunity; projected \$1B - \$3B revenue for Vicineum
-



sesen

b i o

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THANK YOU



# 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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For Investor Purposes Only

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**Appendix**

## **Unmet Medical Need**

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## Significant Unmet Medical Need in NMIBC

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b

~440,000

new cases each year globally<sup>1</sup>

**BCG  
SHORTAGE**

is complicating patient care

Bladder cancer is the 6<sup>th</sup> 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 2020<sup>4</sup>

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 shortage<sup>5</sup>

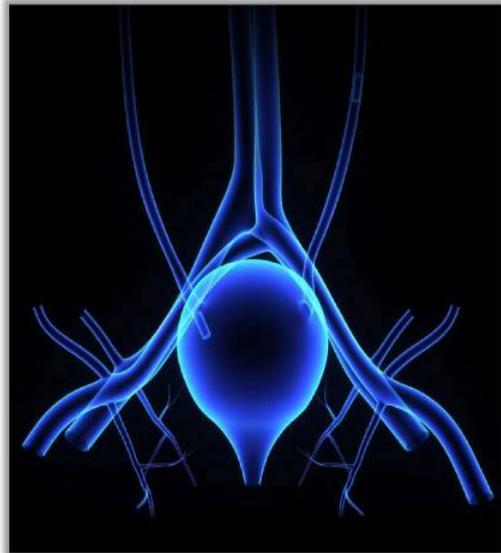
<sup>1</sup>Bray F et al. CA Cancer J Clin, 2018. <sup>2</sup>Anastasiadis et al. Therapeutic Advances in Urology, 2012. <sup>3</sup>Siegel et al. CA Cancer J Clin, 2019. <sup>4</sup>Svatek RS, et al. Eur Oncol. 2014. <sup>5</sup>Office of National Statistics, Aug 2019 Report.

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

ses  
b

### 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 Surgery

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

**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.

## There is a Significant Unmet Need in China



### Bladder Cancer is the 13<sup>th</sup> Most Common Cancer in China<sup>1</sup>

- 1.6-1.7 times the incidence vs. the US<sup>2</sup>
- Case fatality rate is 41% vs. 22.5% in the US<sup>3</sup>

### China has Increasing Diagnosis Rates with Limited Treatment Options

- Diagnosis and treatment rate expected to increase from 85% in 2020 to 92% in 2028<sup>4</sup>
- Chemotherapy treatment is common with high recurrence rates<sup>4</sup>

### >300M Adult Smokers in China<sup>5</sup>

- Largest smoking population in the world
- Smoking is the most important risk factor for bladder cancer

### Improving Reimbursement and Pricing

- Updated provincial pricing and reimbursement policies have been set to improve patient access to innovative therapies in China<sup>6</sup>

Sources: <sup>1</sup>Cancer Statistics in China. American Cancer Society. 2015. <sup>2</sup>ClearView analysis. 2019. <sup>3</sup>GLOBOCAN/IARC. 2018. <sup>4</sup>Qilu business case presentation. April 2020. <sup>5</sup>Transl Lung Cancer Res. Tobacco and the lung cancer epidemic in China. NIH. May 2019. <sup>6</sup>Better Market Access in China – Government Improves Pricing and Reimbursement Environment. April 2019.

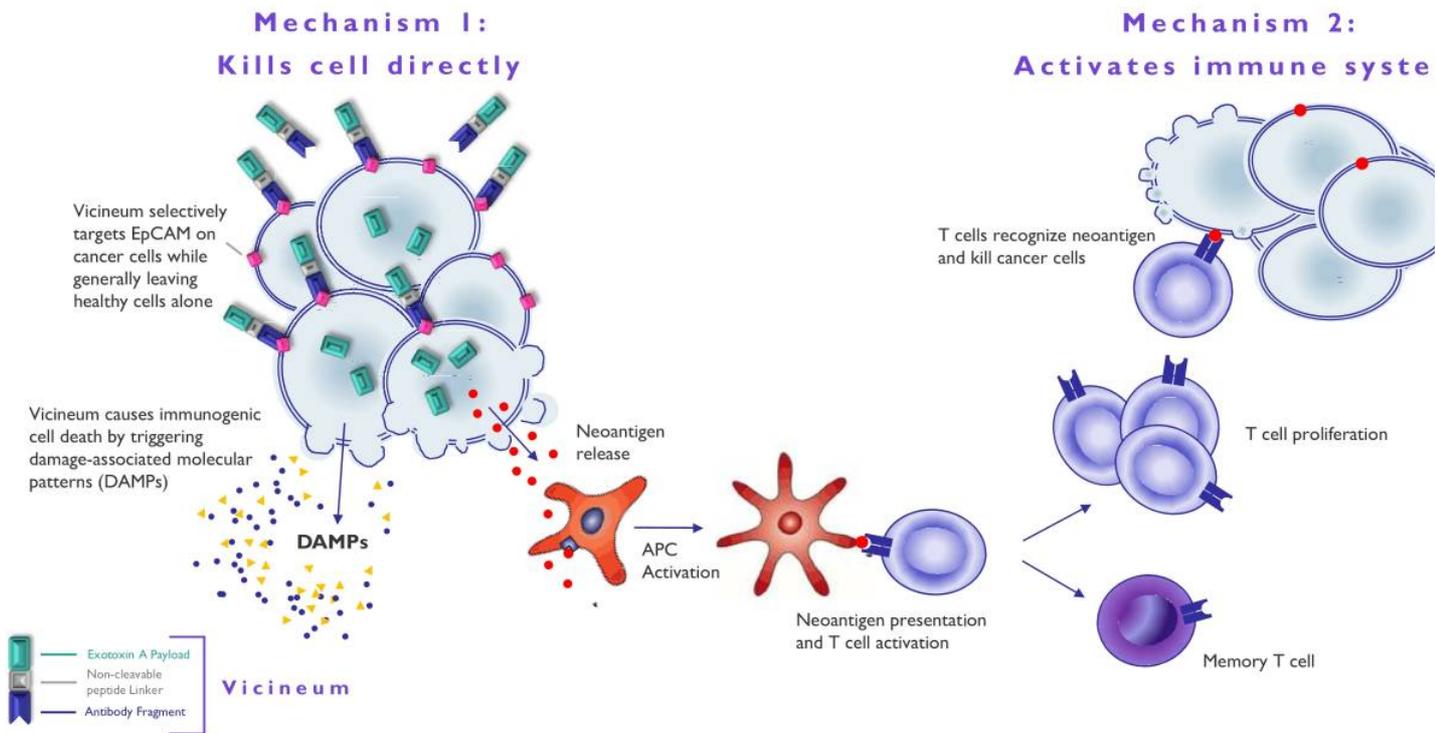
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**Appendix**

## **Dual Mechanism of Action**

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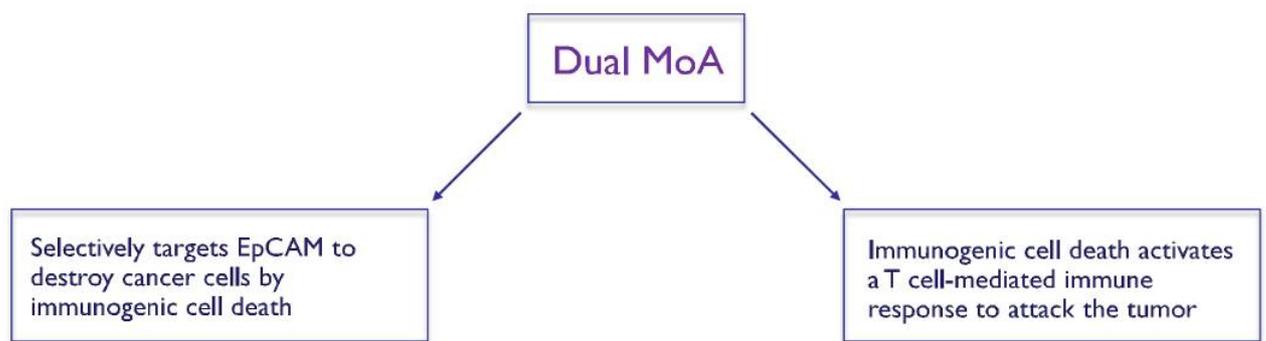
# Vicineum has a Highly Differentiated Mechanism of Action



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

## Vicineum 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 Vicineum works via a dual mechanism of action.

---

## Pre-clinical and Phase I Trial in SCCHN shows evidence of activation of patients' immune systems

### Pre-Clinical Evidence

- Immunogenic Cell Death (ICD)
  - Promotes a pro-inflammatory environment and drives anti-cancer T cell responses
  - ICD is associated with Damage Associated Molecular Patterns (DAMPs) including calreticulin expression, active ATP release and passive release of high mobility group box 1 protein (HMGB1)
  - Vicineum killing of cancer cells induces the expression of these key DAMPs
- In a mouse model, local Vicineum treatment of a tumor induced an immune response that, combined with a checkpoint inhibitor, slowed the growth of a 2<sup>nd</sup> non-injected tumor

Reviewed in Vandenabeele, p et al, Adv. Exp Medical Biology 930:133-49 2016  
Presented at AACR, 2017

### Clinical Evidence

(as seen in Phase I)

Pre-treatment      After 4wks treatment

PATIENT A:



PATIENT B:



**Appendix**

# **Regulatory**

## 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 Vicineum under Rolling Review**

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## Positive Interactions with EMA on Regulatory Pathway for Vicineum



### May 7, 2020 CHMP clinical advice for Vicineum:

- The nonclinical and clinical pharmacology studies, and safety database are all sufficient to support a MAA submission for Vicineum and no additional clinical trials were requested
- There is an unmet need for BCG-unresponsive NMIBC patients, especially for patients who are contraindicated to cystectomy
- CHMP provided Sesen Bio with additional clarity on how to structure data in the MAA submission

### May 29, 2020 CHMP CMC advice for Vicineum:

- Analytic comparability aligned to global standards issued by the ICH
- CHMP agreed that the CMC comparability plan provides a strong analytical package, and no additional clinical trials to establish comparability are deemed necessary at this time
- CHMP agreed to accept the GMP inspections conducted by the FDA

**Based on the guidance received, we expect to submit the MAA for Vicineum to the EMA in early 2022 with potential approval anticipated in early 2022**

CHMP = Committee for Medicinal Products for Human Use

EMA = European Medicines Agency

MAA = marketing authorization application

ICH = International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

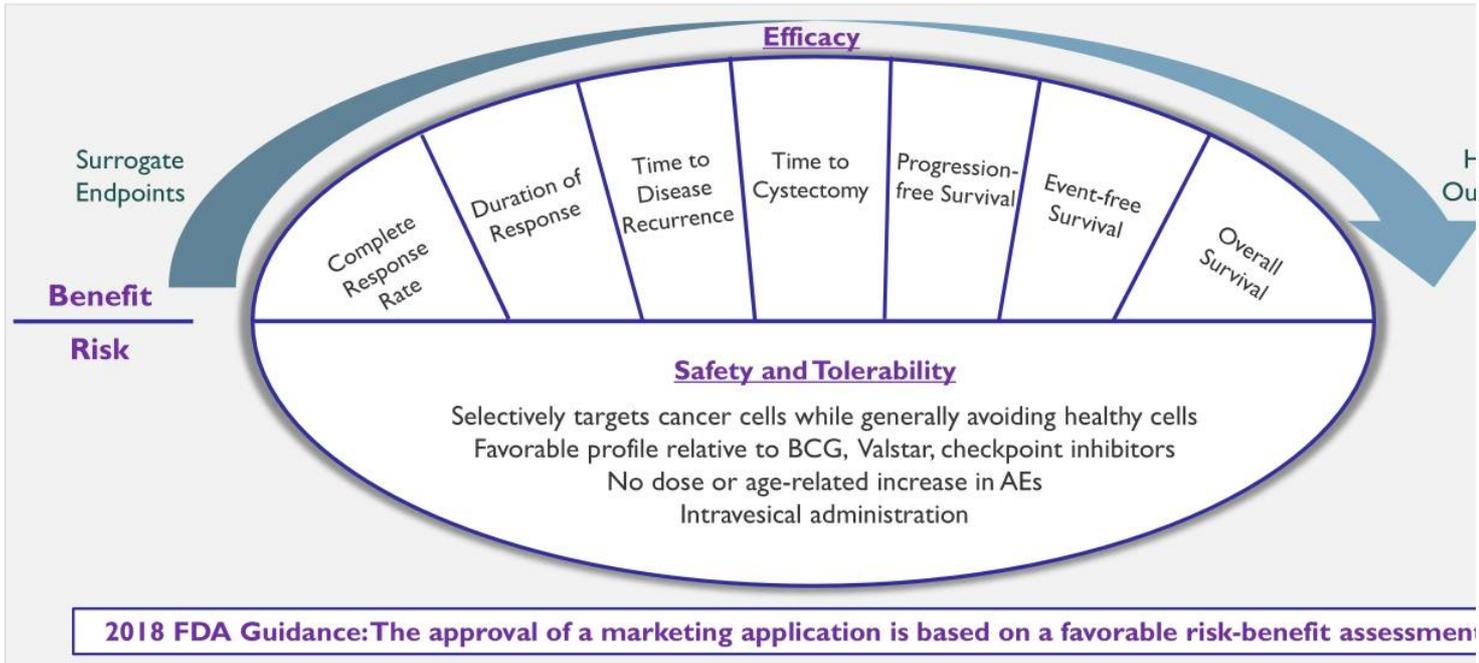
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**Appendix**

## **Clinical Data**

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# Vicineum 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.

## 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 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)	74	68	74
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

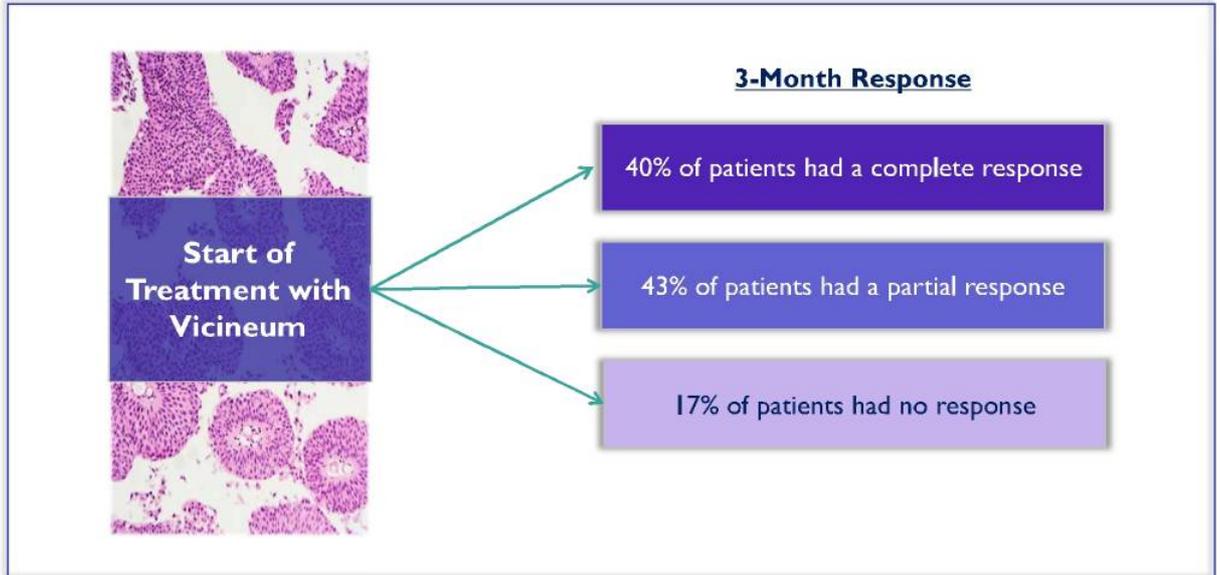
# Compelling Clinical Data Set



Endpoint	How Endpoint is Measured	Results
<b>Complete Response Rate (CRR)</b> 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"> <li>40% CRR at 3 months</li> <li>Lower bound of 95% CI rules out clinically unmeaningful CRR</li> <li>Higher complete response rate in patients receiving less BCG</li> </ul>
<b>Duration of Response (DoR)</b> Primary Endpoint CIS patients	Defined as the time from complete response to treatment failure.	<ul style="list-style-type: none"> <li>52% duration of 9 months (12 months of therapy)</li> <li>39% duration of 15 months or greater (18 months of therapy)</li> <li>The longer the CR, the higher the probability of remaining disease-free</li> </ul>
<b>Time to Disease Recurrence</b> 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"> <li>Median time to recurrence is 402 days</li> <li>50% probability of remaining recurrence-free for 12 months</li> <li>37% probability of remaining recurrence-free for 24 months or greater</li> </ul>
<b>Time to Cystectomy (TtC)</b> 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"> <li>76% of patients are cystectomy-free for 3 years</li> <li>Responders have an 88% probability of remaining cystectomy-free at 3 years</li> <li>Average responder remains cystectomy-free for 1,035 days vs. 631 days non-responders</li> </ul>
<b>Progression-Free Survival (PFS)</b> 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"> <li>96% of patients are progression-free at 12 months</li> <li>90% of patients are progression-free for 24 months or greater</li> <li>Median PFS has not been reached</li> </ul>
<b>Event-Free Survival (EFS)</b> 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"> <li>29% of patients are event-free at 12 months</li> <li>22% of patients remain event-free at 18 months</li> <li>21% of patients remain event-free for 24 months or greater</li> </ul>
<b>Overall Survival (OS)</b> 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"> <li>Overall survival is 98% at 12 months</li> <li>Overall survival is 96% for 24 months or greater vs. 94% for general population at 2 years</li> </ul>
<b>Safety</b> Secondary Endpoint All Cohorts	Full review of all safety data from Phase III	<ul style="list-style-type: none"> <li>2% treatment-related SAEs</li> <li>4% treatment-related Grade 3-5 AEs</li> <li>Increased dosing in Phase III did not increase severity or frequency of AEs</li> </ul>
<b>Tolerability</b> Secondary Endpoint All Cohorts	Full review of all tolerability data from Phase III	<ul style="list-style-type: none"> <li>AEs generally low grade</li> <li>Low rate of discontinuations for AEs</li> <li>No age-related increase in AEs</li> </ul>

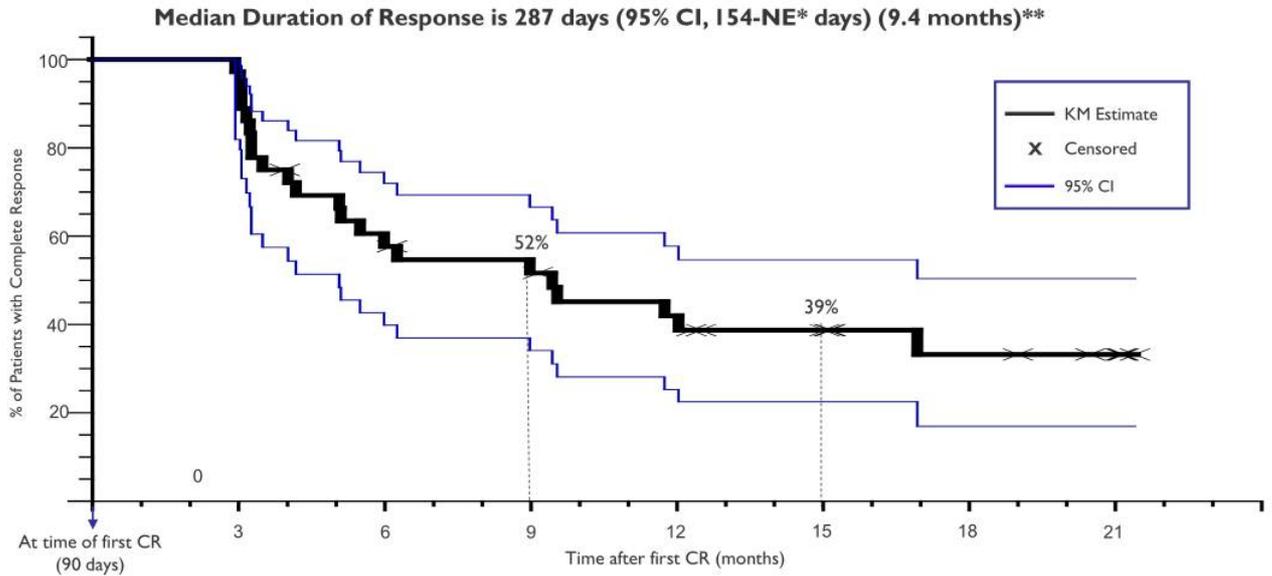
Note: Data are as of May 29, 2019 data cut

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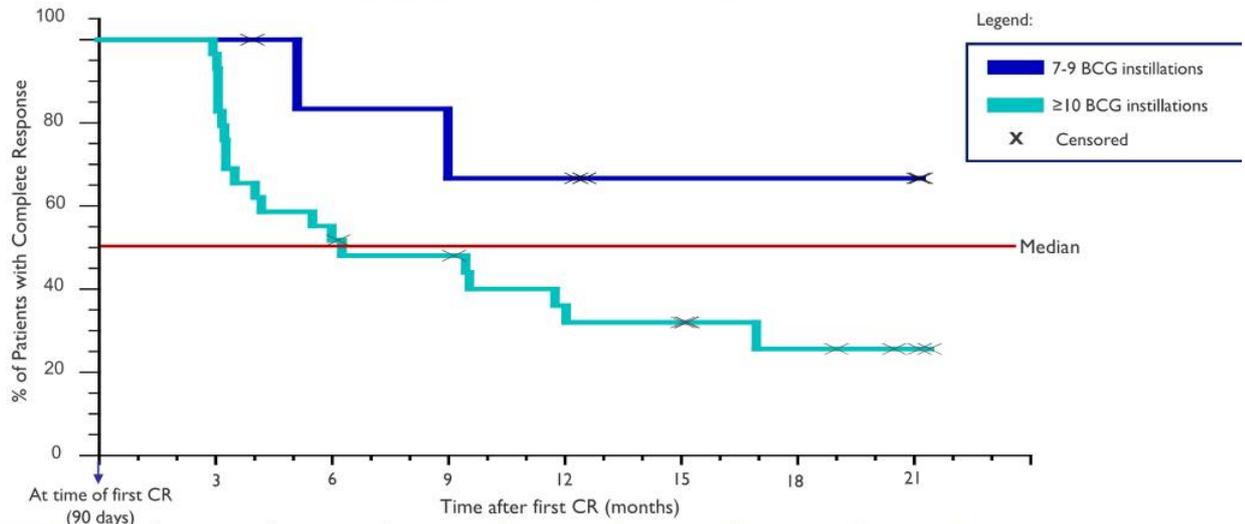
Duration of response: defined as the time of complete response to treatment failure.

\*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 (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:** Vicineum is generally more efficacious in CIS patients treated with less BCG

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



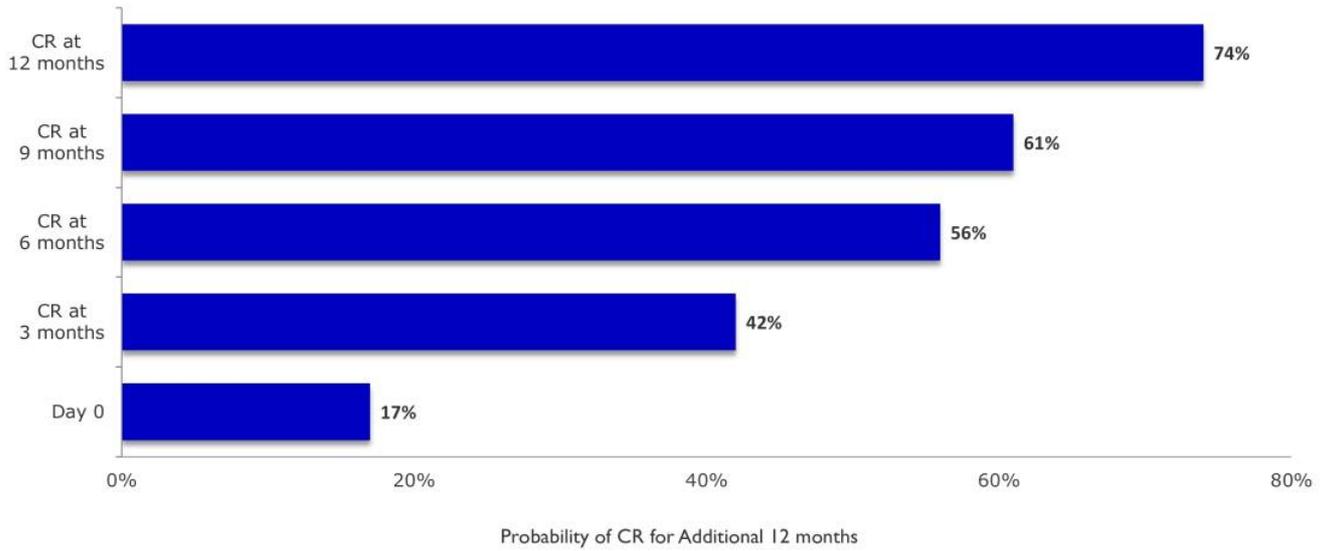
KM Evaluable Patients	7	7	5	4	4	2	2	2
7 - 9 BCG Instillations:	7	7	5	4	4	2	2	2
≥10 BCG Instillations:	29	28	15	13	9	8	4	2

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.

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

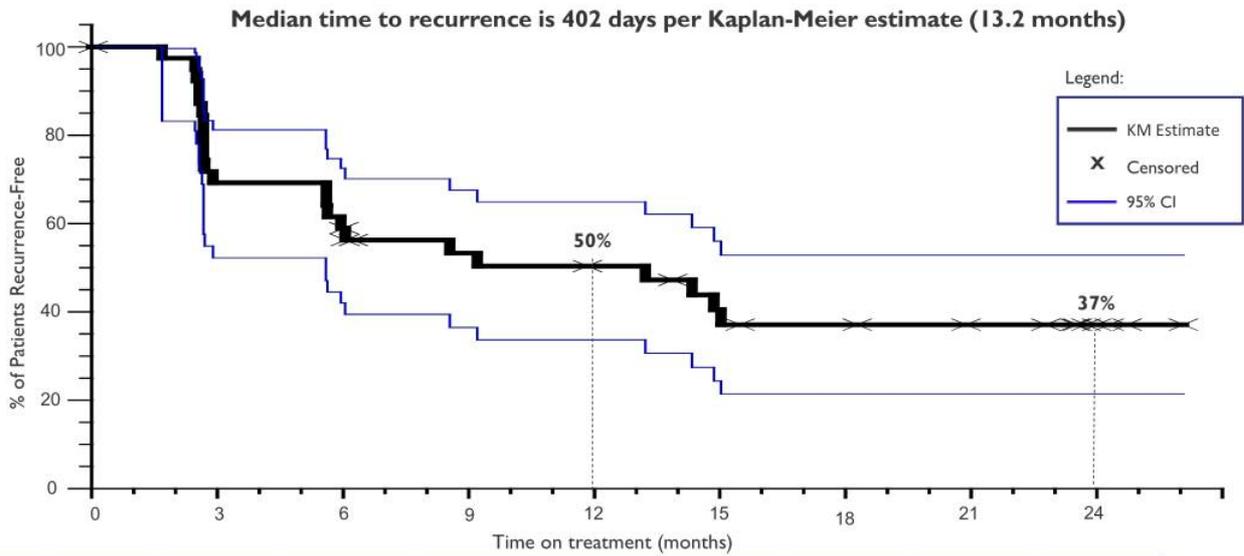


Probability of Maintaining Complete Response (CR) for at Least One Additional Year\*



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.

**Time to Disease Recurrence:** Time to Disease-Recurrence: 50% of high-risk papillary patients who were treated with Vicineum are disease-free at 1 year



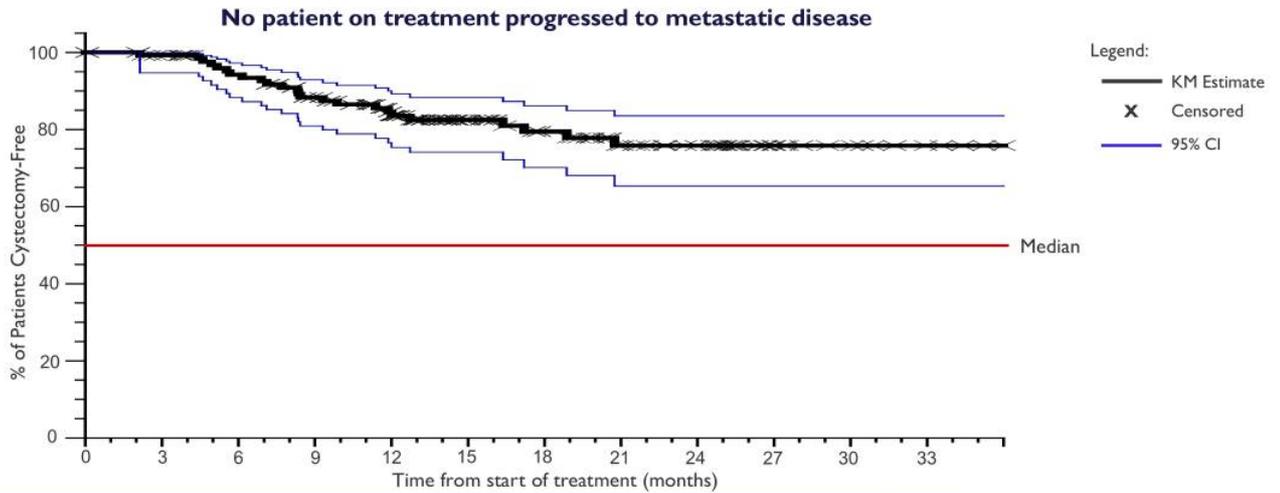
KM Evaluable Patients:	40	27	23	18	16	12	10	8	4
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2018 FDA Guidance: Sponsors can include patients with completely resected lesions and no evidence of CIS in these single-arm trials but should not include them in the evaluation of the primary efficacy 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 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.

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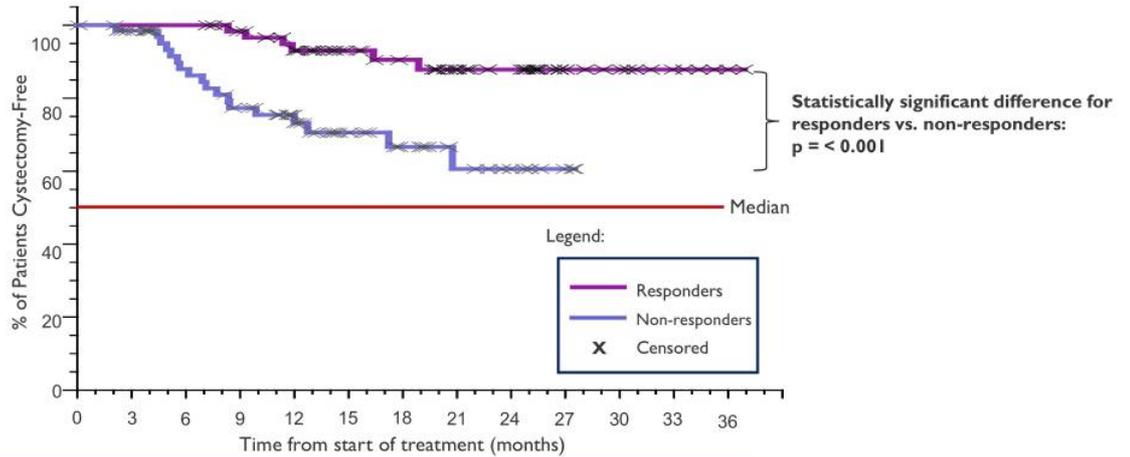
### 2018 FDA Guidance: The goal of therapy in patients with BCG-unresponsive NMIBC is to avoid cystectomy

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.)  
 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).

## Overall Survival



**1- and 2-year survival rates of patients on trial are comparable to those of the general population of similar age and gender demographics (predominantly male in their 70s)**

	Survival Estimates	
	Patients on VISTA Trial	General Population <sup>1</sup>
1 year	98%	97%
2 years	96%	94%

<sup>1</sup>U.S. Social Security Administration Actuarial Life Table (<https://www.ssa.gov/oact/STATS/table4c6.htm>). Based on probability of dying within one year and weighted to match VISTA trial population demogra

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## Additional Vincium 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, followed 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

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



Recurrence-free (RF) 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

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## 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<sup>1</sup>, grade 3 acute kidney injury<sup>2</sup>, 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%)

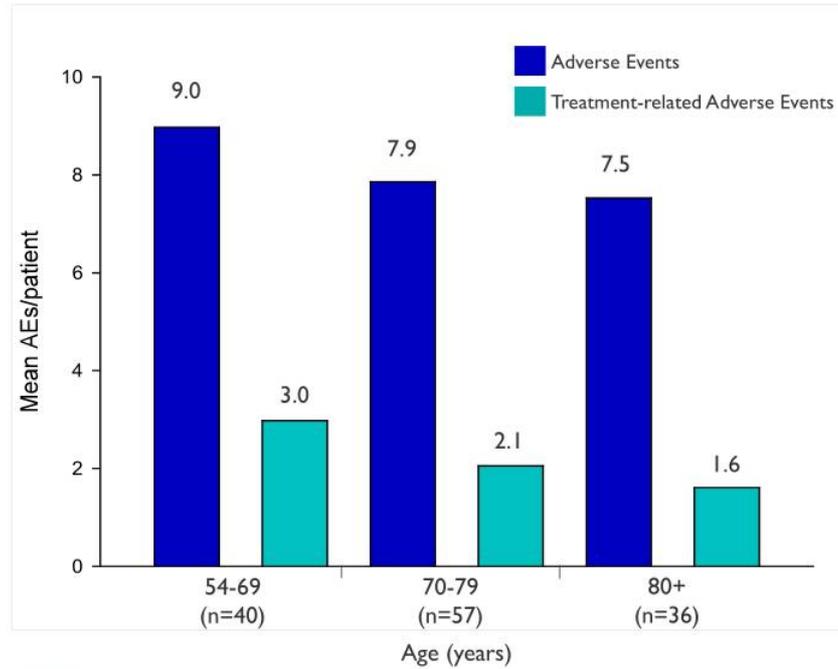
### Vicineum Treatment Exposure:

Average Instillations per Patient	12	27
Average Duration of Exposure (days)	147	240

<sup>1</sup>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. <sup>2</sup>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 (n=133).  
Mean AEs for all patients: 8.1 (range 0-54), Mean treatment-related AEs for all patients: 2.2 (range 0-51).

## High-Level Overview of Planned Confirmatory Trial



Successful in alignment with the FDA on the design of the post-marketing confirmatory trial for Vicineum

### Key Elements

The confirmatory trial will enroll BCG-refractory patients who received less-than-adequate BCG\*

- This represents a broader patient population than the originally proposed BCG-intolerant population
- If the trial is successful, labeling is expected to be expanded to include this additional patient population

The trial is expected to be powered to demonstrate the superior efficacy of Vicineum vs. currently utilized therapies

- Primary endpoints expected to include complete response rate and duration of response
- Secondary endpoints expected to include quality of life, survival and safety assessments, as well as an evaluation of delayed complete response\*\*
- These data are expected to contribute to favorable reimbursement discussions worldwide

\* Adequate BCG is defined by the FDA as at least 5 doses in an initial induction course, plus at least 2 doses in a second course

\*\* In post-hoc analyses requested by the FDA, Vicineum was shown to demonstrate a delayed CR in some patients who were non-CR at 3 months

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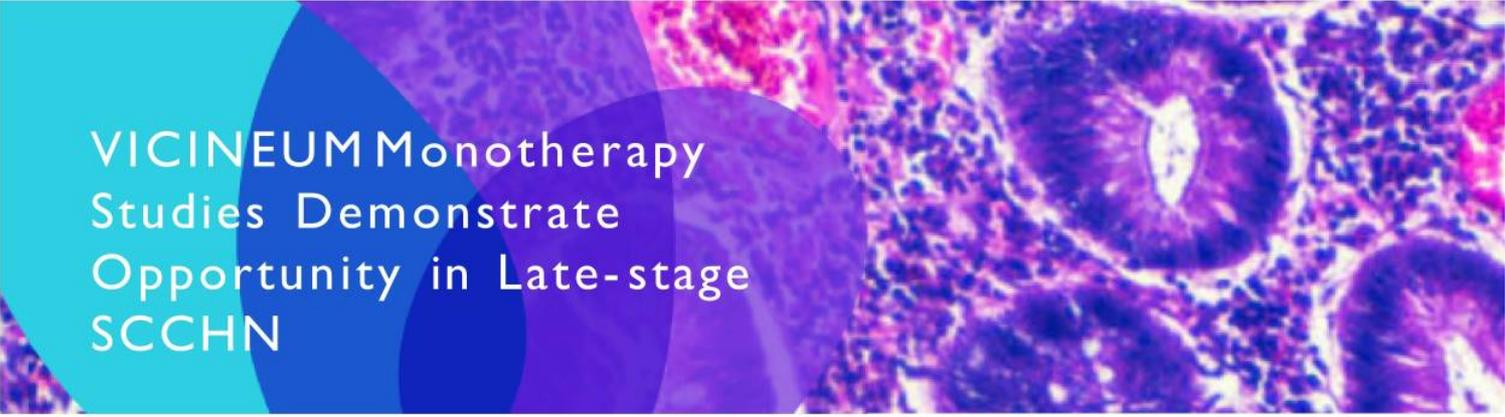
## HEAD AND NECK CANCER: Difficult-to-Treat & Dominated by Primary Tumors

- Head and neck cancers affects >650,000 people worldwide; ~350,000 deaths each year
- 90% are squamous cell carcinomas of the head and neck (SCCHN)<sup>1</sup>
  - Two-thirds diagnosed with advanced disease and severe prognosis
- High risk of recurrence and frequent metastases and development of second primary tumors
- Low rate (~50%) of 5-year survival and limited benefit with combo chemotherapy<sup>2</sup>
- Surgery remains SOC - highly invasive and associated with significant morbidity<sup>2</sup>
- Recurrent SCCHN after multimodal local treatment generally considered incurable
- Two checkpoint inhibitors currently approved for treatment of SCCHN<sup>3,4</sup>

<sup>1</sup> Heroiu et al. *Maedica*, 2013; 8(1), 80-85 <sup>2</sup>Machiels, J. *F1000Prime Rep.* 2014.

<sup>3</sup>OPDIVO (nivolumab) prescribing information <sup>4</sup>KEYTRUDA® (pembrolizumab) prescribing information

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## VICINEUM Monotherapy Studies Demonstrate Opportunity in Late-stage SCCHN

### PHASE I TRIALS ASSESSING DAILY AND WEEKLY DOSES SUGGEST IMMUNE DRIVEN RESPONSE

- Anti-tumor activity of 43% on daily dose; 62% on weekly dose
- Observed regression or complete resolution of non-injected tumors
- 207 days mean overall survival for EpCAM-positive patients vs. 125 days for EpCAM-negative patients
- Generally well-tolerated

### COMPLETED U. S. PHASE 2 TRIAL

- Weekly administration of 500  $\mu$ g or 700  $\mu$ g via intratumoral injection; 700  $\mu$ g established as RP2C
  - Well-tolerated; pain at injection site reported as most common AE
  - Reduction in bi-directional size of principle target tumor observed in 71% (10/14) of evaluable patients
    - RECIST criteria not employed
  - Growth control of initial treated tumor achieved in 100% of five patients with multiple tumors, leading to treatment of additional tumors
-

## Pipeline of Targeted Therapies



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

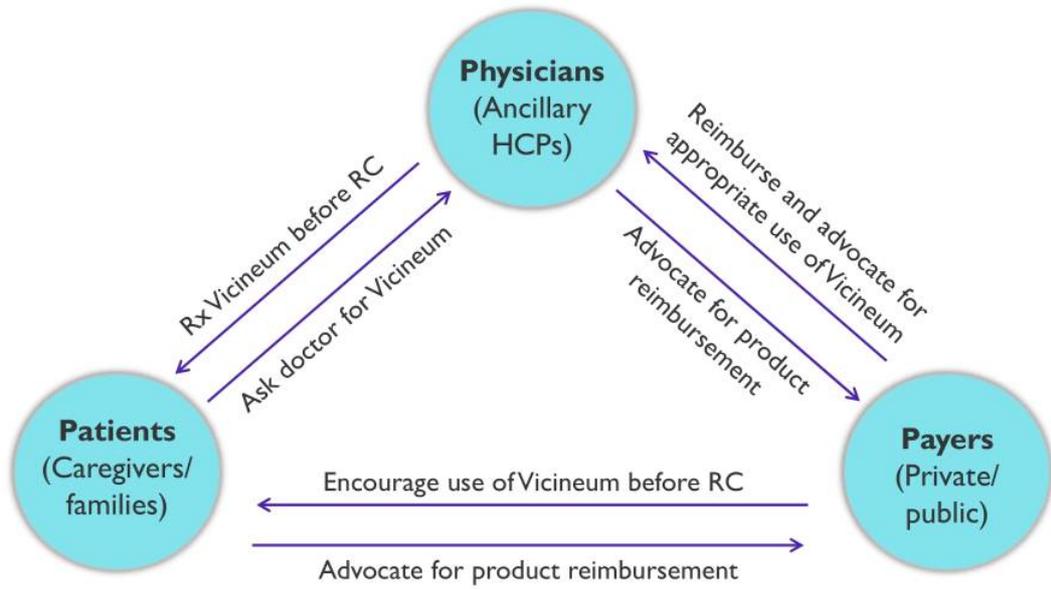
PRODUCT CANDIDATE	PAYLOAD	INDICATION	PRECLINICAL	Ph I	Ph II	Ph III	BLA
Locally administered TPTs							
Vicineum	ETA	BCG-unresponsive high-risk NMIBC	Submission Initiated				
Vicineum	ETA	SCCHN	Complete				
Locally administered TPT + Systemic Checkpoint Inhibitor							
Vicineum + Durvalumab	ETA & IO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

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

## Brand Logo

## Differentiated vs. branded agents in Urology

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



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

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

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## Clinical Data from Emerging Treatments for NMIBC



	Vicineum Profile (Phase III Data)	Keytruda Profile (Phase II Data)	Tecentriq Profile (Phase II Data)
<b>Efficacy</b>	N=89	N=102	N=73
<b>Complete Response Rate</b>			
• <b>At 3 Months</b>	40% (CI: 30-51)	41% (CI: 32-51)	41% (CI: 30-53)
• <b>At 12 Months</b>	17%	20%	No data reported
• <b>At 18 Months</b>	15%	13%	No data reported
<b>Time to Cystectomy</b>	76% of patients were cystectomy-free at 36 months (n=133)	No data reported (not a clinical trial endpoint)	No data reported
<b>Safety</b>	N=133	N=102	N=73
<b>Treatment-Related Grade 3-5 AEs</b>	4%	13%	12%
<b>Discontinuation due to an AE</b>	3%	10%	No data reported
<b>Mode of Administration</b>	Intravesical	Intravenous	Intravenous
<b>Generally Administered by</b>	Urologist	Medical Oncologist	Medical Oncologist

Source: Preliminary data from October 6, 2020 data cut for Vicineum profile; Dec. 2019 FDA briefing book for Keytruda profile; May 2020 ASCO abstract for Tecentriq profile. Note: The data shown are from the respective trials and do not represent head-to-head trial outcomes

## IQ 2020 Market Research Results

### Reasons Urologists Prefer Vicineum Profile



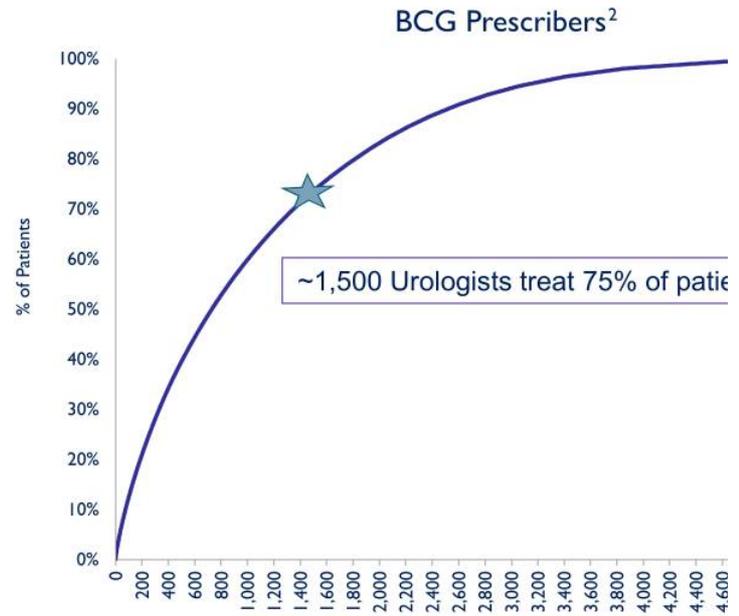
- **Urologists strongly prefer to retain ownership of patient journey**
  - High degree of reluctance to refer to Medical Oncologists
  - Fear of losing follow-up diagnostics with patient after treatment referral
- **Urologists perceive favorable product profile for Vicineum**
  - Comparable efficacy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

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# Highly Concentrated Prescriber Base Allows for Efficient Commercial Model

~60% of Urology practices have  $\geq 5$  Urologists<sup>1</sup>



<sup>1</sup>AUA State of the Urology Workforce and Practice in the United States. 2017. <sup>2</sup>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

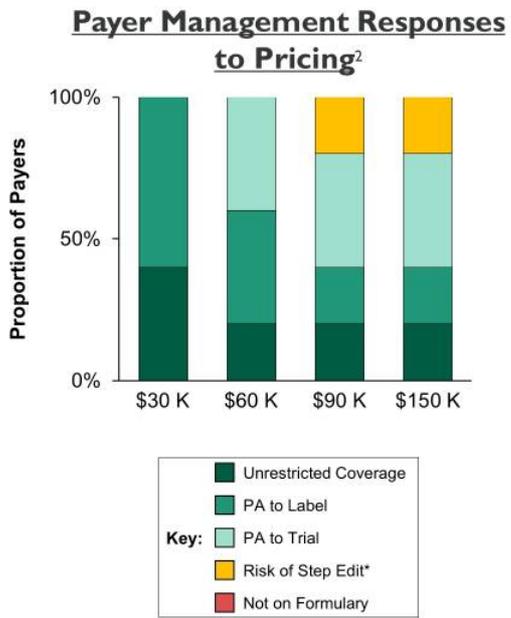
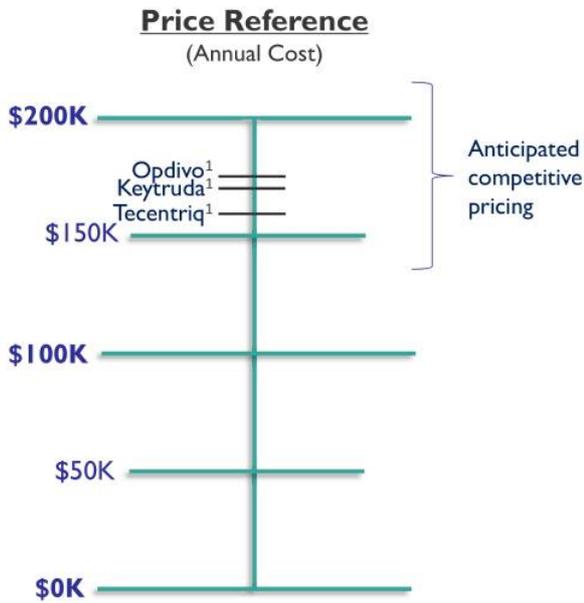


Twitter

Lead gen/CRM

Lead gen = lead generation  
CRM = customer relationship management

# Pricing and Reimbursement US Benchmarks



Sources: <sup>1</sup>Center for Medicare and Medicaid Services (CMS) Average Selling Price (ASP) Price List as of 1Q 2020 (cms.gov).

<sup>2</sup>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

# Competitive Scan



## Approved/Pipeline Products

### Second Line Monotherapies

#### Checkpoint Inhibitors:

##### Keytruda

- Approved for NMIBC January 2020
- Reimbursed at \$175,000/year with minimal payer restrictions

##### Tecentriq

- Awaiting Phase III enrollment
- Phase II closed prematurely as it failed to meet futility endpoint

#### Gene Therapy: Adenovirus Vectors

##### Adstiladrin

- Missed May PDUFA date
- Received a CRL from the FDA in May 2020 citing numerous and manufacturing issues

##### CG0070

- Phase III trial anticipated to start September 2020
- Same adenovirus serotype as Adstiladrin

### Combination Therapies

##### N-803 + BCG (Phase II)

- BLA Filing 2021 (CIS)\*; Breakthrough Therapy Status
- BLA Filing 2022 (Ta/TI)\*

##### Keytruda + BCG (Phase III)

- Phase III trial initiated in December 2018
- Patients with "less than adequate" BCG
- Primary Completion Date: May 2022

## Recently Terminated Programs

#### Phase II Trials

- |                             |               |
|-----------------------------|---------------|
| • Enzalutamide              | October 2018  |
| • Inodiftagene Vixteplasmid | November 2019 |
| • Rogaratinib               | December 2019 |

#### Phase III Trials

- |                         |             |
|-------------------------|-------------|
| • Rapamycin             | June 2019   |
| • Nanoxel               | August 2019 |
| • Mitomycin C + Synergo | April 2020  |

\*JP Morgan Healthcare Conference (January 2020); Jefferies Virtual Health Conference (June 2020)

### Overview

- Vicineum is a product with potential for registration and reimbursement in multiple developed markets
  - OUS opportunity for Vicineum is 2-3 times larger than the US
  - Efficient process to manage strong, engaged relationships with key partners worldwide
  - Partner with 6-10 companies with local expertise who will be the MAH
  - Launch in 60-80 OUS countries with 50-50 value share
-

## Sesen Bio OUS Update



July 31, 2020: Announced partnership with Qilu Pharmaceutical for the manufacture, development and commercialization of Vicineum in Greater China\*

- Represents the first of 6-10 anticipated OUS deals
- Financial terms include significant sources of non-dilutive capital
- Qilu will be the Marketing Authorization Holder and will have the exclusive rights to develop, manufacture and commercialize Vicineum in the region
- Terms of the agreement include tech transfer, creating an opportunity for future CMO partnership to meet significant global demand forecasts

Vicineum is a product with potential for registration and reimbursement in multiple developed markets

- OUS opportunity for Vicineum is roughly double the US opportunity
- Additional partnership opportunities expected in 2H 2020 – 1H 2021

\*Greater China is defined as China, Hong Kong, Macau and Taiwan

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## Partnership Opportunity in China: Qilu Pharmaceutical Profile

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- Top 10 Pharmaceutical Company in China with >\$3B in annual revenue
- Extensive clinical experience
  - 2<sup>nd</sup> largest clinical team in Chinese Big Pharma
  - Focused on biosimilar and innovative drugs, with nearly 40 years of development experience
- Significant oncology experience with a dedicated team of nearly 1000 employees in sales, marketing and medical
  - Among top 3 companies in China for market promotion in oncology
- Three commercially available biologics which are manufactured via microbial expression
  - Microbial drug production facility is NMPA approved and has been inspected by EU QP
  - DS and DP manufacturing capabilities
  - Future opportunity to leverage manufacturing expertise as a second supplier to help meet global demand

DS = Drug Substance; DP = Drug Product; NMPA = National Medical Products Administration (formerly CFDA); QP = Qualified Person

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## Overview of Qilu License Agreement



- Financial terms include significant sources of non-dilutive capital
  - Upfront payment of \$12M in cash
  - Eligibility to receive up to \$23M in regulatory and tech transfer milestones in addition to 12% royalties on net sales for at least 12 years
- Qilu will be the Marketing Authorization Holder (MAH) and will have the exclusive rights to develop, manufacture and commercialize Vicineum in the Greater China\* region
  - Qilu will be responsible for all expenses related to these activities
  - Sesen retains full development and commercialization rights in the US and rest of world excluding Greater China
- Terms of the agreement include tech transfer, creating an opportunity for future CMO partnership to meet significant global demand forecasts

\*Greater China is defined as China, Hong Kong, Macau and Taiwan

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## Building Our Reputation as a Partner of Choice

### Feedback Received from Qilu During the Negotiation Process



Vicineum is a highly differentiated product that addresses a huge unmet need



Highly knowledgeable clinical and manufacturing teams



Significant CMC capabilities and experience



Strong cultural fit between Sesen and Qilu

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## Simulation Inputs: US Market



<b>Estimated patients eligible for branded therapy<sup>1</sup></b> (Annual high-risk NMIBC patients unresponsive to BCG)	
<u>Lower Bound</u> 7,800 patients	<u>Upper Bound</u> 20,400 patients
<b>Estimated peak market share<sup>2</sup></b> (Likely share of branded agents)	
<u>Lower Bound</u> 20%	<u>Upper Bound</u> 75%
<b>Approximate year 1 doses received<sup>3</sup></b> (Percent of possible doses received)	
<u>Lower Bound</u> 67%	<u>Upper Bound</u> 83%
<b>Anticipated reimbursement price for competitive agents<sup>4</sup></b> (Anticipated annual CMS ASP)	
<u>Lower Bound</u> \$100,000	<u>Upper Bound</u> \$175,000

Sources: <sup>1</sup>National Cancer Institute, SEER Cancer Stat Facts: Bladder Cancer, 2019., and ClearView Analysis IQ 2019. <sup>2</sup>Emerging Treatment IDIs with High BCG-Treating UROs, IQ 2020, N=34. <sup>3</sup>Phase III trial data as of May 29, 2019 data cut., <sup>4</sup>Center for Medicare and Medicaid Services (CMS) Average Selling Price (ASP) Price List

## Simulation Inputs: OUS Market

<b>Estimated incidence relative to the US<sup>1</sup></b> (High-risk NMIBC patients unresponsive to BCG)		
	<u>Lower Bound</u>	<u>Upper Bound</u>
<b>Europe</b>	1.1	1.3
<b>China</b>	1.6	1.8
<b>MENA</b>	0.2	0.4
<b>Asia</b> (incl. Japan)	0.8	1.0
<b>Latin America</b>	0.2	0.4
<b>Canada</b>	0.1	0.3
<b>Oceania</b>	0.05	0.2

<b>Estimated price relative to the US<sup>2</sup></b> (Anticipated reimbursed price)		
	<u>Lower Bound</u>	<u>Upper Bound</u>
<b>Europe</b>	0.44	0.84
<b>China</b>	0.20	0.60
<b>MENA</b>	0.66	1.06
<b>Asia</b> (incl. Japan)	0.29	0.69
<b>Latin America</b>	0.30	1.00
<b>Canada</b>	0.35	0.70
<b>Oceania</b>	0.35	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. <sup>1</sup>Relative incidence is calculated from total bladder cancer, and does not account for differences in the distribution of patients between NMIBC and MIBC. <sup>2</sup>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. <sup>3</sup>South Africa price multiplier was based on Keytruda only, as Opdivo has not yet been priced.

**Appendix**

## **Manufacturing & Supply Chain**

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## Reliable and Inexpensive Manufacturing Process



- Vicineum 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 manufacturers
-

**Appendix**

# **Intellectual Property**

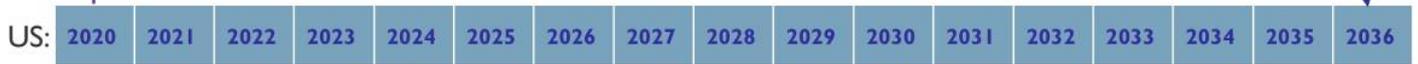
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# Vicineum Patent Life



Stabilized Chimeric Immunoglobulins  
(April 2020 - July 2020)

Pending Applications  
Dosing Strategies for Targeting EpCAM  
positive bladder cancer. If allowed,  
would expire in 2036 or later.

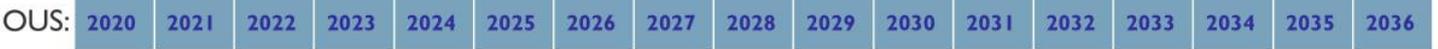


Methods of Treating Cancer Using an  
Immunotoxin (April 2024 - Jun 2025)

Potential for 12 years of biologics marketing exclusivity from date (TBD) of first approval\*

Pending Applications  
Dosing Strategies for Targeting EpCAM  
positive bladder cancer. If allowed,  
would expire in 2036 or later.

Stabilized Chimeric  
Immunoglobulins (April 2020)



Methods of Treating Cancer Using  
an Immunotoxin (Apr 2024)

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))

