

---

**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): October 13, 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  
(L.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 8.01 – Other Events.**

On September 17, 2020, the Institute for Clinical and Economic Review (“ICER”) issued a Draft Evidence Report titled Nadofaragene Firadenovec [Adstiladrin®] and Oportuzumab Monatox [Vicineum™] for BCG-Unresponsive, Non-Muscle Invasive Bladder Cancer: Effectiveness and Value (the “ICER Report”).

On October 13, 2020, Sesen Bio, Inc. posted an updated corporate presentation on its website www.sesenbio.com. Of note, there are three new slides (slides 52, 53 and 54) which provide an overview of the ICER Report.

A copy of the presentation is filed herewith as Exhibit 99.1 and is incorporated herein by reference.

**Item 9.01 - Financial Statements and Exhibits.**

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Sesen Bio, Inc. Corporate Presentation dated October 13, 2020</a>

---

**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: October 13, 2020

Sesen Bio, Inc.

By:

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

Thomas R. Cannell, D.V.M.  
President and Chief Executive Officer



# sesen

b i o

October 2020 Business Update

Thomas Cannell DVM, President & CEO

October 12, 2020

NASDAQ



# FORWARD-LOOKING STATEMENTS

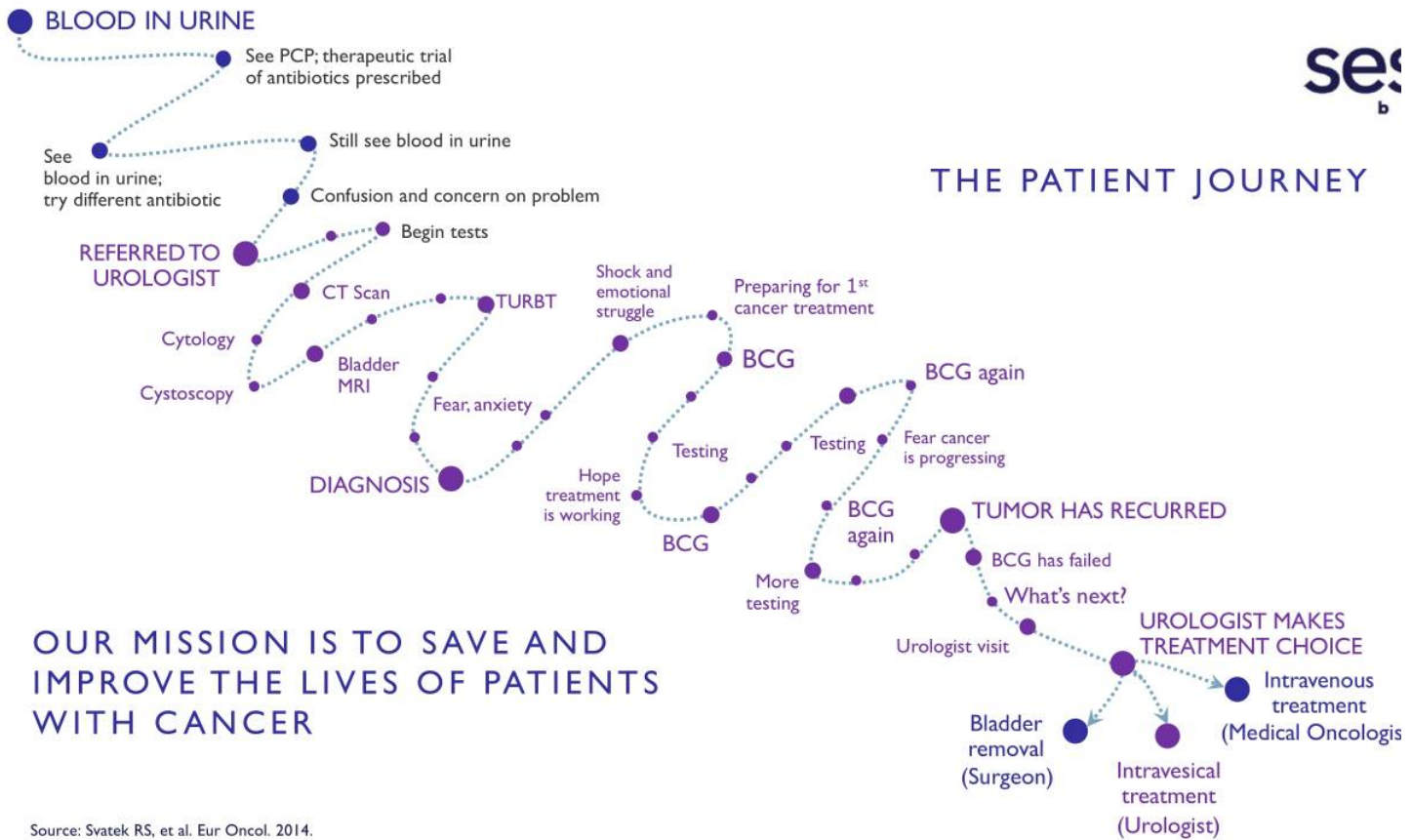


This presentation contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this presentation, including statements regarding our strategy, future operations, clinical development of our protein therapies, 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.

---

## THE PATIENT JOURNEY



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

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

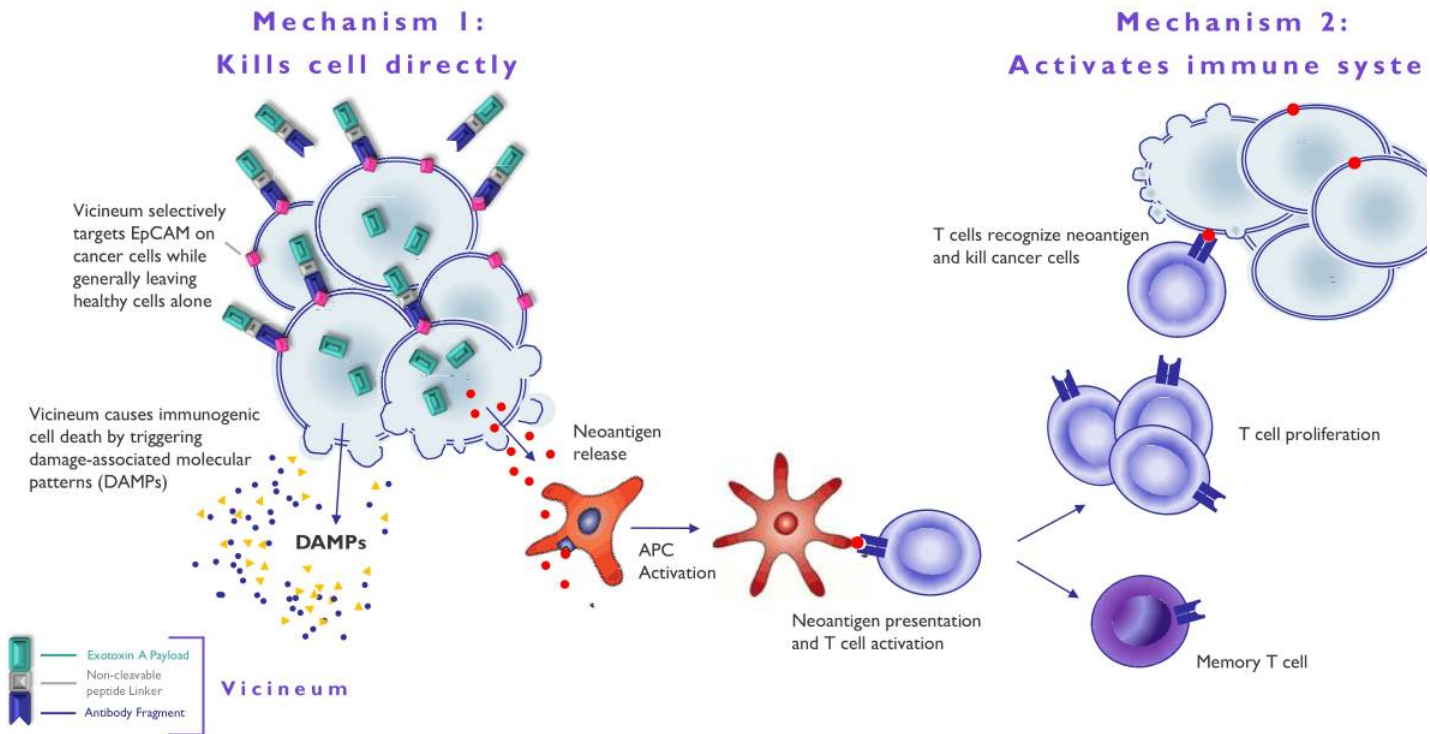


## OCTOBER 2020 BUSINESS UPD.

- Differentiated MOA enables competitive benefit-risk profile for Vicineum
  - Meaningful progress for CMC comparability
  - Clear regulatory path forward in U Europe
  - China partnership with Qilu represents first milestone in realizing significant global commercial opportunity
-



# 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 has a Highly Differentiated Clinical Profile



### Efficacy Data

#### 3-month response data

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

#### Durability of response

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

#### Positive time to cystectomy data

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

#### Encouraging survival data

- Overall survival (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

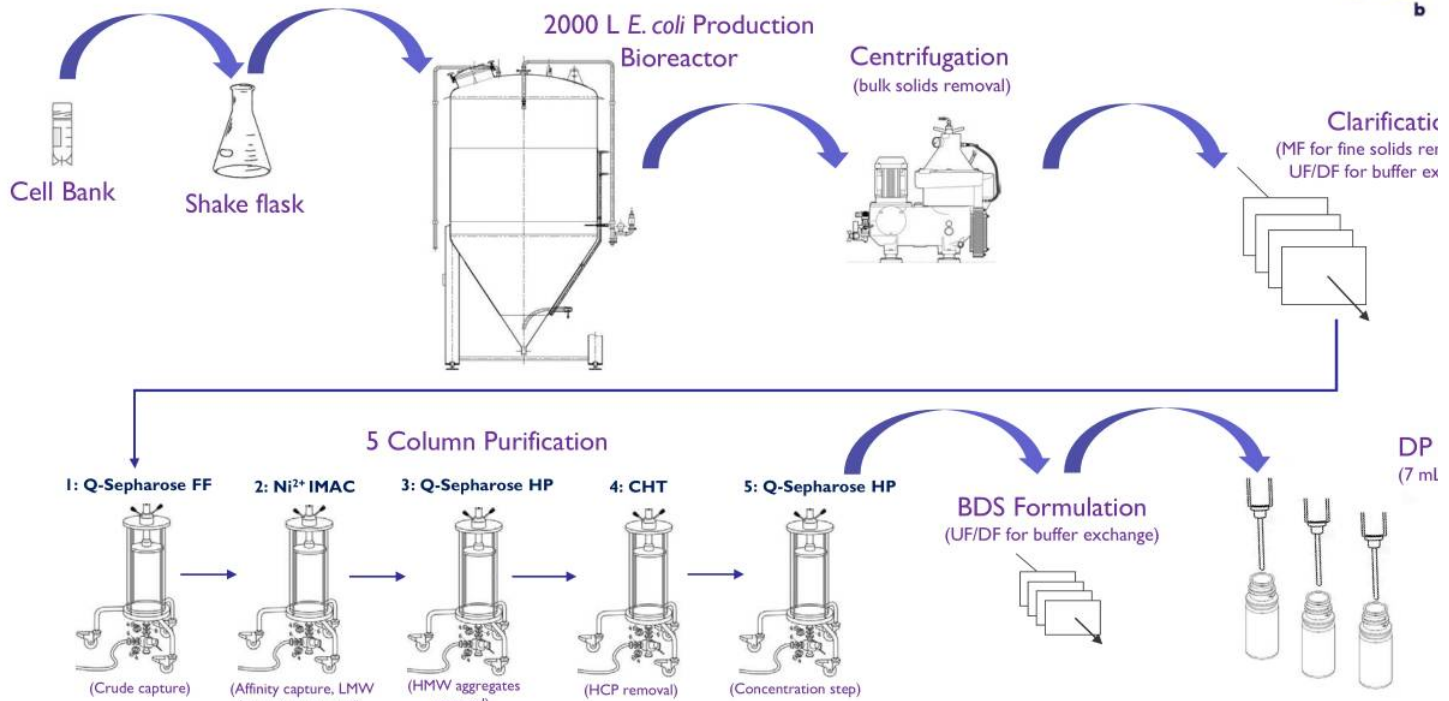
- Low discontinuation rate due to AEs (3%)
- No age-related increase in AEs

\*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 35-52.

# Highly Reliable Manufacturing Process for Vicineum

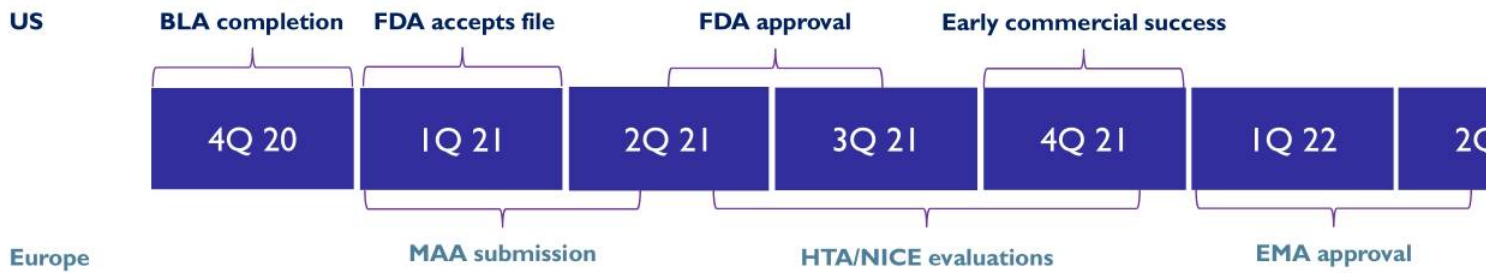


MF, microfiltration; UF, ultrafiltration; DF, diafiltration; FF, Fast-flow; IMAC, immobilized metal affinity chromatography; HP, High-performance; CHT, ceramic hydroxyapatite; BDS, bulk drug substance; DP, drug product; LMW, low molecular weight; HMW, high molecular weight; HCP, host-cell protein.  
 Source: Arjune Premsukh, Joelle Lavoie JM, Jeannick Cizeau, Joycelyn Entwistle, Glen MacDonald. Protein Expression Purification. 2011 Jul;78(1):27-37.

# 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

## Analytical Comparability Progress



Clear FDA requirements for the PPQ Campaign

Considerable in-house manufacturing process expertise from clinical manufacturing

Completed the PPQ drug substance campaign at Fujifilm

Completed the first and second PPQ drug product batches at Baxter; remaining PPQ batch expected to be completed in September

---

## 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

---



## 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.



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



Geography	Peak Revenue Opportunity for Vicineum (captures 80% of variance)
US	\$423M - \$942M
Europe	\$227M - \$556M
China	\$194M - \$522M
Rest of Asia (incl. Japan)	\$128M - \$330M
MENA	\$74M - \$187M
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 slides 11-12, the model calculated a range of alternative futures and possibilities. Peak sales presented capture 80% of uncertainty (10th-90th percentiles)

---

## Updated Financial Overview



**We have an expected cash runway into 2Q 2021<sup>1</sup> with no outstanding debt**

- Cash and cash equivalents of approximately \$38M as of June 30, 2020

**We continue to efficiently strengthen our balance sheet, supporting stage-gated investment in US commercial build**

- ATM
  - 1Q 2020: net proceeds of \$3.2M
  - 2Q 2020: net proceeds of \$4.8M
- Licensing deal
  - 2H 2020: expected gross proceeds of \$12M

**~\$24M available on a \$35M ATM facility administered by Jefferies, which was declared effective by the SEC on November 29, 2019<sup>2</sup>**

\*Net proceeds are estimated based on gross proceeds less commissions and prorated estimated quarterly fees

<sup>1</sup>Assumes receipt of upfront payment under the Qilu License Agreement prior to December 31, 2020

<sup>2</sup>Pursuant to a shelf registration statement on form S-3 (File no. 333-223750)

SEC = Securities and Exchange Commission

---

## Recent and Upcoming IR Events

### Completed 2020 IR Presentations

- 4Q 2019 Business Update - March 16
- 1Q 2020 Business Update - May 11
- Investor Conference - June 2
- OUS Business Update - July 31
- Investor Conference - August 12
- H.C.Wainwright Conference - September 15

### Anticipated 2020 IR Presentations

- 3Q 2020 Business Update - November
- Regulatory Update - December





sesen

b i o

---

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

## Appendix - Table of Contents



Section	Slide number
Unmet Medical Need	19-23
Dual Mechanism of Action	24-25
Regulatory	26-34
Clinical Data	35-55
Commercial Opportunity	56-71
Manufacturing & Supply Chain	72-75
Intellectual Property	76-77

For Investor Purposes Only

---

**Appendix**

## **Unmet Medical Need**

---



## Significant Unmet Medical Need in NMIBC

ses  
b



~440,000  
new cases each year globally<sup>1</sup>

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>

**BCG  
SHORTAGE**  
is complicating patient care

<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.



## 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.

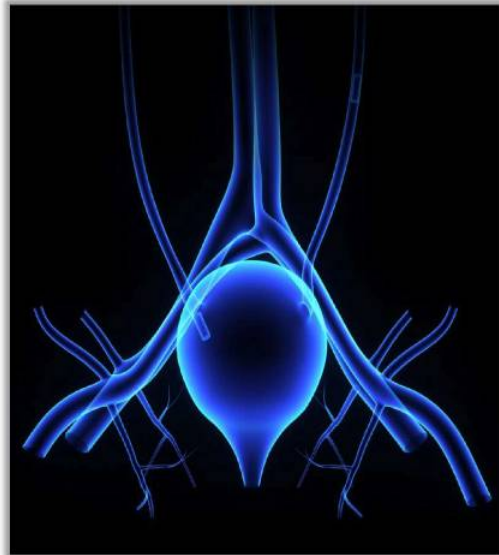
---

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.

## Latest global BCG shortage expected to last through 2020



### BCG Shortage Current Events:

- Since 2012, Merck has been the sole supplier of BCG in the US and the majority of countries worldwide.
- Merck has changed its TICE BCG distribution strategy, now allocating exclusively to distributors and wholesalers based on product supply and historical purchasing patterns.
- Merck anticipates this global supply constraint to continue throughout 2020.
- Prominent groups such as AUA, BCAN, and the LUGPA are advocating with the FDA and payers to find solutions.
- The AUA has issued updated guidance for high-risk NMIBC to maximize patient care, including decreased dosing, delayed maintenance therapy, first line use of alternative therapies, and earlier surgical intervention via radical cystectomy.
- Two clinical trials are underway to examine if the TICE BCG vaccine protects people against infection with COVID-19 virus.

#### Sources and Additional Information:

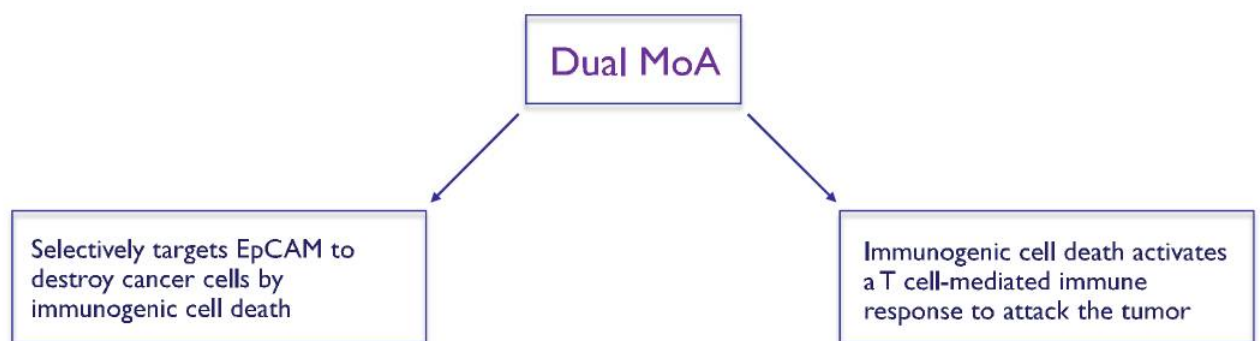
Wall Street Journal. *Sanofi to Stop Production of Bladder Cancer Drug BCG*. Peter Loftus. 2016. <https://www.auanet.org/practice-resources/bcg-info/bcg-shortage-notice>  
<https://www.bcan.org/2019-bcg-shortage-bladder-cancer/>. [https://www.who.int/news-room/commentaries/detail/bacille-calmette-gu%C3%A9rin-\(bcg\)-vaccination-and-covid-19](https://www.who.int/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

**Appendix**

## **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.

---

**Appendix**

# **Regulatory**

---

# FDA Conditional Acceptance of Vicineum Tradename Differentiated vs. branded agents in Urology

ses  
b

**VALSTAR**  
(valrubicin) 200 mg/5 mL Sterile Solution for Intravesical Instillation

**PROVENGE**  
(sipuleucel-T)

**ONCE-YEARLY VANTAS**  
(histrelin acetate) subcutaneous implant

**AVEED**  
(testosterone undecanoate) injection @ 750 mg/3 mL

**FIRMAGON**  
(degarelix for injection)

**VICINEUM**<sup>TM</sup>  
(oportuzumab monatox)  
FOR INTRAVESICAL INSTILLATION

**TESTOPEL**<sup>®</sup>  
(testosterone pellets) @

**Eligard**<sup>®</sup>  
(leuprolide acetate for injectable suspension)

**KEYTRUDA**<sup>®</sup>  
(pembrolizumab) Injection 100 mg

**XIAFLEX**  
collagenase clostridium histolyticum





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



2018 FDA Guidance

Vicineum Clinical Program

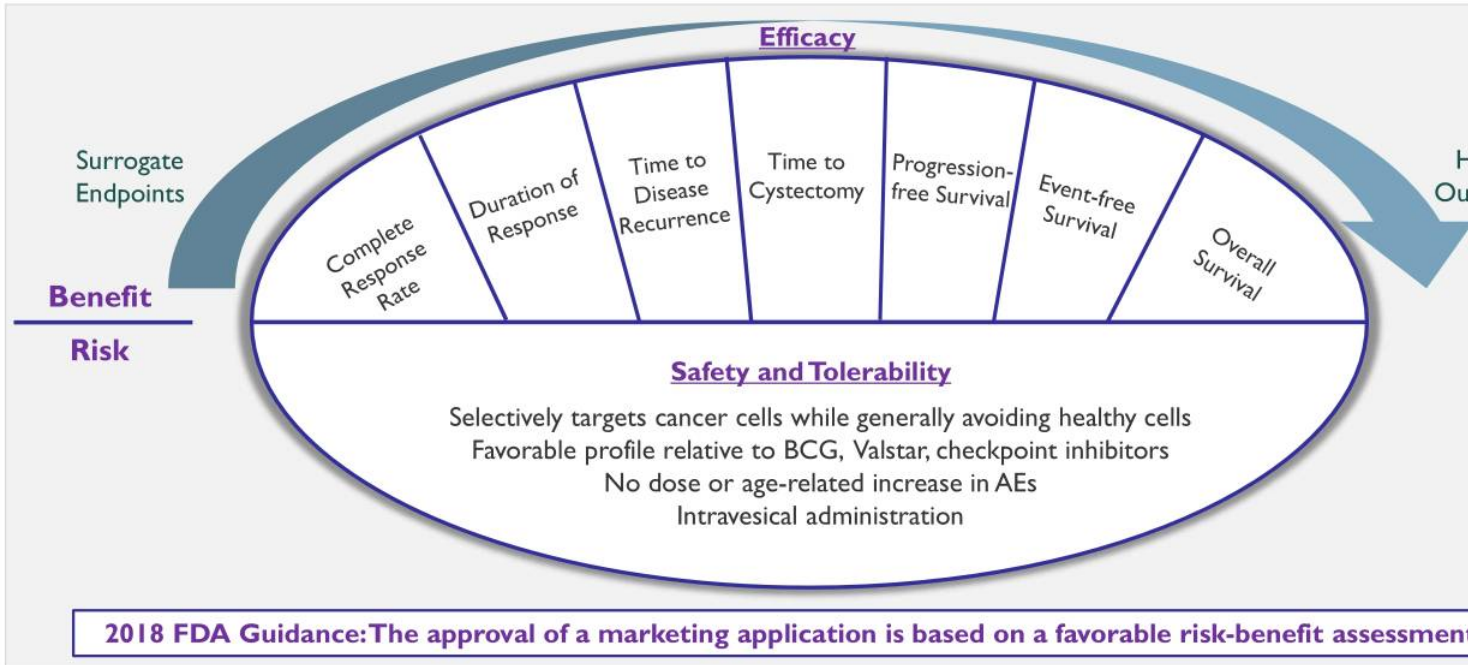
- Conduct nonclinical studies to assess toxicity in animal models ✓
- Conduct nonclinical studies to demonstrate anti-tumor activity ✓
- Conduct nonclinical studies to determine optimal dose and schedule ✓
- Examine anti-tumor activity and optimal dose schedule in early phase clinical trial ✓
- Papillary 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 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 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.

**Oncology Products Reviewed by FDA 2006 - 2015**

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

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

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

---

## Significant Progress in 2019



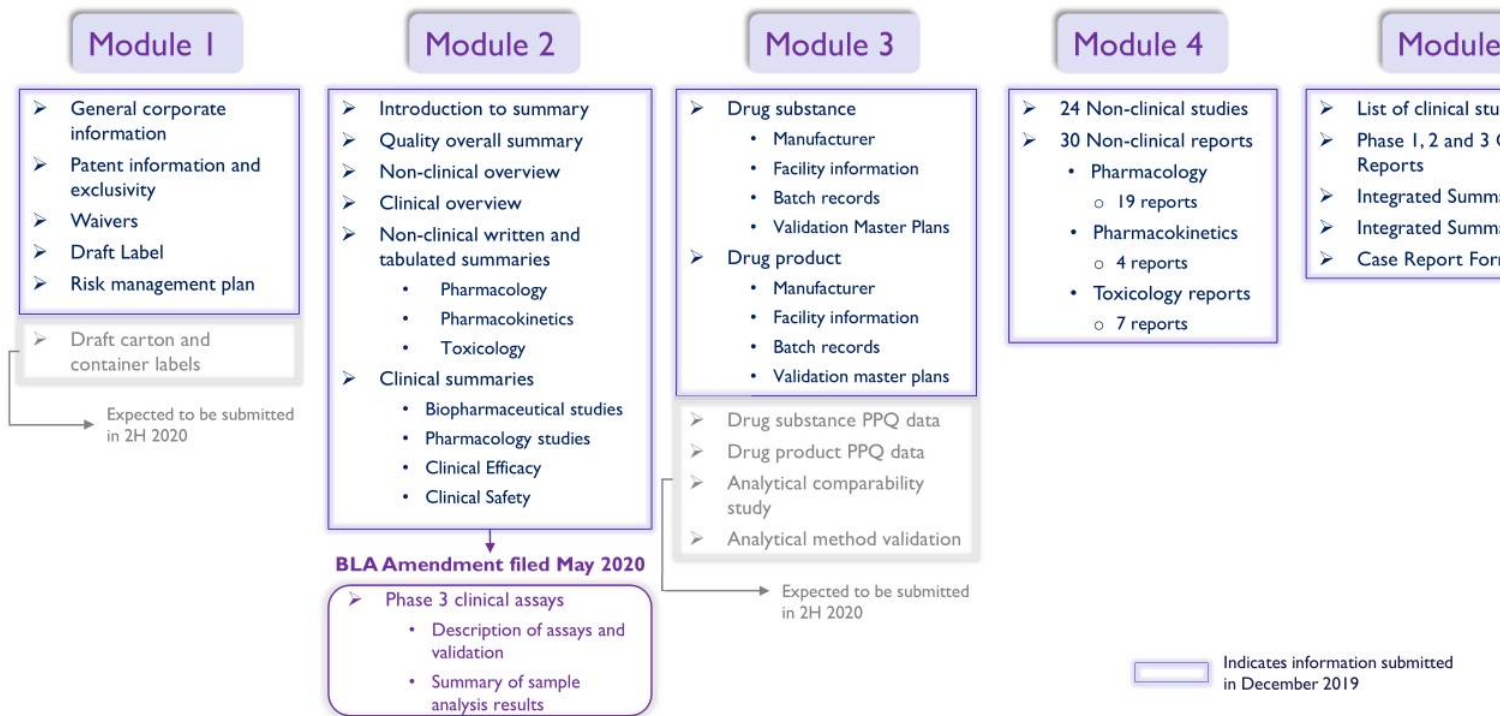
### 4 Pivotal Face-to-Face Meetings Led to BLA Submission of Clinical/Nonclinical Data

- ✓ **May 2019:** FDA Accepts CMC Analytical Comparability Plan
  - No additional clinical trials deemed necessary at this time, subject to final review of comparability data in the BLA
- ✓ **June 2019:** FDA Recommends Accelerated Approval Pathway and Rolling Review
  - Nonclinical data, clinical pharmacology data, and the safety database are sufficient to support a BLA submission
- ✓ **November 2019:** Gained alignment with FDA on post-marketing confirmatory trial
  - Creates opportunity for future label expansion in broader population
- ✓ **December 2019:** Gained alignment with the FDA on the final content of the BLA
  - Shared commitment to accelerate the timing of the pre-license inspection

**December 2019: Initiated BLA submission for Vicineum under Rolling Review**

---

# BLA Amendment filed in May 2020 further supports favorable safety and tolerability profile of Vicineum



## November 2019: Type C FDA meeting



We were successful in gaining alignment with the FDA on the design of our 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

---



## 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 2021 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

---

**Appendix**

## **Clinical Data**

---

## 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

## Additional Vicineum 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%)

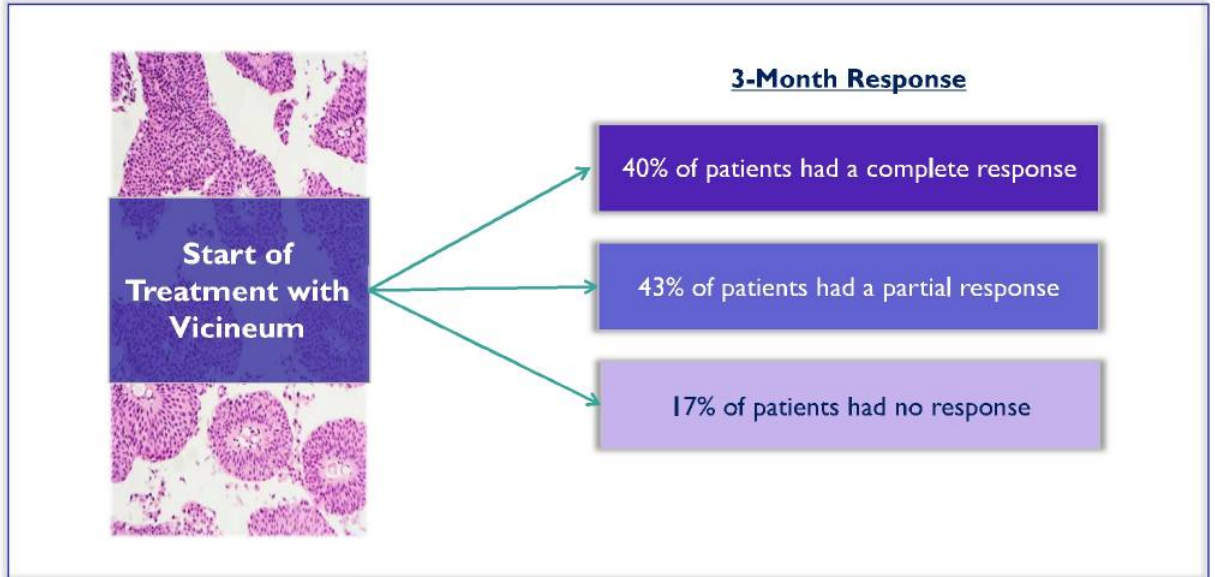
### Cohort 2 (n=7) Complete Response Rate

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

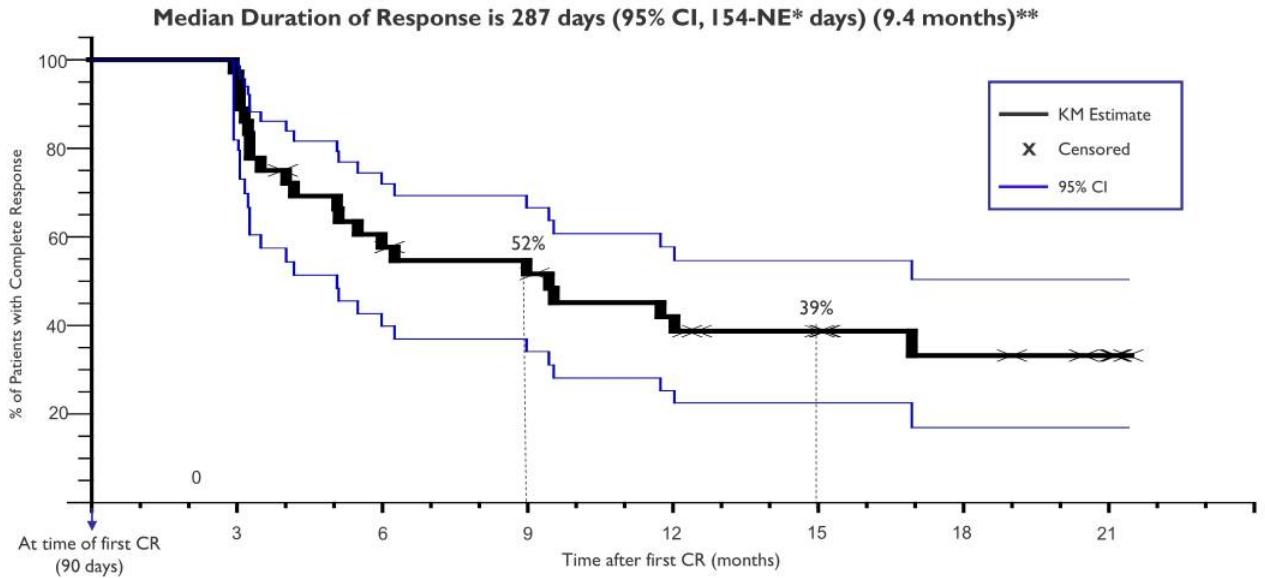
---

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



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

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



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

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

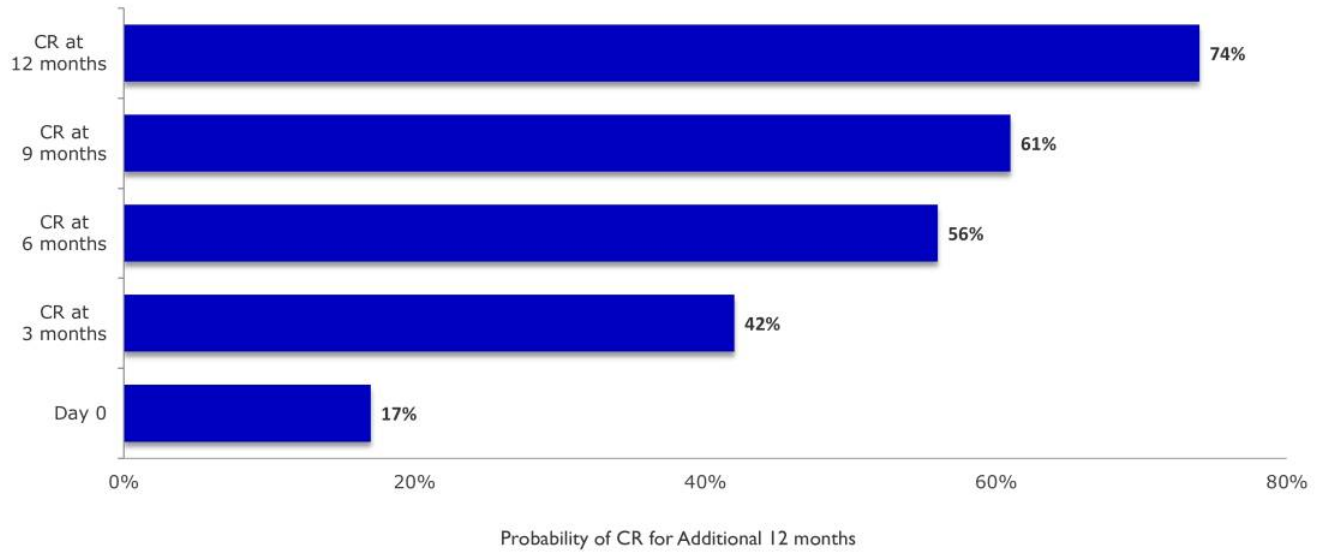
\*Not Estimable, the upper bound for the 95% confidence interval has not reached the median.

\*\*Note: Data reflect an *ad hoc* analysis of pooled results of patients in cohorts 1&2. Median duration of response for the primary endpoint, Cohort 1 (n=86) is 273 days (95% CI=122-NE), and duration of response for Cohort 2 (n=7) is 290 days (95% CI=167-NE), based on the Kaplan-Meier method.

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



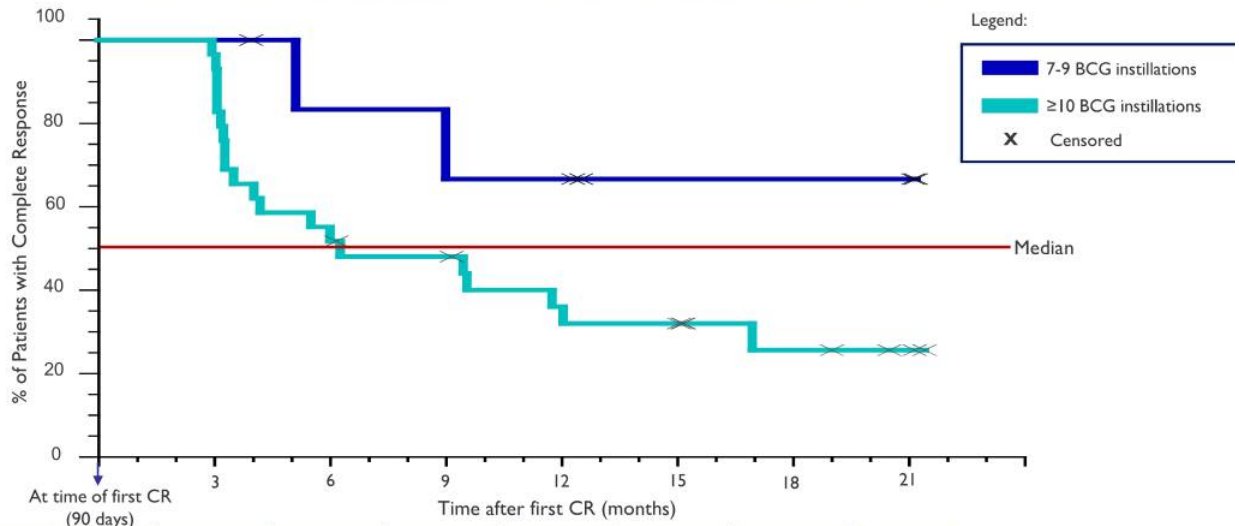
Probability of Maintaining Complete Response (CR) for at Least One Additional Year\*



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.

**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

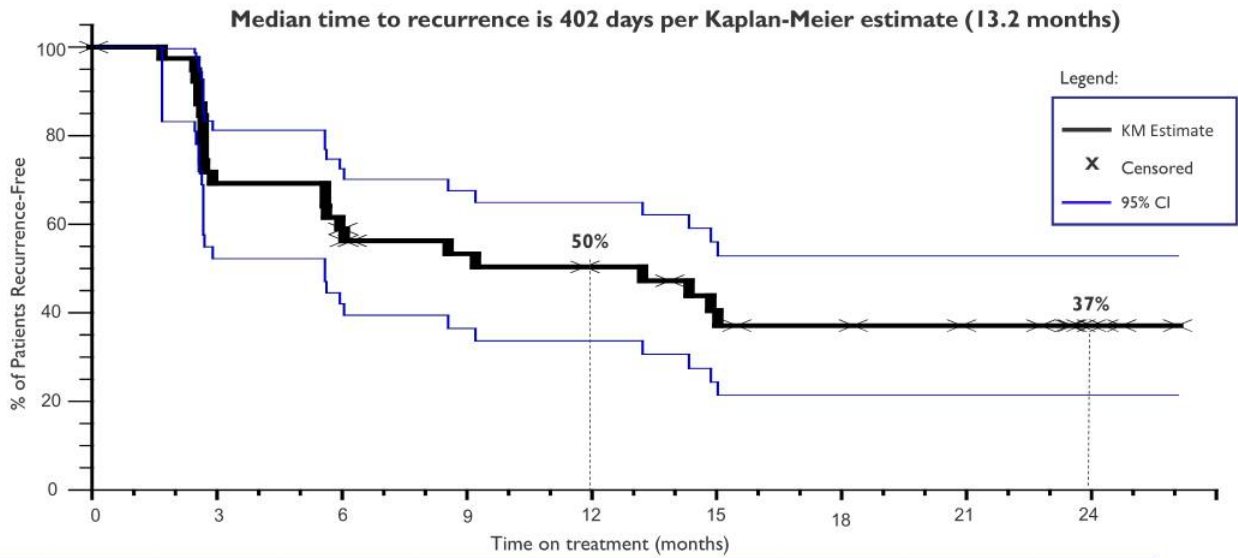


	At time of first CR (90 days)	3	6	9	12	15	18	21
KM Evaluable Patients 7 - 9 BCG Instillations:	7	7	5	4	4	2	2	2
KM Evaluable Patients ≥10 BCG Instillations:	29	28	15	13	9	8	4	2

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



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



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

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

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

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



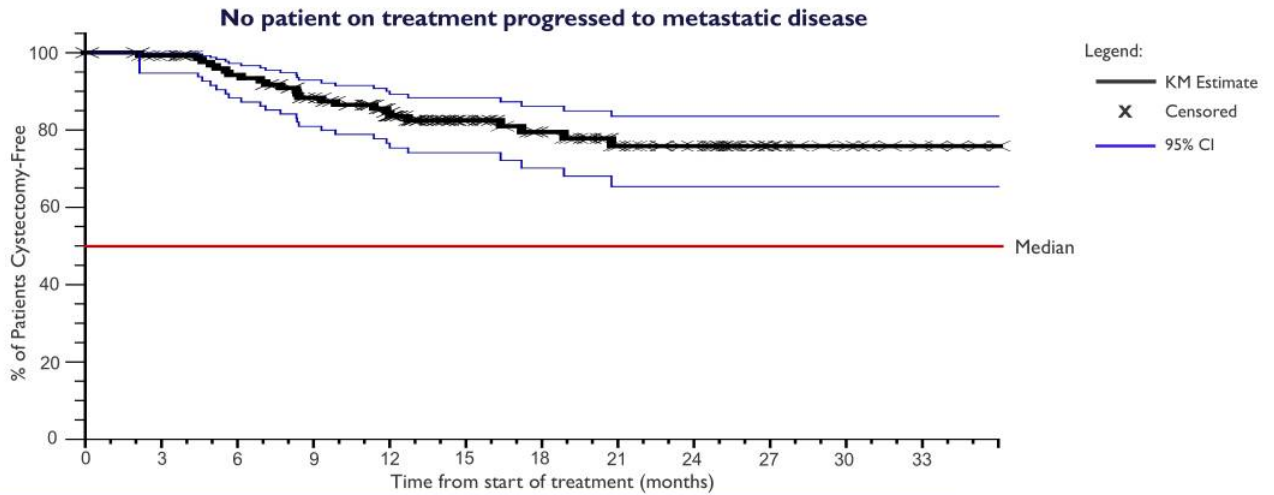
Recurrence-free (RF) Rate (Papillary patients)		
Time Point	Evaluable Patients	RF Rate (95% Confidence Interval)
3-months	n=38	71% (54%-85%)
6-months	n=38	58% (41%-74%)
9-months	n=38	45% (29%-62%)
12-months	n=38	42% (26%-59%)

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

---

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

## 76% of patients are cystectomy-free for 3 years



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

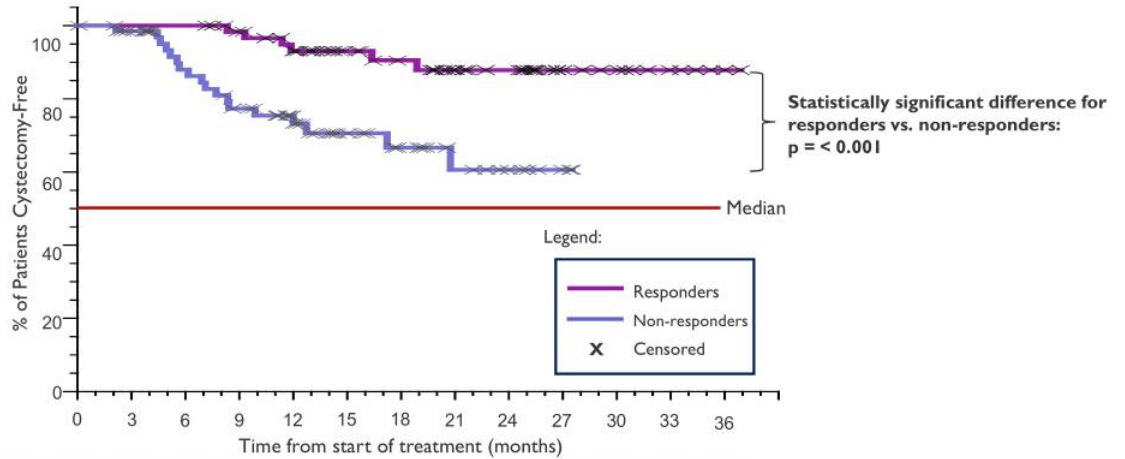
### 2018 FDA Guidance: The goal of therapy in patients with BCG-unresponsive NMIBC is to avoid cystectomy

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

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



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



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

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

## 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

---

## 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%)

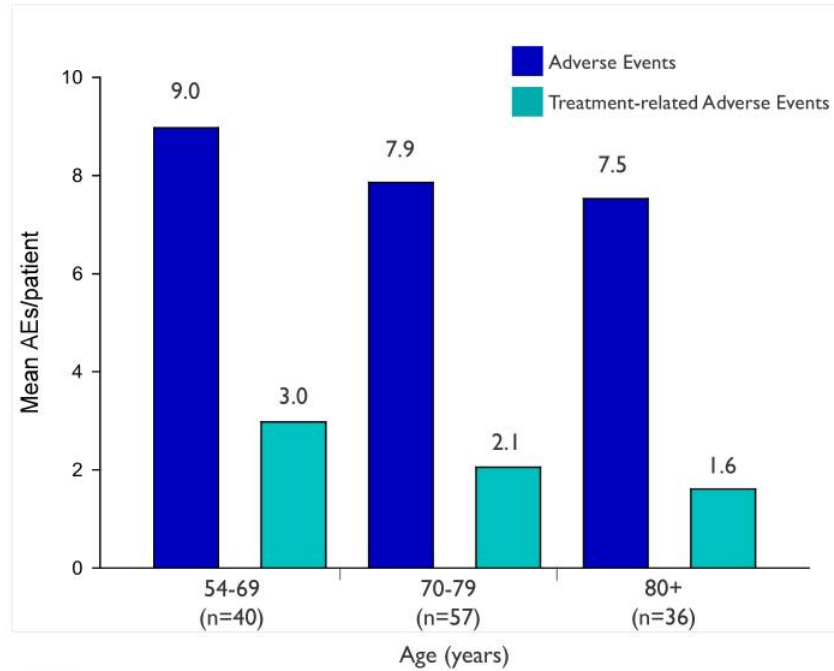
### Vicineum Treatment Exposure:

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



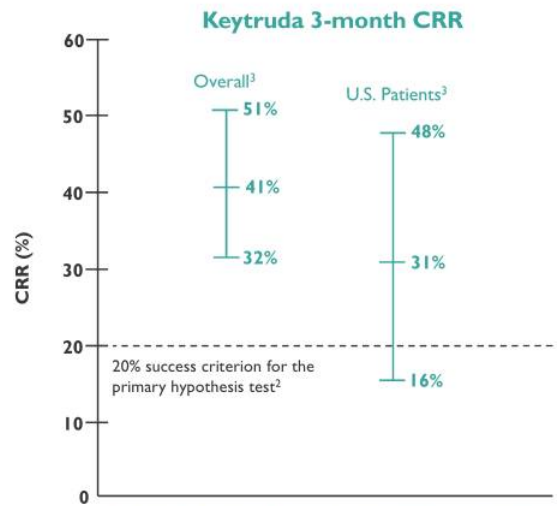
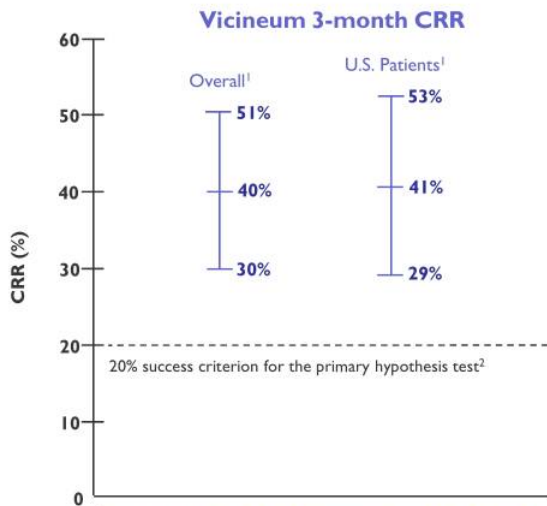
Note: Data consist of patients from all cohorts (n=133).  
Mean AEs for all patients: 8.1 (range 0-54), Mean treatment-related AEs for all patients: 2.2 (range 0-51).



# 3-month complete response rate data from different clinical trials



Please use caution when drawing comparisons across different clinical trials



<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 Keytruda ODAC panel discussion on Dec. 17, 2019 and based on the 18% CRR of Valstar

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

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

## Institute for Clinical and Economic Review (ICER) Overview



ICER is an independent non-profit, research organization whose role is to collect evidence that can be used to improve patient outcomes and control costs

- Combines clinical data and stakeholder input
- Known as one of the “nation’s independent watchdog” on drug pricing
- Private, non-partisan organization funded through government grants and non-profit foundations to ensure objectivity of reports

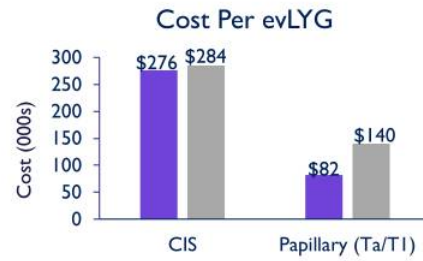
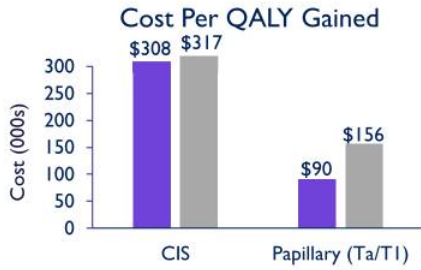
On September 17, 2020 ICER issued a draft evidence report on the cost-effectiveness and value of Vicin and Adstiladrin

- The report focused on adults with BCG-unresponsive, high-risk NMIBC, including those with *Carcinoma in situ*, as well as those with Papillary (Ta/T1) NMIBC
- The report scope included clinical benefits, as well as the safety and tolerability of these agents compared to each other and to systemic Keytruda and intravesical gemcitabine ± docetaxel

Source: Institute for Clinical and Economic Review, 2020. [https://icer-review.org/wp-content/uploads/2020/02/ICER\\_Bladder-Cancer\\_Draft-Report\\_091720.pdf](https://icer-review.org/wp-content/uploads/2020/02/ICER_Bladder-Cancer_Draft-Report_091720.pdf)

---

# Vicineum has an Advantage vs. Adstiladrin on Cost Effectiveness Metrics Calculations Relative to Usual Care



Key ■ Vicineum ■ Adstiladrin

QALY= Quality-Adjusted Life Year, evLYG= equal value Life Year Gained, LYG= Life Year Gained, PFS= Progression-Free Survival, CIS= Carcinoma in situ  
 Source: Institute for Clinical and Economic Review, *Nadofaragene Firadenovec and Oportuzumab Monatox for BCG-Unresponsive, Non-Muscle Invasive Bladder Cancer: Effectiveness and Value*, Draft Evidence Report, 2020.  
 Notes: Cost-effectiveness is evaluated vs. usual care. Prices for Vicineum and Adstiladrin were based on the annual price of Keytruda, with differences in dosing frequency taken into account. Prices shown are the total discounted lifetime

# Vicineum has a Higher Probability of Cost Effectiveness vs. Adstiladrin



## Probabilistic Sensitivity Analysis Results

Relative to Usual Care Papillary (Ta/T1)			Relative to Keytruda and Usual Care Carcinoma in situ		
	Vicineum Probability (%)	Adstiladrin Probability (%)		Vicineum Probability (%)	Adstiladrin Probability (%)
\$50,000/QALY	14%	0%	\$50,000/QALY	0%	0%
\$100,000/QALY	69%	4%	\$100,000/QALY	0%	0%
\$150,000/QALY	95%	46%	\$150,000/QALY	0%	0%
\$200,000/QALY	100%	91%	\$200,000/QALY	4%	0%
\$250,000/QALY	100%	100%	\$250,000/QALY	23%	6%

~90% of high-risk patients<sup>2</sup>

~10% of high-risk patients<sup>2</sup>

Sources: <sup>1</sup>Institute for Clinical and Economic Review, *Nadofaragene Firadenovec and Opportuzumab Monatox for BCG-Unresponsive, Non-Muscle Invasive Bladder Cancer: Effectiveness and Value*, Draft Evidence Report, 2020, <sup>2</sup>Anastasiadis et al. *Therapeutic Advances in Urology*, 2012.  
 Notes: Price for both Vicineum and Adstiladrin for Papillary was based on the annual price of Keytruda; this analysis shows the overall variability in the model for Adstiladrin and Vicineum, compared with each other and with usual care. Price for Adstiladrin for Carcinoma in situ was based on the annual price of Keytruda; this analysis shows the overall variability in the model for Adstiladrin and Vicineum compared with each other and with Keytruda and usual care. For each population, usual care was intentionally left undefined. For the base case, the effectiveness of usual care was set to a CR probability of 0%.

## 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**

---

## Large Global Commercial Opportunity

Substantial US opportunity and OUS potential of roughly two 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

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

---



## 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.

---

## Market Research Input

### Clinical Data from Emerging Treatments for NMIBC



	Vicineum (Phase III Data)	Tecentriq (Phase II Data)
<b>Characteristics</b>		
<b>Median Patient Age</b>	73	73
<b>Median # of BCG Instillations</b>	12	12
<b>Efficacy</b>	N=89	N=73
• <b>At 3 Months</b>	40%	41%
• <b>At 6 Months</b>	28%	28%
<b>Safety</b>		
	N=133	N=73
<b>Treatment-Related Grade 3-5 AEs</b>	4%	12%
<b>Mode of Administration</b>	Intravesical	Intravenous

Source: May 2020 ASCO abstract for Tecentriq profile; Dec. 2019 BLA submission for Vicineum profile.  
 Note: The data shown are from the respective trials and do not represent head-to-head trial outcomes

# Competitive Scan: August 2020

## BCG-Unresponsive NMIBC Monotherapies



### Approved/Pipeline Products

#### 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 CMC and manufacturing issues

##### CG0070

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

### 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  |

## **IQ 2020 Intent-to-Prescribe Market Research Results**

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

## Market Research Input

### Profile of Emerging Treatments for NMIBC

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

Source: Dec. 2019 FDA briefing book for Keytruda profile; Dec. 2019 BLA submission for Vicineum 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

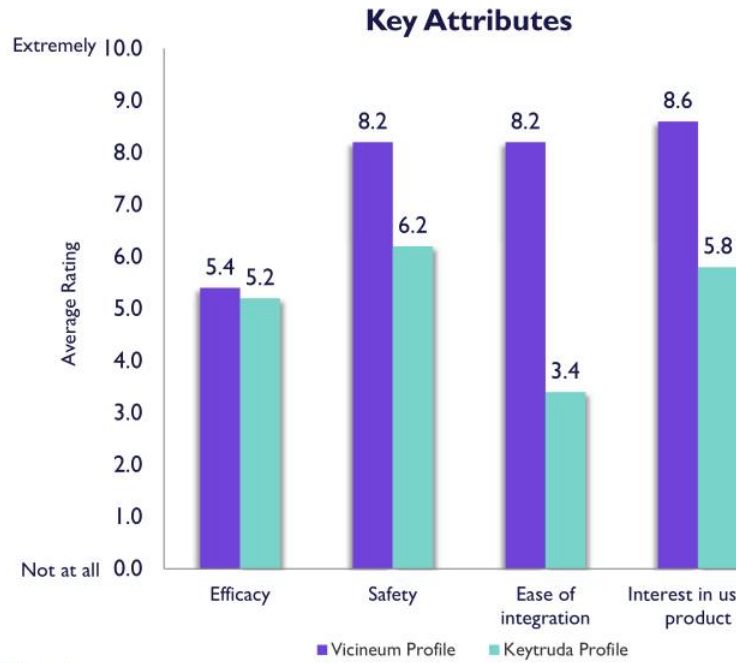
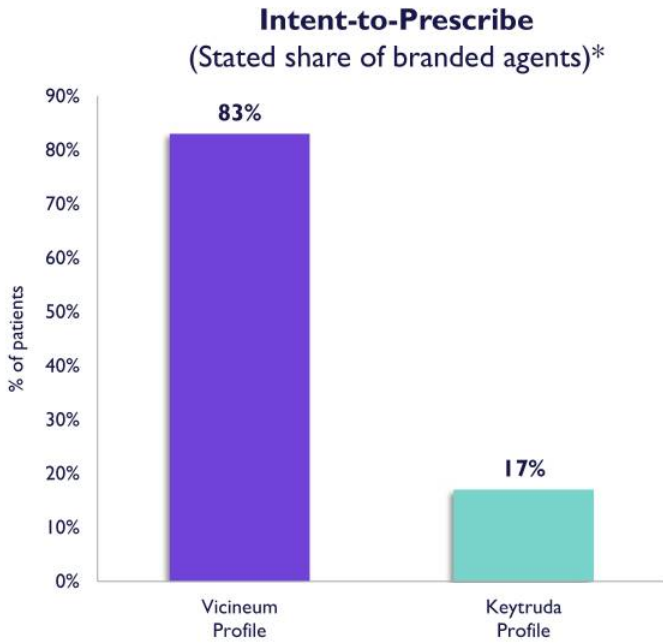


	Vicineum Profile	Keytruda Profile
<b>Efficacy</b>	N=89	N=102
<b>Complete Response Rate</b>		
• <b>At 3 Months</b>	40% (CI: 30-51)	41% (CI: 32-51)
• <b>At 12 Months</b>	17%	20%
• <b>At 18 Months</b>	11%	13%
<b>Time to Cystectomy</b>	76% of patients were cystectomy-free at 36 months (n=133)	No data reported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

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

# IQ 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



## IQ 2020 Market Research Results

### Reasons Urologists Prefer Vicineum Profile



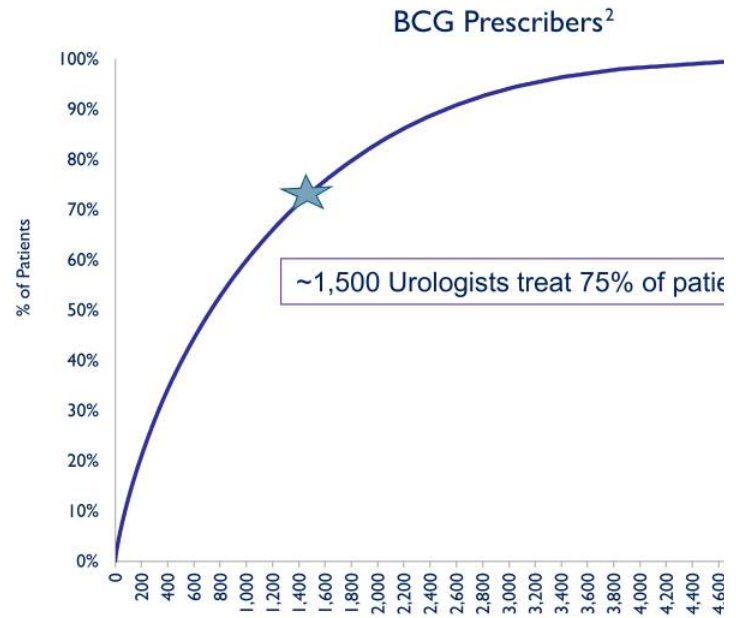
- **Urologists strongly prefer to retain ownership of patient journey**
  - High degree of reluctance to refer to Medical Oncologists
  - Fear of losing follow-up diagnostics with patient after treatment referral
- **Urologists perceive favorable product profile for Vicineum**
  - Comparable efficacy 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 chemotherapy on patients**
  - Stigma of seeing an Oncologist/going to large academic medical center
  - Patient perception of more advanced disease (e.g. terminal patients)

Source: Emerging treatment IDIs with high BCG-treating Urologists, 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  $\geq 5$  Urologists<sup>1</sup>

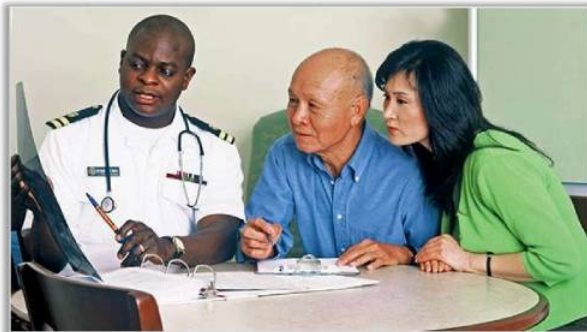


<sup>1</sup>AUA State of the Urology Workforce and Practice in the United States. 2017. <sup>2</sup>Health Verity 2019.

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

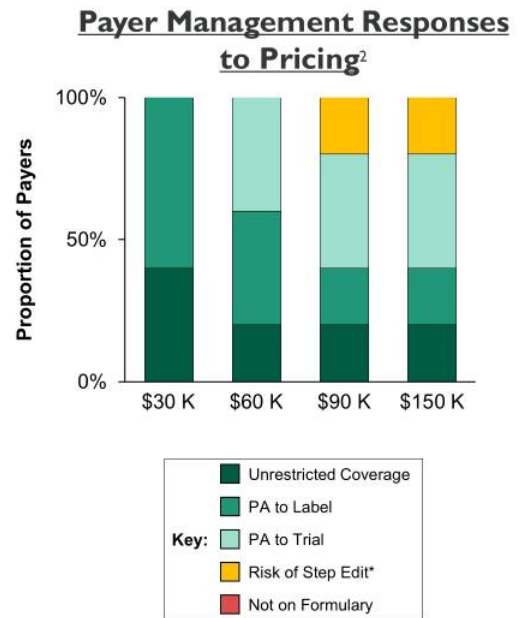
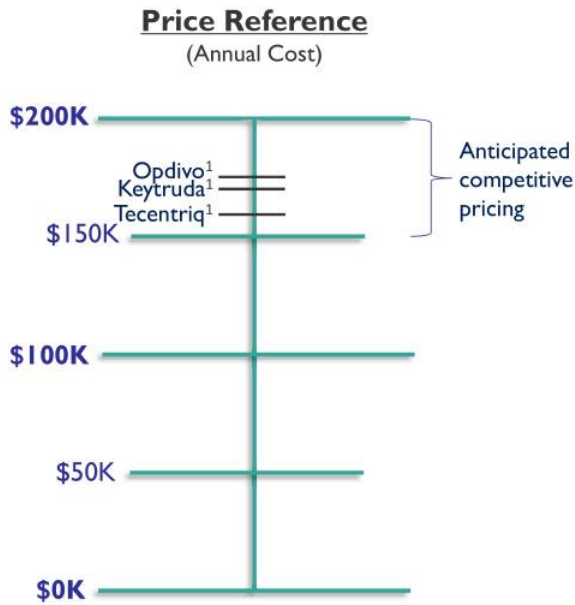


Twitter

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

## Partnership Opportunity in China: Qilu Pharmaceutical Profile

ses  
b



- Top 10 Pharmaceutical Company in China with >\$3B in annual r
- 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 employees in sales, marketing and medical
  - Among top 3 companies in China for market promotion in oncolog
- Three commercially available biologics which are manufactured v microbial expression
  - Microbial drug production facility is NMPA approved and has been i 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

---

## 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

---



## 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

---



**Appendix**

## **Manufacturing & Supply Chain**

---

## 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 manufactur

---

## We have Experienced Partners for the Global Manufacturing and Supply of Vicineum

ses  
b



- 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 Vicineum manufacture
  - Proven track record with FDA and worldwide regulatory agencies



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

**Appendix**

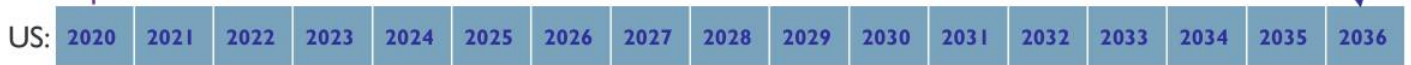
# **Intellectual Property**

---

# Vicineum Patent Life



Stabilized Chimeric Immunoglobulins  
(April 2020 - July 2020)

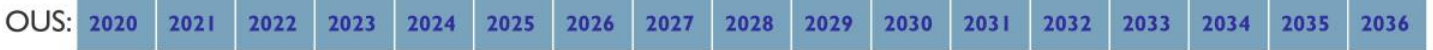


Methods of Treating Cancer Using an Immunotoxin (April 2024 - Jun 2025)

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

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)

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

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))

