CURRENT REPORT
Pursuant to Section 13 OR 15 (d)
of the Securities Exchange Act of 1934
Date of Report (Date of earliest event reported): January 11, 2021

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

Delaware
(State or other jurisdiction
of incorporation)
001-36296
(Commission
File Number)
26-2025616
(I.R.S. Employer
Identification No.)
245 First Street, Suite 1800
Cambridge, MA
(Address of principal executive offices)
02142
(Zip Code)

Registrant's telephone number, including area code: (617) 444-8550
Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- [] o Reporting under Section 13 or 15(d) of the Exchange Act
- [] o Soliciting to vote at a meeting of shareholders to elect directors (as provided for under Check box 2 below)
- [] o Soliciting proxy statement, or other communiation to secure votes at a meeting of shareholders
- [] o Attorney-in-fact or other securities law purpose
- [] o Other (specify in a box below)
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 January 11, 2021, Sesen Bio, Inc. (the “Company”) disclosed in an updated corporate presentation that it had cash, cash equivalents, and restricted cash of approximately $55 million as of December 31, 2020. This amount is preliminary, has not been audited and is subject to change upon completion of the Company’s financial statements for the year ended December 31, 2020. Of note, during 2020 the Company strengthened its balance sheet while minimizing dilution, ahead of the potential FDA approval and commercial launch of Vicineum™ in the United States later this year.

The information under this Item 2.02 shall be deemed to be “filed” for the purposes of the Securities Exchange Act of 1934, as amended.

Item 8.01 – Other Events.


CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS:

This Current Report on Form 8-K contains forward-looking statements, including, but not limited to, expectations regarding the timing of the Company’s potential FDA approval and commercial launch of Vicineum in the United States. These forward-looking statements are based on the Company’s current expectations and inherently involve significant risks and uncertainties. The Company’s actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties. A further description of the risks and uncertainties relating to the business of the Company is contained in the Company’s most recent annual report on Form 10-K and the Company’s quarterly reports on Form 10-Q, as well as any amendments thereto reflected in subsequent filings with the SEC. The Company undertakes no duty or obligation to update any forward-looking statements contained in this report as a result of new information, future events or changes in its expectations.

Item 9.01 - Financial Statements and Exhibits.

(d) Exhibits.

<table>
<thead>
<tr>
<th>Exhibit No.</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>99.1</td>
<td>Sesen Bio, Inc. Corporate Presentation dated January 11, 2021</td>
</tr>
</tbody>
</table>
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: January 11, 2021

Sesen Bio, Inc.

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

   Thomas R. Cannell, D.V.M.
   President and Chief Executive Officer
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 impact of COVID-19 on our business, expectations regarding the timing of the submission of our MAA for Vicineum to the EMA, expectations regarding the timing of potential approval of our BLA submission by the FDA, 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, expectations regarding potential cost savings of Vicineum, 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 the timing of our anticipated clinical trial in connection with the LUMC agreement, 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.
1. Differentiated MOA and clinical profile creates opportunity for Vicineum to be best-in-class therapeutic

2. Clear regulatory path forward for potential approval in US in 2021 and Europe in 2022

3. Significant global commercial opportunity; projected $1B - $3B peak revenue for Vicineum
OUR MISSION IS TO SAVE AND IMPROVE THE LIVES OF PATIENTS WITH CANCER

BLOOD IN URINE
- See PCP: therapeutic trial of antibiotics prescribed
- See blood in urine: try different antibiotic

DIAGNOSIS
- Cytology
- Bladder MRI
- Cystoscopy

REFERRER TO UROLOGIST
- Start tests
- Urologist visit

TREATMENT CHOICE
- Bladder removal
- See blood in urine: try different antibiotic
- Urologist visit
- Intravesical treatment (Urologist)
- Intravenous treatment (Medical Oncologist)

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

2020: A Year of Execution Excellence
Corporate Highlights

- Received PIP waiver from EMA
- Positive Pre-Submission meeting with EMA
- Advanced partnership with LUMC

**1Q 2020**
- Favorable market research results vs. Keytruda
- Favorable Scientific Advice from EMA (CMC)

**2Q 2020**
- Signed 1st OUS deal with Qilu for Greater China
- Completed DS PPQ campaign
- Positive analytical comparability data

**3Q 2020**
- Signed OUS deal with Hema for MENA
- Favorable Scientific Advice from EMA (Clinical)
- Completed DP PPQ campaign

**4Q 2020**
- Signed agreement with Qilu as additional CMO
- Submitted BLA to FDA

CMO=Chemistry, manufacturing and controls; EMA=European Medicines Agency; PIP=Paediatric Investigation Plan; DS=Drug Substance; PPQ=Process Performance; OUS=Outside of the United States; DP=Drug Product; MENA=Middle East and North Africa; CMO=Commercial Manufacturing Organization; LUMC=Leiden University Medical Center; BLA=Biologic License Application; FDA=Food and Drug Administration
There is a Significant Unmet Need for Patients with Bladder Cancer with Limited Treatment Options Available

<table>
<thead>
<tr>
<th>Common Types of Cancer</th>
<th>Estimated New Cases 2020</th>
<th>Estimated Deaths 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Breast Cancer (Female)</td>
<td>276,480</td>
<td>42,690</td>
</tr>
<tr>
<td>2. Lung and Bronchus Cancer</td>
<td>228,820</td>
<td>135,720</td>
</tr>
<tr>
<td>3. Prostate Cancer</td>
<td>191,930</td>
<td>33,330</td>
</tr>
<tr>
<td>4. Colorectal Cancer</td>
<td>147,950</td>
<td>53,200</td>
</tr>
<tr>
<td>5. Melanoma of the Skin</td>
<td>100,350</td>
<td>6,850</td>
</tr>
<tr>
<td>6. Bladder Cancer</td>
<td>81,400</td>
<td>17,980</td>
</tr>
<tr>
<td>7. Non-Hodgkin Lymphoma</td>
<td>77,240</td>
<td>19,940</td>
</tr>
<tr>
<td>8. Kidney and Renal Pelvis Cancer</td>
<td>73,750</td>
<td>14,830</td>
</tr>
<tr>
<td>9. Uterine Cancer</td>
<td>65,620</td>
<td>12,590</td>
</tr>
<tr>
<td>10. Leukemia</td>
<td>60,530</td>
<td>23,100</td>
</tr>
</tbody>
</table>

Bladder Cancer represents 4.5% of all new cancer cases in the U.S.

Vicineum has a Highly Differentiated Dual Mechanism of Action (MoA)
An Important Advancement in the Category of Precision Oncology

- 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

Dual MoA

1. Selectively targets EpCAM to destroy cancer cells by immunogenic cell death
2. Immunogenic cell death activates a T cell-mediated immune response to attack the tumor

Based on preclinical studies, we believe Vicineum works via a dual mechanism of action.
### 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

---


Source: Phase III data as of May 26, 2019 data cut.

For additional information regarding Phase III clinical trial data please refer to slides 33-34.
### Partnership Opportunity with LUMC Further Supports the Targeting Specificity of Vicineum

**Imaging Agent** is designed to delineate tumor from normal tissue during surgery.

<table>
<thead>
<tr>
<th>Cancer Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colorectal</td>
<td>Imaging agent being co-developed by LUMC and Sesen Bio</td>
</tr>
<tr>
<td></td>
<td>Comprised of an antibody fragment of Vicineum and an imaging molecule supplied by LUMC</td>
</tr>
<tr>
<td>Gastric</td>
<td>Successful Phase 1/2 clinical trial by LUMC with favorable tolerability and demonstrated tumor detection</td>
</tr>
<tr>
<td>Esophageal</td>
<td>Agreement signed on December 8, 2020 providing Sesen Bio the option to obtain an exclusive, worldwide, license</td>
</tr>
<tr>
<td>Cancer</td>
<td>Next clinical trial anticipated to begin after the anticipated approval of Vicineum for NMIBC in mid-2021</td>
</tr>
</tbody>
</table>

LUMC = Leiden University Medical Center, the university hospital affiliated with Leiden University. LUMC is a modern university medical center for research, education and patient care, located in Leiden, Netherlands.
Favorable Cost-Effectiveness Profile for Vicineum Based on the Final Evidence Report Issued by the Institute for Clinical and Economic Review (ICER)

Overview:
- ICER is the leading Health Technology Assessment body in the United States, and is an independent non-profit, research organization that conducts assessments to examine the clinical and economic value of health care innovations such as prescription medications
- On December 17, 2020, ICER issued their final report on the cost-effectiveness and value of Vicineum

Key Findings:
- Vicineum was found to be superior to best supportive care
  - ICER Council voted 8 to 3 in favor of Vicineum
- Treatment with Vicineum results in a decrease in cumulative health care costs compared to usual care of approximately $101,000 by year five
- Vicineum demonstrates Complete Response and Recurrence-Free Survival rates that appear to be greater than would be expected, based on historical data

We will continue to work with payers to reduce healthcare costs while improving patient care

Note: All clinical data presented in this corporate presentation is consistent with the findings published in the final ICER report.
BLA Finalized and Submitted to the FDA on December 18, 2020
Positive Analytical Comparability Data Led to BLA Completion

Updated December 2020
- General corporate information
- Patent information and exclusivity
- Waivers
- Draft Label
- Risk management plan
- Draft carton and container labels

Submitted December 2020
- Introduction to summary
- Quality overall summary
- Non-clinical overview
- Clinical overview
- Non-clinical written and tabulated summaries
  - Pharmacology
  - Pharmacokinetics
  - Toxicology
- Clinical summaries
  - Biopharmaceutical studies
  - Pharmacology studies
  - Clinical Efficacy
  - Clinical Safety
- Phase 3 clinical assays
  - Description of assays and validation
  - Summary of sample analysis results

Submitted December 2019
- Drug substance
  - Manufacturer
  - Facility information
  - Batch records
  - Validation Master Plans
- Drug product
  - Manufacturer
  - Facility information
  - Batch records
  - Validation master plans
- Analytical comparability study utilizing DS and DP PPQ data
- Analytical method validation

- List of clinical studies
- Phase 1, 2 and 3 Clinical Study Reports
- Integrated Summary of Efficacy
- Integrated Summary of Safety
- Case Report Forms
Completion of Vicineum BLA Submission in December 2020

Oncology Products Reviewed by FDA 2006 - 2015

<table>
<thead>
<tr>
<th>Phase</th>
<th>Probability of Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Products at end of Phase I</td>
<td>5%</td>
</tr>
<tr>
<td>Products at end of Phase II</td>
<td>8%</td>
</tr>
<tr>
<td>Products at end of Phase III</td>
<td>33%</td>
</tr>
<tr>
<td>Products with BLA Submission</td>
<td>82%</td>
</tr>
</tbody>
</table>

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.

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

**US**
- BLA completion
- FDA accepts BLA
- BLA approval
- Early commercial success

- 4Q 20
- 1Q 21
- 2Q 21
- 3Q 21
- 4Q 21
- 1Q 22
- 2Q 22

**Europe**
- MAA submission
- HTA/NICE evaluations
- MAA approval

BLA=Biologics License Application; MAA=Marketing Authorization Application; HTA=Health Technology Assessment; NICE=National Institute for Clinical Excellence
Potential for Peak Revenue of $1B - $3B Globally for Vicineum

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

- 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 in the US

- Highly concentrated US market of ~1,500 Urologists treating ~75% of BCG patients allows for efficient targeting
  - Estimated 40-50 sales representatives required in the US
  - Allows for efficient digital/social strategies to activate patients/caregivers

Source: Sesen Bio Qualitative market research, Urologist IDIs June 2019, n = 30
Key partnership with leading partner in MENA
Hikma Pharmaceuticals Profile

- Multi-national pharma company specializing in the development and commercialization of a broad range of high-quality medicines across the US, the MENA and Europe
- Public company headquartered in London with a market cap of >$6B and >$2B in annual revenue
- Global experts with a local presence:
  - Operations in >50 countries
- Fifth largest pharma company in the MENA region
  - Trusted and leading licensing partner in the MENA region
  - Extensive regulatory affairs capabilities
- ~2,000 sales and marketing employees in the MENA region
Significant Milestones Achieved through Qilu Pharmaceutical Partnership
Overview of Key Progress

• $12M upfront received on September 29, 2020

• CMO framework agreement signed on December 4, 2020
  • Helps to ensure reliable global supply and creates opportunity for a reduction in COGS

• $3M milestone expected upon IND approval by the CDE

• Tech transfer has been initiated and is on track for completion in mid-2021
  • $2M milestone expected upon completion

Note: Dollar amounts shown on this slide are presented as gross proceeds before deductions.
We Estimate the OUS Opportunity for Vicineum is Roughly Double the US Geography Peak Year Revenue Opportunity for Vicineum (captures 80% of variance)

<table>
<thead>
<tr>
<th>Geography</th>
<th>Peak Year Revenue Opportunity for Vicineum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Europe</td>
<td>$450M - $1,125M</td>
</tr>
<tr>
<td>United States(^*)</td>
<td>$423M - $942M</td>
</tr>
<tr>
<td>MENA(^\checkmark)</td>
<td>$158M - $420M</td>
</tr>
<tr>
<td>China(^\checkmark)</td>
<td>$155M - $418M</td>
</tr>
<tr>
<td>Rest of Asia (incl. Japan)</td>
<td>$109M - $282M</td>
</tr>
<tr>
<td>Latin America</td>
<td>$51M - $150M</td>
</tr>
<tr>
<td>Canada</td>
<td>$28M - $81M</td>
</tr>
<tr>
<td>Oceania(^**)</td>
<td>$17M - $53M</td>
</tr>
<tr>
<td>Total</td>
<td>$1,391M - $3,471M</td>
</tr>
</tbody>
</table>

\(^*\)Sesen Bio to commercialize in the United States
\(^**\)Australia, New Zealand, Micronesia, Polynesia

Note: The peak year sales ranges above were calculated using a Monte Carlo revenue simulation model using the inputs listed on backup slides 72-74; the model calculated a range of alternative futures and possibilities. Peak year sales presented capture 80% of uncertainty (10th-90th percentiles) related to commercial risk, and assumes regulatory approval is granted in each country/region.
2020 Financial Highlights
Strengthening the Balance Sheet while Minimizing Dilution

<table>
<thead>
<tr>
<th></th>
<th>YE 2019</th>
<th>YE 2020</th>
<th>% Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash, cash equivalents and</td>
<td>$48M</td>
<td>$55M(^1)</td>
<td>+15%</td>
</tr>
<tr>
<td>restricted cash</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stock price</td>
<td>$1.04</td>
<td>$1.35</td>
<td>+30%</td>
</tr>
<tr>
<td>Market cap</td>
<td>$111M</td>
<td>$190M</td>
<td>+71%</td>
</tr>
</tbody>
</table>

- No outstanding debt
- ~$44M\(^2\) available on an $85M ATM facility administered by Jefferies

\(^1\)Amount is preliminary, has not been audited and is subject to change upon completion of the Company’s audited financial statements for the year ended December 31, 2020.
\(^2\)As of 12/31/2020
SESEN BIO HIGHLIGHTS

1. Differentiated MOA and clinical profile creates opportunity for Vicineum to be best-in-class therapeutic

2. Clear regulatory path forward for potential approval in US in 2021 and Europe in 2022

3. Significant global commercial opportunity; projected $1B - $3B peak revenue for Vicineum
THANK YOU
## Senior Management

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thomas Cannell, DVM</td>
<td>President, CEO and Director</td>
</tr>
<tr>
<td>Monica Forbes</td>
<td>Chief Financial Officer</td>
</tr>
<tr>
<td>Glen MacDonald, Ph.D.</td>
<td>Chief Technology Officer</td>
</tr>
<tr>
<td>Erin Clark</td>
<td>Vice President, Corporate Strategy and Investor Relations</td>
</tr>
<tr>
<td>Mark Sullivan</td>
<td>General Counsel and Corporate Secretary</td>
</tr>
<tr>
<td>Omar Rifi</td>
<td>Vice President, Business Development and Alliance Management</td>
</tr>
<tr>
<td>Louise Stojiljch</td>
<td>Commercial Advisor</td>
</tr>
<tr>
<td>Jeannick Ciezau, Ph.D.</td>
<td>Head of Research</td>
</tr>
<tr>
<td>Jeannette Kohlbrenner</td>
<td>Human Resources Advisor</td>
</tr>
</tbody>
</table>

## Board of Directors

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jay Duker, M.D.</td>
<td>Chair of the Board of Directors</td>
</tr>
<tr>
<td>Carrie L. Bourdow</td>
<td>Director</td>
</tr>
<tr>
<td>Thomas Cannell, DVM</td>
<td>President, CEO and Director</td>
</tr>
<tr>
<td>Jane V. Henderson</td>
<td>Director</td>
</tr>
<tr>
<td>Jason Keyes</td>
<td>Director</td>
</tr>
</tbody>
</table>
## Appendix - Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Slide number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unmet Medical Need</td>
<td>23-26</td>
</tr>
<tr>
<td>Dual Mechanism of Action</td>
<td>27-29</td>
</tr>
<tr>
<td>Regulatory</td>
<td>30-32</td>
</tr>
<tr>
<td>Clinical Data</td>
<td>33-54</td>
</tr>
<tr>
<td>Commercial Opportunity</td>
<td>55-74</td>
</tr>
<tr>
<td>Manufacturing &amp; Supply Chain</td>
<td>75-80</td>
</tr>
<tr>
<td>Intellectual Property</td>
<td>81-82</td>
</tr>
</tbody>
</table>
Unmet Medical Need
Significant Unmet Medical Need in NMIBC

Bladder cancer is the 6th most prevalent cancer in the US, of which 75%-85% is NMIBC\(^2,3\)

Bladder cancer is the most expensive cancer to treat in the US with projected costs of \sim \$6B by 2020\(^4\)

One of the worst patient experiences among common cancers

Survival rates for bladder cancer have decreased in recent years in the UK, during which time there was also a BCG shortage\(^5\)

---

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

**Your Bladder: An Essential Organ**
- Self-controlled storage organ in the body
- Holds urine for release so the body is not exposed to harmful toxins and waste
- Part of the urinary system; partners with lungs, skin, and intestines to keep chemicals and water in the body balanced and healthy
- Integrated with male and female reproductive systems

**Radical Cystectomy: Life-Altering 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.

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.

Sanofi suspends production of BCG Connaught strain during facility renovations.

Merck announces shortages of BCG Tice strain.

Sanofi discontinues all global production of BCG Connaught strain.

Merck announces supply constraints of BCG Tice strain expected to last throughout 2020.

FerGene receives a complete response letter for Adstiladrin for multiple CMC and manufacturing issues.

Merck is constructing a new facility that may expand BCG production; anticipated completion in 2025/2026.

Sources and Additional Information:
Dual Mechanism of Action
Vicineum has a Highly Differentiated Mechanism of Action

**Mechanism 1: Kills cell directly**
- Vicineum selectively targets EpCAM on cancer cells while generally leaving healthy cells alone.
- Vicineum causes immunogenic cell death by triggering damage-associated molecular patterns (DAMPs).

**Mechanism 2: Activates immune system**
- T cells recognize neoantigen and kill cancer cells.
- T cell proliferation.
- Neotrogen presentation and T cell activation.
- APC Activation.

For illustrative purposes only. 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 2nd non-injected tumor

**Clinical Evidence**

<table>
<thead>
<tr>
<th>Pre-treatment</th>
<th>After 4wks on treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PATIENT A:</strong></td>
<td></td>
</tr>
<tr>
<td>Injected Tumor</td>
<td></td>
</tr>
<tr>
<td><strong>PATIENT B:</strong></td>
<td></td>
</tr>
<tr>
<td>Non-Injected Tumor</td>
<td>Injected Tumor</td>
</tr>
</tbody>
</table>

Presented at AACR, 2017
Regulatory
Our long-term relationship with the FDA has allowed us to shape our nonclinical and clinical programs in alignment with the agency guidance.

<table>
<thead>
<tr>
<th>2018 FDA Guidance</th>
<th>Vicineum Clinical Program</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Conduct nonclinical studies to assess toxicity in animal models</td>
<td>✔</td>
</tr>
<tr>
<td>• Conduct nonclinical studies to demonstrate anti-tumor activity</td>
<td>✔</td>
</tr>
<tr>
<td>• Conduct nonclinical studies to determine optimal dose and schedule</td>
<td>✔</td>
</tr>
<tr>
<td>• Examine anti-tumor activity and optimal dose schedule in early phase clinical trial</td>
<td>✔</td>
</tr>
<tr>
<td>• Papillary cohort endpoint of recurrence-free survival (time to event endpoint)</td>
<td>✔</td>
</tr>
<tr>
<td>• CIS studied in single-arm trial with CRR &amp; DoR as primary endpoints</td>
<td>✔</td>
</tr>
<tr>
<td>• Papillary cohort not in primary efficacy endpoint</td>
<td>✔</td>
</tr>
<tr>
<td>• Prefer intravesical vs. systemic administration</td>
<td>✔</td>
</tr>
<tr>
<td>• Specifically define trial entry criteria</td>
<td>✔</td>
</tr>
<tr>
<td>• Definition of BCG-unresponsive disease</td>
<td>✔</td>
</tr>
<tr>
<td>• 2004 WHO classification for tumor grading</td>
<td>✔</td>
</tr>
<tr>
<td>• Central pathology review of biopsy tissue and urine cytology</td>
<td>✔</td>
</tr>
<tr>
<td>• Collect data on patients’ previous anti-cancer therapies</td>
<td>✔</td>
</tr>
<tr>
<td>• Enroll patients who reflect clinically relevant patient population</td>
<td>✔</td>
</tr>
<tr>
<td>• Optimize risk-benefit balance with dose selection</td>
<td>✔</td>
</tr>
<tr>
<td>• Definition of CRR</td>
<td>✔</td>
</tr>
<tr>
<td>• Collect time to cysectomy data</td>
<td>✔</td>
</tr>
<tr>
<td>• Lower bound of 95% confidence interval rules out clinically unimportant CRR</td>
<td>✔</td>
</tr>
<tr>
<td>• Nonclinical studies to determine need for evaluation of systemic toxicity</td>
<td>✔</td>
</tr>
<tr>
<td>• Consistent efficacy and safety data across Phase I, II and III trials</td>
<td>✔</td>
</tr>
</tbody>
</table>

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 for 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
Clinical Data
Vicineum demonstrates a strong benefit-risk profile in our Phase III Trial

**Efficacy**
- Complete Response Rate
- Duration of Response
- Time to Disease Recurrence
- Time to Cystectomy
- Progression-Free Survival
- Event-free Survival
- Overall Survival

**Surrogate Endpoints**

**Risk**
- Safety and Tolerability
  - Selectively targets cancer cells while generally avoiding healthy cells
  - Favorable profile relative to BCG, Valstar, checkpoint inhibitors
  - No dose or age-related increase in AEs
  - Intravesical administration

**Benefit**

**Health Outcomes**

**2018 FDA Guidance:** The approval of a marketing application is based on a favorable risk-benefit assessment

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

<table>
<thead>
<tr>
<th>CHARACTERISTICS</th>
<th>COHORT 1</th>
<th>COHORT 2</th>
<th>COHORT 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>CIS that was refractory or recurred within 6 months of adequate BCG</td>
<td>86</td>
<td>7</td>
<td>40</td>
</tr>
<tr>
<td>CIS that recurred &gt;6 months but ≤11 months of adequate BCG</td>
<td>86</td>
<td>7</td>
<td>40</td>
</tr>
<tr>
<td>Papillary tumors (without CIS) that recurred within 6 months of adequate BCG</td>
<td>86</td>
<td>7</td>
<td>40</td>
</tr>
</tbody>
</table>

| 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 | 3 (range 2-13) | 16 (range 8-45) | 3 (range 2-13) |
| BCG cycles (courses) | 1 (range 0-23) | 4 (range 0-28) | 15 (range 7-48) |
| BCG cycles (instillations) | 1 (range 0-6) | 4 (range 0-10) |
| Intravesical chemotherapy | 1 (range 0-23) | 4 (range 0-28) | 1 (range 0-6) |
| TURBT | 1 (range 0-23) | 4 (range 0-28) | 1 (range 0-6) |

TURBT: transurethral resection of bladder tumor

Note: Data are as of May 29, 2019 data cut.
## Compelling Clinical Data Set

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>How Endpoint is Measured</th>
<th>Results</th>
</tr>
</thead>
</table>
| **Complete Response Rate (CRR)** | Defined as the proportion of patients who show no evidence of high-risk disease, or disease progression (e.g., T2 or more advanced disease). | - 46% CRR at 3 months  
- Lower bound of 95% CI rules out clinically meaningful CRR  
- Higher complete response rate in patients receiving Bacillus Calmette-Guérin (BCG)** |
| **Duration of Response (DoR)** | Defined as the time from complete response to treatment failure. | - 52% duration of 9 months (12 months of therapy)  
- 39% duration of 15 months or greater (18 months of therapy)  
- The longer the DoR, the higher the probability of remaining disease-free |
| **Time to Disease Recurrence** | **Secondary Endpoint**  
**Papillary patients** | Defined as the time from the date of first dose of study treatment to treatment failure. | - Median time to recurrence is 402 days  
- 50% probability of remaining recurrence-free for 12 months  
- 37% probability of remaining recurrence-free for 24 months or greater |
| **Time to Cystectomy (TtC)** | **Secondary Endpoint**  
**All Cohorts** | Defined as the time from the date of first dose of study treatment to surgical bladder removal. | - 74% of patients are cystectomy-free for 3 years  
- Responders have an 80% probability of remaining cystectomy-free at 3 years  
- Average responder remains cystectomy-free for 1,035 days vs. 631 days for non-responders |
| **Progression-Free Survival (PFS)** | **Secondary Endpoint**  
**All Cohorts** | Defined as the time from the date of first dose of study treatment to disease progression (e.g., T2 or more advanced disease) or death as a first event. | - 96% of patients are progression-free at 12 months  
- 90% of patients are progression-free for 24 months or greater  
- Median PFS has not been reached |
| **Event-Free Survival (EFS)** | **Secondary Endpoint**  
**All Cohorts** | Defined as the time from the date of first dose of study treatment to treatment failure or death as a first event. | - 39% of patients are event-free at 12 months  
- 25% of patients remain event-free at 18 months  
- 21% of patients remain event-free for 24 months or greater |
| **Overall Survival (OS)** | **Secondary Endpoint**  
**All Cohorts** | Defined as the time from the date of first dose of study treatment to death from any cause. | - Overall survival is 98% at 12 months  
- Overall survival is 98% for 24 months or greater vs. 94% for general population at 3 years |
| **Safety** | **Secondary Endpoint**  
**All Cohorts** | Full review of all safety data from Phase III | - 3% treatment-related SAEs  
- 4% treatment-related Grade 3-5 AEs  
- Increased dosing in Phase III did not increase severity or frequency of AEs |
| **Tolerability** | **Secondary Endpoint**  
**All Cohorts** | Full review of all tolerability data from Phase III | - AEs generally low grade  
- Low rate of discontinuations for AEs  
- No age-related increase in AEs |

Note: Data 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.

40% of patients had a complete response
43% of patients had a partial response
17% of patients had no response

*Note: Data are from Phase II clinical trial, n=45. 45% of patients had a complete response at 3 months; 60% of patients did not have a complete response and, of those, 71% of patients had a partial response. Partial response, as measured by bladder mapping, is defined by non-complete response patients who had either a reduction in tumor size or did not experience an increase in bladder area affected. Bladder mapping was not done as part of the Phase III trial, therefore partial response data are not available.
Duration of Response: 52% of CIS patients who had a complete response at 3 months remained disease-free for a total of 12 months after starting treatment.

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

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 all-hazards analysis of pooled results of patients in cohorts 1&2. Median duration of response for the primary endpoint, Cohort 1 (n=186) is 273 days (95% CI=122-NE), and duration of response for Cohort 2 (n=8) is 290 days (95% CI=147-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.

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.

<table>
<thead>
<tr>
<th>Duration</th>
<th>Probability of Maintaining Complete Response (CR) for at Least One Additional Year*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 0</td>
<td>17%</td>
</tr>
<tr>
<td>CR at 3 months</td>
<td>42%</td>
</tr>
<tr>
<td>CR at 6 months</td>
<td>50%</td>
</tr>
<tr>
<td>CR at 9 months</td>
<td>61%</td>
</tr>
<tr>
<td>CR at 12 months</td>
<td>74%</td>
</tr>
</tbody>
</table>

*Data reflect an ad hoc analysis of pooled results of patients in cohorts 1 & 2.
Time to Disease Recurrence: 50% of high-risk papillary patients who were treated with Vicineum are disease-free at 1 year.

Median time to recurrence is 402 days per Kaplan-Meier estimate (13.2 months).

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

Legend:
- KM Estimate
- Censored
- 95% CI

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 <196 – 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 cohorts 3 (n = 40) with high-grade T2 or T3 tumors (without CIS) in the absence of adequate BCG.
2018 FDA Guidance: The goal of therapy in patients with BCG-unresponsive NMIBC is to avoid cystectomy.

Highly Differentiated Time to Cystectomy Data vs. Currently Available Agents
76% of patients are cystectomy-free for 3 years

Time to cystectomy: defined as the time from the date of first dose of study treatment to surgical bladder removal. Data reflects 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, Peterjoe S, et al., 2013

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. Statistically significant difference for responders vs. non-responders: \( p < 0.001 \).

*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).*

---

**Legend:**
- Responders
- Non-responders
- Censored

<table>
<thead>
<tr>
<th>KM Evaluable</th>
<th>Responder Patients</th>
<th>Non-responder Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time from start of treatment (months)</td>
<td>63</td>
<td>70</td>
</tr>
<tr>
<td>0</td>
<td>63</td>
<td>64</td>
</tr>
<tr>
<td>3</td>
<td>63</td>
<td>50</td>
</tr>
<tr>
<td>6</td>
<td>50</td>
<td>42</td>
</tr>
<tr>
<td>9</td>
<td>53</td>
<td>34</td>
</tr>
<tr>
<td>12</td>
<td>29</td>
<td>21</td>
</tr>
<tr>
<td>15</td>
<td>34</td>
<td>15</td>
</tr>
<tr>
<td>18</td>
<td>23</td>
<td>10</td>
</tr>
<tr>
<td>21</td>
<td>13</td>
<td>6</td>
</tr>
<tr>
<td>24</td>
<td>9</td>
<td>0</td>
</tr>
<tr>
<td>27</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>30</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>33</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>36</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>27</td>
<td>13</td>
<td>9</td>
</tr>
<tr>
<td>30</td>
<td>27</td>
<td>15</td>
</tr>
<tr>
<td>33</td>
<td>21</td>
<td>10</td>
</tr>
<tr>
<td>36</td>
<td>13</td>
<td>6</td>
</tr>
<tr>
<td>0</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>0</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>0</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

---

43
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)

<table>
<thead>
<tr>
<th>Survival Estimates</th>
<th>Patients on VISTA Trial</th>
<th>General Population¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 year</td>
<td>98%</td>
<td>97%</td>
</tr>
<tr>
<td>2 years</td>
<td>96%</td>
<td>94%</td>
</tr>
</tbody>
</table>

¹U.S. Social Security Administration Actuarial Life Table (https://www.ssa.gov/oact/STATS/table404.html). Based on probability of dying within one year and weighted to match VISTA trial population demographics.
Preliminary Phase II vs. Phase III Complete Response Rate

<table>
<thead>
<tr>
<th>Time Point</th>
<th>Phase II Pooled CRR (95% Confidence Interval)</th>
<th>Phase III Pooled CRR (95% Confidence Interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 months</td>
<td>40% (26%-56%)</td>
<td>40% (30%-51%)</td>
</tr>
<tr>
<td>6 months</td>
<td>27% (15%-42%)</td>
<td>28% (19%-39%)</td>
</tr>
<tr>
<td>6 months</td>
<td>18% (8%-32%)</td>
<td>21% (13%-31%)</td>
</tr>
<tr>
<td>12 months</td>
<td>16% (7%-30%)</td>
<td>17% (10%-26%)</td>
</tr>
</tbody>
</table>

**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

<table>
<thead>
<tr>
<th>Time Point</th>
<th>Evaluable Patients</th>
<th>Complete Response Rate (95% Confidence Interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3-months</td>
<td>n=82</td>
<td>39% (28%-50%)</td>
</tr>
<tr>
<td>6-months</td>
<td>n=82</td>
<td>26% (17%-36%)</td>
</tr>
<tr>
<td>9-months</td>
<td>n=82</td>
<td>20% (12%-30%)</td>
</tr>
<tr>
<td>12-months</td>
<td>n=82</td>
<td>17% (10%-27%)</td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th>Time Point</th>
<th>Evaluable Patients</th>
<th>Complete Response Rate (95% Confidence Interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3-months</td>
<td>n=7</td>
<td>57% (18%-90%)</td>
</tr>
<tr>
<td>6-months</td>
<td>n=7</td>
<td>57% (18%-90%)</td>
</tr>
<tr>
<td>9-months</td>
<td>n=7</td>
<td>43% (10%-82%)</td>
</tr>
<tr>
<td>12-months</td>
<td>n=7</td>
<td>14% (0%-58%)</td>
</tr>
</tbody>
</table>

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)

<table>
<thead>
<tr>
<th>Time Point</th>
<th>Evaluable Patients</th>
<th>RF Rate (95% Confidence Interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3-months</td>
<td>n=38</td>
<td>71% (54%-85%)</td>
</tr>
<tr>
<td>6-months</td>
<td>n=38</td>
<td>58% (41%-74%)</td>
</tr>
<tr>
<td>9-months</td>
<td>n=38</td>
<td>45% (29%-62%)</td>
</tr>
<tr>
<td>12-months</td>
<td>n=38</td>
<td>42% (26%-55%)</td>
</tr>
</tbody>
</table>

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.
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

<table>
<thead>
<tr>
<th>Category</th>
<th>Phase II Patients (%)</th>
<th>Phase III Patients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any AE</td>
<td>43 (94%)</td>
<td>117 (88%)</td>
</tr>
<tr>
<td>Grade 3-5 AEs</td>
<td>9 (20%)</td>
<td>29 (22%)</td>
</tr>
<tr>
<td>Treatment-related AEs</td>
<td>30 (65%)</td>
<td>66 (50%)</td>
</tr>
<tr>
<td>Treatment-related Grade 3-5 AEs</td>
<td>3 (7%)</td>
<td>5 (4%)</td>
</tr>
<tr>
<td>Any SAE</td>
<td>6 (13%)</td>
<td>19 (14%)</td>
</tr>
<tr>
<td>Treatment-related SAEs</td>
<td>0 (0%)</td>
<td>3 (2%)</td>
</tr>
<tr>
<td>Discontinuations due to AEs</td>
<td>0 (0%)</td>
<td>4 (3%)</td>
</tr>
</tbody>
</table>

Vicineum Treatment Exposure:

<table>
<thead>
<tr>
<th></th>
<th>Phase II</th>
<th>Phase III</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average Instillations per Patient</td>
<td>12</td>
<td>27</td>
</tr>
<tr>
<td>Average Duration of Exposure (days)</td>
<td>147</td>
<td>240</td>
</tr>
</tbody>
</table>

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, grade 3 acute kidney injury, and grade 2 pyrexia.

- 90-year-old man started the trial Mar. 2016, in Mar. 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.
- Increased dosing and duration of exposure does not appear to lead to an increase in incidence or severity of AEs.
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

![Graph showing mean AEs and treatment-related adverse events across different age groups.]

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 0-12).
Vicineum confidence interval above FDA success criterion based upon complete response of other agents in patients with Carcinoma *in situ*

For Keytruda 3-month CRR:
- Overall: 50% (95% CI: 41% - 59%)
- U.S. Patients: 48% (95% CI: 39% - 57%)

For Vicineum 3-month CRR:
- Overall: 51% (95% CI: 41% - 60%)
- U.S. Patients: 53% (95% CI: 43% - 62%)

20% success criterion for the primary hypothesis test.

Data are as of May 29, 2019 data cut from the Phase III VISTA trial. 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.
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 a 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.
HEAD AND NECK CANCER: Difficult-to-Treat & Dominated by Primary Tumor

- Head and neck cancer affects >650,000 people worldwide; ~350,000 deaths each year¹
- 90% are squamous cell carcinomas of the head and neck (SCCHN)¹
  - Two-thirds diagnosed with advanced disease and severe prognosis
- High risk of recurrence and frequent metastases and development of second primary tumor¹
- Low rate (~50%) of 5-year survival and limited benefit with combo chemotherapy²
- Surgery remains SOC - highly invasive and associated with significant morbidity²
- Recurrent SCCHN after multimodal local treatment generally considered incurable²
- Two checkpoint inhibitors currently approved for treatment of SCCHN³,⁴

² OPOVI® (nivolumab) prescribing information. KEYTRUDA® (pembrolizumab) prescribing information
³ OPDIVO® (nivolumab) prescribing information. KEYTRUDA® (pembrolizumab) prescribing information
PHASE 1 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 µg or 700 µg via intratumoral injection; 700 µg established as RP2D
- Well-tolerated; pain at injection site reported as most common AE
- Reduction in bi-directional size of principle targeted tumor observed in 71% (10/14) of evaluable patients
- RECIST criteria not employed
- Growth control of initial treated tumor achieved in four 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.

<table>
<thead>
<tr>
<th>PRODUCT CANDIDATE</th>
<th>PAYLOAD</th>
<th>INDICATION</th>
<th>PRECLINICAL</th>
<th>Ph I</th>
<th>Ph II</th>
<th>Ph III</th>
<th>BLA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vicineum</td>
<td>ETA</td>
<td>BCG-unresponsive high-risk NMIBC</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vicineum</td>
<td>ETA</td>
<td>SCCHN</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vicineum + Durvalumab</td>
<td>ETA &amp; IO</td>
<td>BCG-unresponsive high-risk NMIBC</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vicineum (Combination with checkpoint inhibitor)</td>
<td>ETA &amp; IO</td>
<td>SCCHN</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

We have deferred further development of Vicineum, for the treatment of squamous cell carcinomas 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, exosome A; IO, immune-escape agent.
Commercial Opportunity
Virtuous Cycle: High possibility that all three key segments are advocates & take action

Physicians (Ancillary HCPs)
- Reimburse and advocate for appropriate use of Vicineum
- Advocate for product reimbursement

Patients (Caregivers/families)
- Ask doctor for Vicineum
- Encourage use of Vicineum before RC

Payers (Private/public)
- Advocate for product reimbursement

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=36) 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
Vicineum has the Potential to Provide Continuity of Care for Patients with NMIBC

<table>
<thead>
<tr>
<th>Treatment Protocol</th>
<th>BCG</th>
<th>Vicineum</th>
<th>Checkpoint Inhibitors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment at Urology office</td>
<td>✓</td>
<td>✓</td>
<td>✗</td>
</tr>
<tr>
<td>Directed by Urologist</td>
<td>✓</td>
<td>✓</td>
<td>✗</td>
</tr>
<tr>
<td>Administration by Urology nurse</td>
<td>✓</td>
<td>✓</td>
<td>✗</td>
</tr>
<tr>
<td>Bladder infusion via urinary catheter</td>
<td>✓</td>
<td>✓</td>
<td>✗</td>
</tr>
<tr>
<td>2-hour infusion, hold, and rotation</td>
<td>✓</td>
<td>✓</td>
<td>✗</td>
</tr>
</tbody>
</table>

Source: Sesen Bio Qualitative market research, Urologist IDIs June 2019, n = 30.
<table>
<thead>
<tr>
<th></th>
<th>Vicineum Profile (Phase III Data)</th>
<th>Keytruda Profile (Phase II Data)</th>
<th>Tecentriq Profile (Phase II Data)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Efficacy</strong></td>
<td>N=89</td>
<td>N=102</td>
<td>N=73</td>
</tr>
<tr>
<td><strong>Complete Response Rate</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• At 3 Months</td>
<td>40% (CI: 30-51)</td>
<td>41% (CI: 32-51)</td>
<td>41% (CI: 30-53)</td>
</tr>
<tr>
<td>• At 12 Months</td>
<td>17%</td>
<td>20%</td>
<td>No data reported</td>
</tr>
<tr>
<td>• At 18 Months</td>
<td>15%</td>
<td>13%</td>
<td>No data reported</td>
</tr>
<tr>
<td><strong>Time to Cystectomy</strong></td>
<td>76% of patients were cystectomy-free at 36 months (n=133)</td>
<td>No data reported (not a clinical trial endpoint)</td>
<td>No data reported</td>
</tr>
<tr>
<td><strong>Safety</strong></td>
<td>N=133</td>
<td>N=102</td>
<td>N=73</td>
</tr>
<tr>
<td><strong>Treatment-Related Grade 3-5 AEs</strong></td>
<td>4%</td>
<td>13%</td>
<td>12%</td>
</tr>
<tr>
<td><strong>Discontinuation due to an AE</strong></td>
<td>3%</td>
<td>10%</td>
<td>No data reported</td>
</tr>
<tr>
<td><strong>Mode of Administration</strong></td>
<td>Intravesical</td>
<td>Intravenous</td>
<td>Intravenous</td>
</tr>
<tr>
<td><strong>Generally Administered by</strong></td>
<td>Urologist</td>
<td>Medical Oncologist</td>
<td>Medical Oncologist</td>
</tr>
</tbody>
</table>

2020 Market Research Results
High Prescribing Urologists Prefer Vicineum Profile

Intent-to-Prescribe
(Stated share of branded agents)*

<table>
<thead>
<tr>
<th></th>
<th>Vicineum Profile</th>
<th>Keytruda Profile</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of patients</td>
<td>83%</td>
<td>17%</td>
</tr>
</tbody>
</table>

Key Attributes

<table>
<thead>
<tr>
<th></th>
<th>Efficacy</th>
<th>Safety</th>
<th>Ease of integration</th>
<th>Interest in use of product</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average Rating</td>
<td>5.4</td>
<td>6.2</td>
<td>3.4</td>
<td>8.6</td>
</tr>
<tr>
<td>Extremely</td>
<td>9.0</td>
<td>8.2</td>
<td>8.2</td>
<td>8.6</td>
</tr>
</tbody>
</table>

Source: Emerging treatment in-depth interviews (IDIs) with high BCG-treated 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 ~88% 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 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 E2k with high BCG-missing 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 ≥5 Urologists

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

Price Reference (Annual Cost)

$200K

Keytruda

Opdivo

$150K

Tecentriq

$100K

Anticipated competitive pricing

$50K

$0K

Payer Management Responses to Pricing

Key:

- Unrestricted Coverage
- PA to Label
- PA to Trial
- Risk of Step Edit
- Not on Formulary

Sources:


*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

<table>
<thead>
<tr>
<th><strong>Checkpoint Inhibitors:</strong></th>
<th><strong>Second Line Monotherapies</strong></th>
<th><strong>Gene Therapy: Adenovirus Vectors</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Keytruda</td>
<td></td>
<td>Adstiladrin</td>
</tr>
<tr>
<td>• Approved for NMIBC January 2020</td>
<td>• Missed May PDUFA date</td>
<td>• Received a CRL from the FDA in May 2020 citing numerous CMC and manufacturing issues</td>
</tr>
<tr>
<td>• Reimbursed at $175,000/year with minimal payer restrictions</td>
<td>• Phase III trial enrollment started in October 2020; primary completion December 2022</td>
<td>• Same adenovirus serotype as Adstiladrin</td>
</tr>
</tbody>
</table>

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

**CG0070**
- Phase III trial enrollment started in October 2020; primary completion December 2022
- Same adenovirus serotype as Adstiladrin

### Combination Therapies

**Keytruda + BCG (Phase III)**
- Phase III trial initiated in December 2018
- Patients with “less than adequate” BCG
- BCG control arm to isolate treatment effect of BCG vs. Keytruda

### Recently Terminated Programs

#### Phase II Trials
- N-803 + BCG (Phase II)
  - BLA Filing 2H 2021 (CIS); Breakthrough Therapy Status
  - BLA Filing 2022 (TaT1)
- Enzalutamide
- NofilitageneVixteplasmid
- Rofaratinib

#### Phase III Trials
- Rapamycin
- Nanoxel
- Mitomycin C + Synergo

---

*JP Morgan Healthcare Conference (January 2020); Jefferies Virtual Health Conference (June 2020)
### Competitive Summary: BCG-Unresponsive NMIBC therapies

<table>
<thead>
<tr>
<th>Description</th>
<th>Vicineum</th>
<th>Keytruda</th>
<th>Adstiladrin</th>
<th>BCG + N-803</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Treatment</strong></td>
<td>Monotherapy</td>
<td>Monotherapy</td>
<td>Monotherapy</td>
<td>Combination Therapy***</td>
</tr>
<tr>
<td><strong>Report CR rate at discrete timepoints</strong></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓** (only reported cumulatively)</td>
</tr>
<tr>
<td><strong>Patient failures taken off therapy</strong></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓** (re-induction is allowed)</td>
</tr>
<tr>
<td><strong>Local and Central review of pathology</strong></td>
<td>✓</td>
<td>✓</td>
<td>✓** (local pathology only)</td>
<td>Not reported***</td>
</tr>
</tbody>
</table>

---

***No control arm to isolate the treatment effect of BCG vs. rIL-15 (therefore it is unclear how much of the benefit is simply due to BCG); Combination products involving BCG may be at significant risk during the long-standing BCG shortage

**This difference in study design or data presentation may overstate the reported Complete Response (CR) rate.
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
- CMO framework agreement signed on December 4, 2020 to support product supply for anticipated significant global demand for Vicineum
  - Tech transfer is in-process and is expected to be completed in mid-2021
  - $2M milestone payment to Sesen Bio expected upon completion

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
Partnership Opportunity in China:
Qilu Pharmaceutical Profile

- Top 10 Pharmaceutical Company in China with >$3B in annual revenue
- Extensive clinical experience
  - 2nd largest clinical team in Chinese Big Pharma
  - Focused on biosimilar and innovative drugs, with nearly 40 years of clinical development experience
- Significant oncology experience with a dedicated team of nearly 5,000 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 secondary 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**
Forecast Simulation Model Key Assumptions
US and OUS

US Inputs
- High-risk NMIBC patients unresponsive to BCG
- Estimated peak market share
- Approximate year 1 doses received
- Anticipated annual CMS ASP

OUS Inputs
- Prevalence (relative to US)
- Price (relative to US)

Output
Peak Revenue Opportunity for Vicineum: $1B - $3B

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

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

\(^1\)Seermen: 1)National Cancer Institute SEER Cancer Stat Fact: Bladder Cancer, 2019; and ClearView Analysis 1Q 2019.  
2)Emerging Treatment Idios with High BCG-Treating 
UROs, 1Q 2020, N=34.  
3)Phase III trial data as of May 29, 2019 data cut.  
4)Center for Medicare and Medicaid Services (CMS) Average Selling Price (ASP) Price List.
### Simulation Inputs: OUS Market

#### Estimated incidence relative to the US\(^1\)
(High-risk NMIBC patients unresponsive to BCG)

<table>
<thead>
<tr>
<th>Region</th>
<th>Lower Bound</th>
<th>Upper Bound</th>
</tr>
</thead>
<tbody>
<tr>
<td>Europe</td>
<td>1.1</td>
<td>1.3</td>
</tr>
<tr>
<td>China</td>
<td>1.6</td>
<td>1.8</td>
</tr>
<tr>
<td>MENA</td>
<td>0.2</td>
<td>0.4</td>
</tr>
<tr>
<td>Asia (incl. Japan)</td>
<td>0.8</td>
<td>1.0</td>
</tr>
<tr>
<td>Latin America</td>
<td>0.2</td>
<td>0.4</td>
</tr>
<tr>
<td>Canada</td>
<td>0.1</td>
<td>0.3</td>
</tr>
<tr>
<td>Oceania</td>
<td>0.05</td>
<td>0.2</td>
</tr>
</tbody>
</table>

#### Estimated price relative to the US\(^2\)
(Anticipated reimbursed price)

<table>
<thead>
<tr>
<th>Region</th>
<th>Lower Bound</th>
<th>Upper Bound</th>
</tr>
</thead>
<tbody>
<tr>
<td>Europe</td>
<td>0.44</td>
<td>0.84</td>
</tr>
<tr>
<td>China</td>
<td>0.20</td>
<td>0.60</td>
</tr>
<tr>
<td>MENA</td>
<td>0.66</td>
<td>1.06</td>
</tr>
<tr>
<td>Asia (incl. Japan)</td>
<td>0.29</td>
<td>0.69</td>
</tr>
<tr>
<td>Latin America</td>
<td>0.30</td>
<td>1.00</td>
</tr>
<tr>
<td>Canada</td>
<td>0.35</td>
<td>0.70</td>
</tr>
<tr>
<td>Oceania</td>
<td>0.35</td>
<td>0.70</td>
</tr>
</tbody>
</table>

Sources: Ferlay, Int. J. Canc, 2015; UN World Population Reports; SEER; GLOBOCAN; RedBook; Lauertaxe; Ameli; NICE; Vademecum; AIFA; NICE; CADTH; ANVISA; CBP; Danish Medicines Agency; The Pharmaceutical Benefits Scheme; South Food & Drug Authority; South African Medicine Price Registry; FiercePharma; ClearView Analysis. \(^1\)Relative incidence is calculated from total bladder cancer, and does not account for differences in the distribution of patients between NMIBC and MIBC.

\(^2\)Pricing multiplier is based on publicly available pricing information; averaged based on ex-manufacturer prices of Keytruda and Opdivo, and is likely to vary greatly for each pharmaceutical, and across different countries within each region. South Africa price multiplier was based on Keytruda only, as Opdivo has not yet been priced.
Appendix

Manufacturing & Supply Chain
Vicineum End-to-End Supply Chain

World-class manufacturing and distribution capabilities ensure execution excellence

- Vicineum Drug Substance manufacturer
- 7 commercial products launched from site where Vicineum is manufactured
  - 3 produced via E. coli
  - 2 oncology products
- 30+ years manufacturing biologics
- 325+ protein-based therapeutics in development and/or manufacturing
- Proven track record with FDA and worldwide regulatory agencies

- Vicineum Drug Product manufacturer
- >40 clinical and commercial oncology programs
  - >55 biologics
  - >5 commercial products
- 60+ years of experience in manufacturing of oncology products
- Proven track record with FDA and worldwide regulatory agencies

- 3PL services (storage, ordering and accounts receivable management)
- Best-in-class warehousing and transportation solutions
- Specialty pharmaceutical distribution
- Leading distributor of specialty pharmaceuticals with an extensive oncology portfolio, including Uro-oncology

- Shipment to accredited Urology clinics
- Board certified specialists for NMIBC care
- Patient visits same Urology clinic as for BCG administration
- Same treatment administration process for patient and HCP as for BCG

Our mission is to save and improve the lives of patients with NMIBC
Highly Reliable Manufacturing Process for Vicineum Cell Bank 2000 L E. coli Production

1: Q-Sepharose FF
2: Ni²⁺ IMAC
3: Q-Sepharose HP
4: CHT
5: Q-Sepharose HP

BDS Formulation (UF/DF for buffer exchange)

DP Fill Finish (7 mL @ 5mg/mL)

Cell Bank
Shake flask

2000 L E. coli Production Bioreactor

Centrifugation (bulk solids removal)

Clarification (UF for fine solids removal and UF/DF for buffer exchange)

5 Column Purification

(MF for fine solids removal and UF/DF for buffer exchange)


MF, microfiltration; UF, ultrafiltration; DF, dead-end filtration; FF, flow-through; IMAC, immobilised 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.
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
We aligned with the FDA on assessing analytical comparability in support of approval for commercial manufacturing at our CMOs.

<table>
<thead>
<tr>
<th>Drug Substance</th>
<th>Clinical Supply</th>
<th>Commercial Supply</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sesen</td>
<td>FUJIFILM Diosynth Biotechnologies (CMO)</td>
</tr>
<tr>
<td>Drug Product</td>
<td>Sesen</td>
<td>Baxter (CMO)</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Test</th>
<th>Phase III</th>
<th>PPQ1</th>
<th>PPQ2</th>
<th>PPQ3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>pH</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Identity</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Concentration</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Polysorbate 80</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Purity</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Charge Variants</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Potency</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Binding</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Host Cell Protein</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Residual DNA</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Endotoxin</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

✓ Indicates acceptance criteria met for batches used in clinical trials (Sesen) or technology transfer (FUJIFILM Diosynth Biotechnologies)
Intellectual Property
Potential for 12 years of biologics marketing exclusivity from date (TBD) of first approval* 

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

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)

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))