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): August 5, 2020

SESEN BIO, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-36296**	**26-2025616**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

245 First Street, Suite 1800 **Cambridge, MA**	**02142**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 444-8550

Not Applicable
(Former name or former address, if changed since last report.)

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

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a–12 under the Exchange Act (17 CFR 240.14a–12)

☐ Pre–commencement communications pursuant to Rule 14d–2(b) under the Exchange Act (17 CFR 240.14d–2(b))

☐ Pre–commencement communications pursuant to Rule 13e–4(c) under the Exchange Act (17 CFR 240.13e–4(c))

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001	SESN	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 – Other Events.

On August 5, 2020, Sesen Bio, Inc. posted an updated corporate presentation on its website www.sesenbio.com. 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.

Exhibit No.	**Description**
99.1	Sesen Bio, Inc. Corporate Presentation dated August 5, 2020

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: August 5, 2020

Sesen Bio, Inc.

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

Thomas R. Cannell, D.V.M.

President and Chief Executive Officer

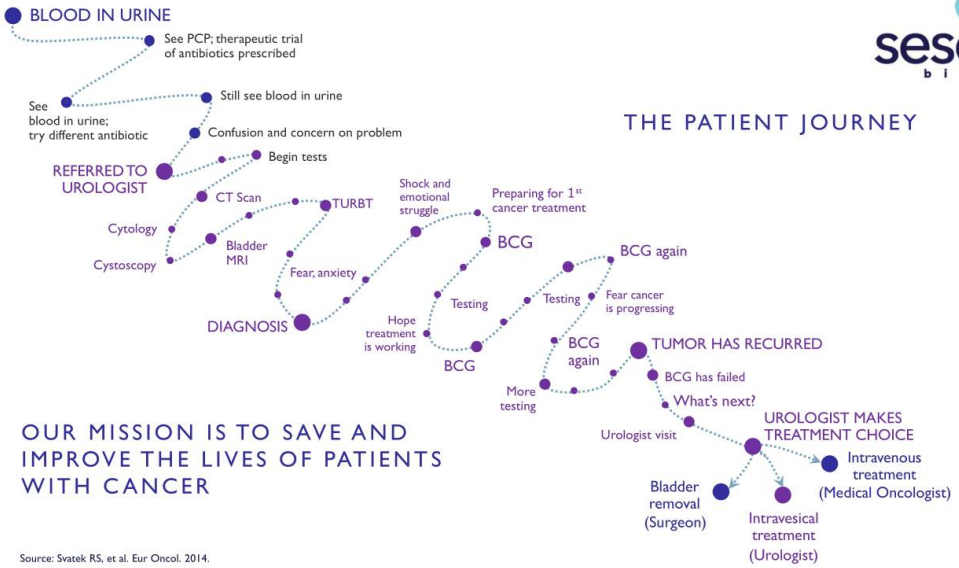

sesen
bio
2020 Canaccord Genuity Global Growth Conference
Fireside Chat with Dr. Tom Cannell, President and CEO
and John Newman Ph.D., Managing Director
Slides for reference only and will not be presented
August 13, 2020
NASDAQ: SESN

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 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

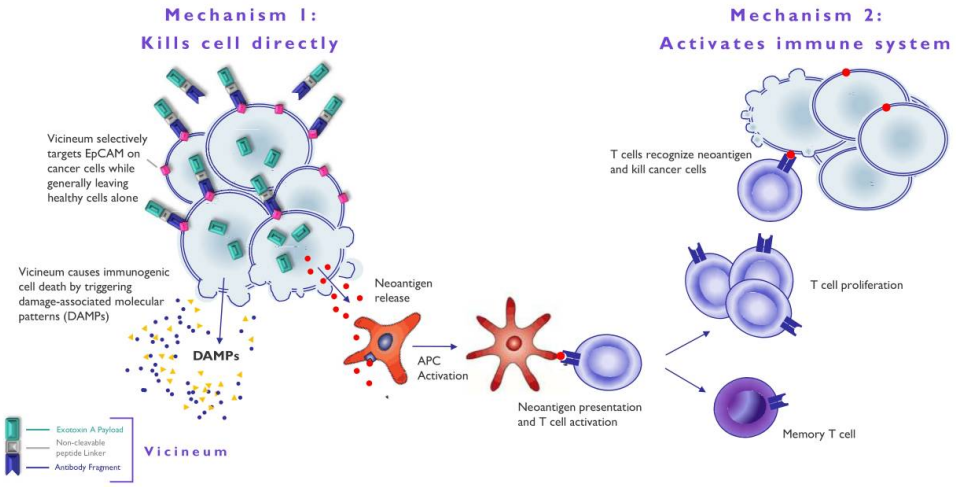
Source: Svatek RS, et al. Eur Oncol. 2014.

AUGUST 2020 BUSINESS UPDATE

- FDA conditional acceptance of Vicineum tradename represents important milestone in commercial readiness in the US
- Differentiated MOA enables compelling benefit-risk profile for Vicineum
- China partnership with Qilu represents first of 6-10 anticipated OUS deals
- Clear regulatory path forward in US and Europe with significant global commercial opportunity

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

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
- OS rates of patients on trial are comparable to the general population with similar demographics

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 40-57

Partnership Opportunity in China: Qilu Pharmaceutical Profile

- Top 10 Pharmaceutical Company in China with >$3B in annual revenues
- 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

There is a Significant Unmet Need in China

Bladder Cancer is the 13th Most Common Cancer in China[1]

- 1.6-1.7 times the incidence vs. the US[2]
- Case fatality rate is 41% vs. 22.5% in the US[3]

China has Increasing Diagnosis Rates with Limited Treatment Options

- Diagnosis and treatment rate expected to increase from 85% in 2020 to 92% in 2028[4]
- Chemotherapy treatment is common with high recurrence rates[4]

>300M Adult Smokers in China[5]

- 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[6]

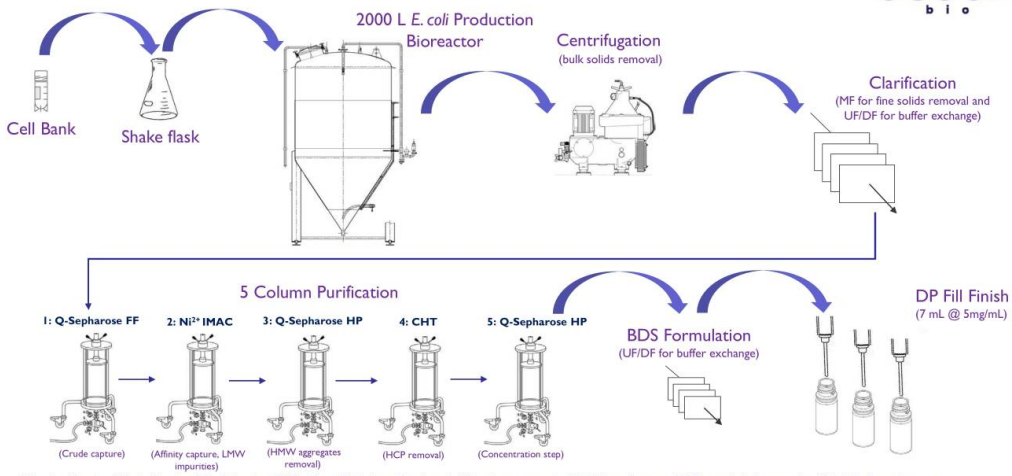
Sources: [1]*Cancer Statistics in China*. American Cancer Society. 2015. [2]ClearView analysis. 2019. [3]GLOBOCAN/IARC. 2018. [4]Qilu business case presentation. April 2020. [5]Transl Lung Cancer Res. *Tobacco and the lung cancer epidemic in China*. NIH. May 2019. [6]Better Market Access in China – Government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

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

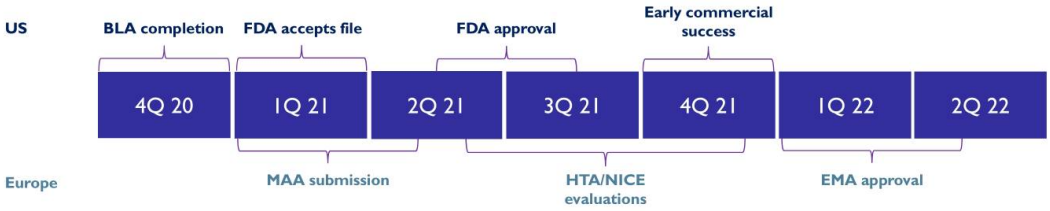
Highly Reliable, Industry-Standard Manufacturing Process for Vicineum



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

Sesen Bio OUS Strategy

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

Simulation Inputs: US Market

Estimated patients eligible for branded therapy[1]
(Annual high-risk NMIBC patients unresponsive to BCG)

Lower Bound	Upper Bound
7,800 patients	20,400 patients

Estimated market share[2]
(Likely share of branded agents)

Lower Bound	Upper Bound
20%	75%

Approximate year 1 doses received[3]
(Percent of possible doses received)

Lower Bound	Upper Bound
67%	83%

Anticipated reimbursement price for competitive agents[4]
(Anticipated annual CMS ASP)

Lower Bound	Upper Bound
$100,000	$175,000

Sources: [1]National Cancer Institute, SEER Cancer Stat Facts: Bladder Cancer, 2019., and ClearView Analysis 1Q 2019. [2]Emerging Treatment IDIs 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)

	Lower Bound	Upper Bound
Europe	1.1	1.3
China	1.6	1.8
MENA	0.2	0.4
Asia (incl. Japan)	0.8	1.0
Latin America	0.2	0.4
Canada	0.1	0.3
Oceania	0.05	0.2

Estimated price relative to the US[2]
(Anticipated reimbursed price)

	Lower Bound	Upper Bound
Europe	0.44	0.84
China	0.20	0.60
MENA	0.66	1.06
Asia (incl. Japan)	0.29	0.69
Latin America	0.30	1.00
Canada	0.35	0.70
Oceania	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. [1]Relative incidence is calculated from total bladder cancer, and does not account for differences in the distribution of patients between NMIBC and MIBC. [2]Pricing multiplier is based on publicly available pricing information; averaged based on ex-manufacturer price of Keytruda and Opdivo, and is likely to vary greatly for each pharmaceutical, and across different countries within each region. [3]South Africa price multiplier was based on Keytruda only, as Opdivo has not yet been priced.

We estimate the OUS opportunity for Vicineum is 2-3 times larger than 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 15-16, 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[1] with no outstanding debt

- Cash and cash equivalents of approximately $38M as of June 30, 2020[2]

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[3]

[1]Assumes receipt of upfront payment under the Qilu License Agreement prior to December 31, 2020
[2]Unaudited
[3]Pursuant to a shelf registration statement on form S-3 (File no. 333-223750)
SEC = Securities and Exchange Commission

AUGUST 2020 HIGHLIGHTS

- FDA conditional acceptance of Vicineum tradename represents important milestone in commercial readiness in the US
- Differentiated MOA enables compelling benefit-risk profile for Vicineum
- Partnership with Qilu represents first of 6-10 anticipated OUS deals
- Clear regulatory path forward in US and Europe with significant global commercial opportunity


sesen
bio
THANK YOU

Talented and Experienced Leadership Team Prepared for Commercial Launch

Senior Management

Thomas Cannell, DVM
President, CEO and Director

Monica Forbes
Chief Financial Officer

Glen MacDonald, Ph.D.
Chief Technology Officer

Erin Clark
Vice President, Corporate Strategy and Investor Relations

Mark Sullivan
General Counsel and Corporate Secretary

Omar Rifi
Vice President, Business Development and Alliance Management

Louise Stejbach
Commercial Advisor

Jeannick Cizeau, Ph.D.
Head of Research

Jeanette Kohlbrenner
Human Resources Advisor

Board of Directors

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

Carrie L. Bourdow
Director

Thomas Cannell, DVM
President, CEO and Director

Jane V. Henderson
Director

Jason Keyes
Director

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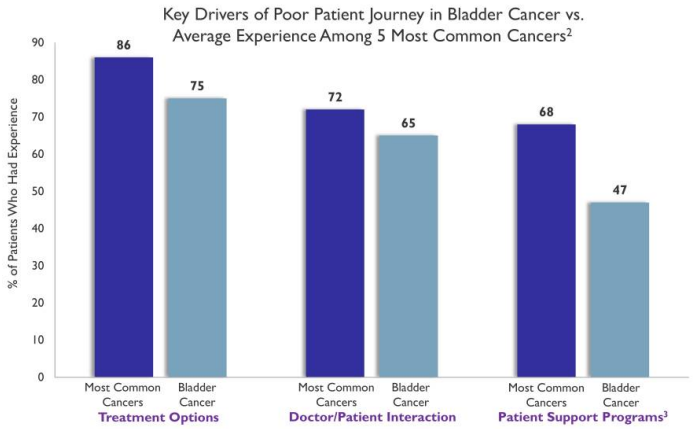
Appendix

Patient Journey

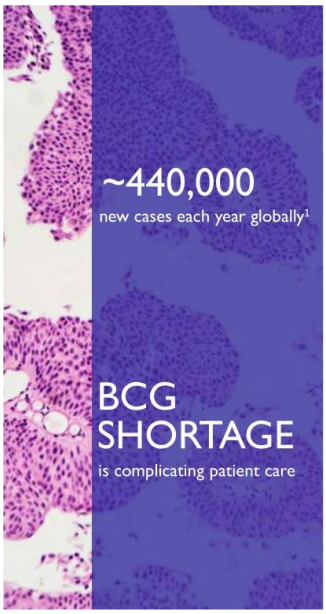
Patient surveys have shown that the experience of those with bladder cancer is one of the poorest[1]



[1]Cancer Patient Experience Survey 2011/12. Department of Health. N=71,793. https://www.quality-health.co.uk/resources/surveys/national-cancer-experience-survey/201112-national-cancer-patient-experience-survey-1/201112-national-cancer-patient-experience-survey-reports/495-cancer-patient-experience-survey-national-report-2011-12/file. [2]Most common cancers include breast, lung, prostate, colorectal, and skin cancers. SEER Database. https://seer.cancer.gov/statfacts/html/urinb.html. [3]Includes self-help groups and financial assistance.

Appendix

Unmet Medical Need



Significant Unmet Medical Need in NMIBC

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 ~$6B by 2020[4]

One of the worst patient experiences among common cancers

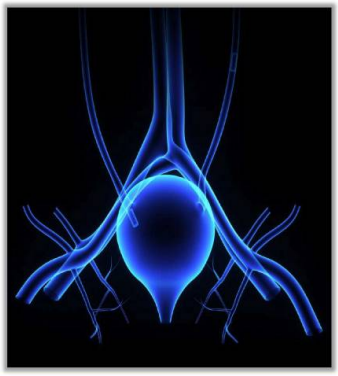
Survival rates for bladder cancer have decreased in recent years in the UK, during which time there was also a BCG shortage[5]

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

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

Your Bladder: An Essential Organ

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



Radical Cystectomy: Life-Altering 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 catheterization and 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 a BCG vaccine protects people against infection with COVID-19 virus.

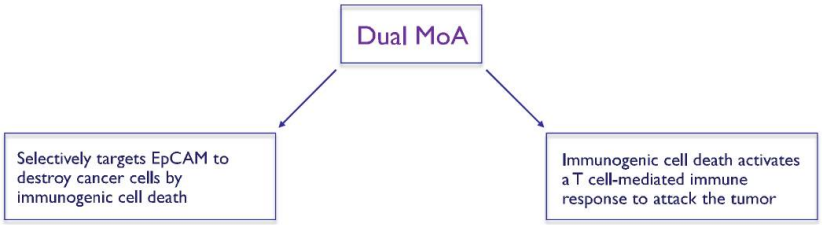
Sources and Additional Information:
Wall Street Journal. *Sanofi to Stop Production of Bladder Cancer Drug BCG*. Peter Loftus. 2016. https://www.auanet.org/practice-resources/bcg-info/bcg-shortage-notice
https://www.bcan.org/2019-bcg-shortage-bladder-cancer/. https://www.who.int/news-room/commentaries/detail/bacille-calmette-gu%C3%A9rin-(bcg)-vaccination-and-cov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

Appendix

Dual Mechanism of Action

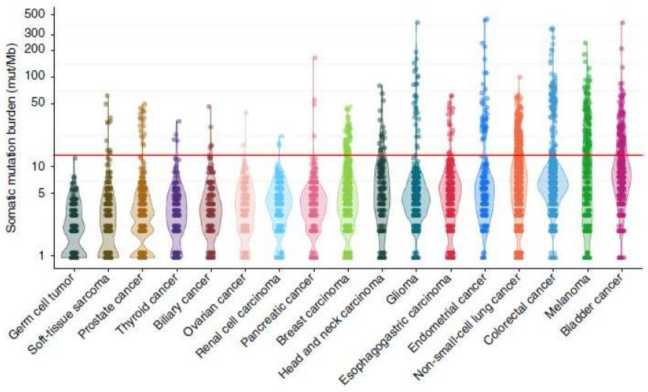
Vicineum is Highly Differentiated and has a Dual Mechanism of Action

- 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 dual mechanism of action.

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



Adapted from Zahir et al. Nature Medicine, 2017

Appendix

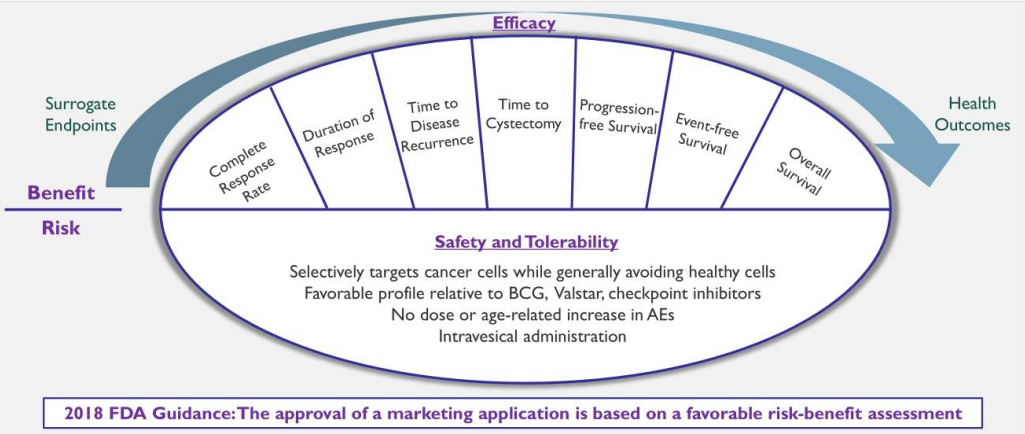
Regulatory

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

2018 FDA Guidance	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	✓
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



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.

Initiation of Vicineum BLA submission under Rolling Review on December 6, 2019

Oncology Products Reviewed by FDA 2006 - 2015

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

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

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

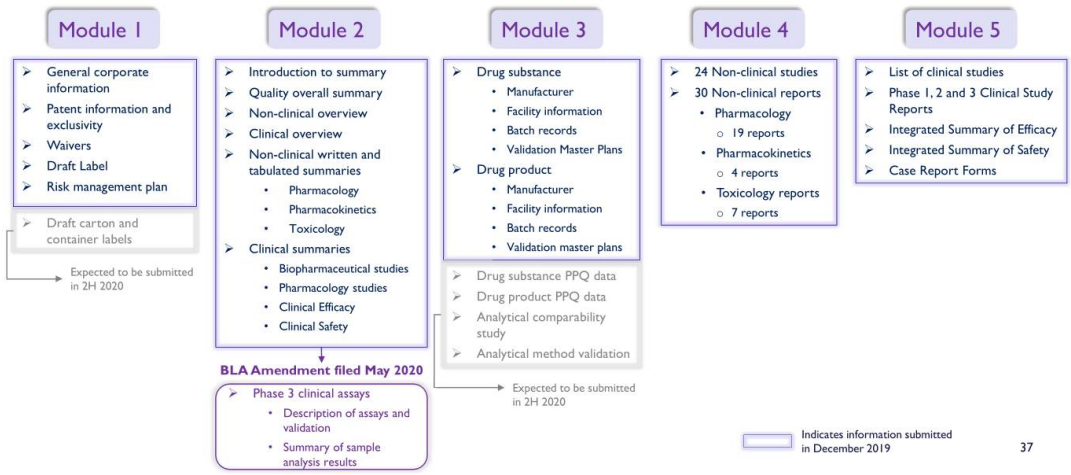
Significant Progress in 2019

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

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

December 2019: Initiated BLA submission for Vicineum under Rolling Review

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



Analytical Comparability Outlook

Clear FDA requirements for the PPQ Campaign

- Three manufacturing runs for both drug substance and drug product

Considerable in-house manufacturing process expertise from clinical manufacturing

- Successfully manufactured 10 drug substance and 12 drug product batches in support of Vicineum clinical trials*

Completed two commercial-scale GMP runs at Fujifilm and Baxter

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

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

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

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

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

Appendix

Clinical Data

Phase III Trial: Patient Demographics

CHARACTERISTICS	COHORT 1 CIS that was refractory or recurred within 6 months of adequate BCG	COHORT 2 CIS that recurred >6 months but ≤11 months of adequate BCG	COHORT 3 Papillary tumors (without CIS) that 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
Complete Response Rate (CRR) Primary Endpoint CIS patients	Defined as the proportion of patients who show no evidence of high-risk disease, or disease progression (e.g., T2 or more advanced disease).	• 40% CRR at 3 months • Lower bound of 95% CI rules out clinically unmeaningful CRR • Higher complete response rate in patients receiving less BCG
Duration of Response (DoR) Primary Endpoint CIS patients	Defined as the time from complete response to treatment failure.	• 52% duration of 9 months (12 months of therapy) • 39% duration of 15 months or greater (18 months of therapy) • The longer the CR, the higher the probability of remaining disease-free
Time to Disease Recurrence Secondary Endpoint Papillary patients	Defined as the time from the date of first dose of study treatment to treatment failure.	• Median time to recurrence is 402 days • 50% probability of remaining recurrence-free for 12 months • 37% probability of remaining recurrence-free for 24 months or greater
Time to Cystectomy (TtC) Secondary Endpoint All Cohorts	Defined as the time from the date of first dose of study treatment to surgical bladder removal.	• 76% of patients are cystectomy-free for 3 years • Responders have an 88% probability of remaining cystectomy-free at 3 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.	• 29% of patients are event-free at 12 months • 22% of patients remain event-free at 18 months • 21% of patients remain event-free for 24 months or greater
Overall Survival (OS) Secondary Endpoint All Cohorts	Defined as the time from the date of first dose of study treatment to death from any cause.	• Overall survival is 98% at 12 months • Overall survival is 96% for 24 months or greater • Median OS has not been reached
Safety Secondary Endpoint All Cohorts	Full review of all safety data from Phase III	• 2% treatment-related SAEs • 4% treatment-related Grade 3-5 AEs • Increased dosing in Phase III did not increase severity or requency of 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

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

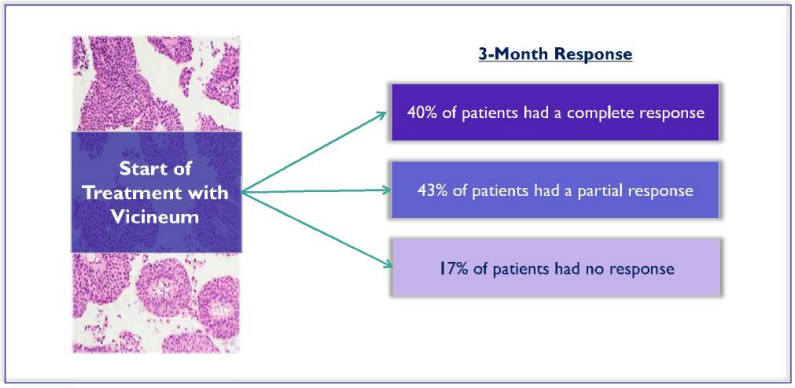
Phase III Trial: Evaluable Patient Data Tables by Cohort for Carcinoma *in situ*

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%)

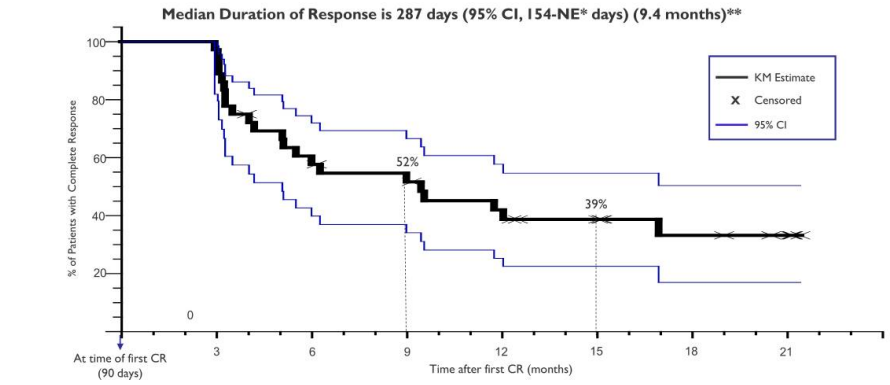
Response-evaluable population includes any modified intention-to-treat (mITT) subject who completed the induction phase
Note: Data are as of May 29, 2019 data cut

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.

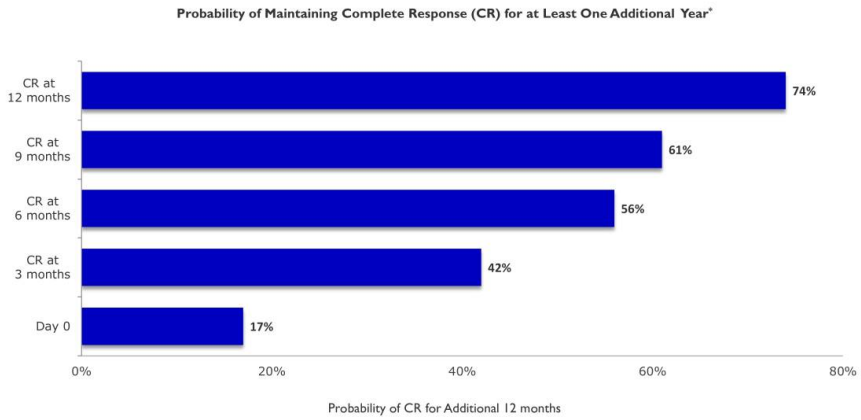
Duration of Response: 52% of CIS patients who had a complete response at 3 months remained disease-free for a total of 12 months after starting treatment



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.

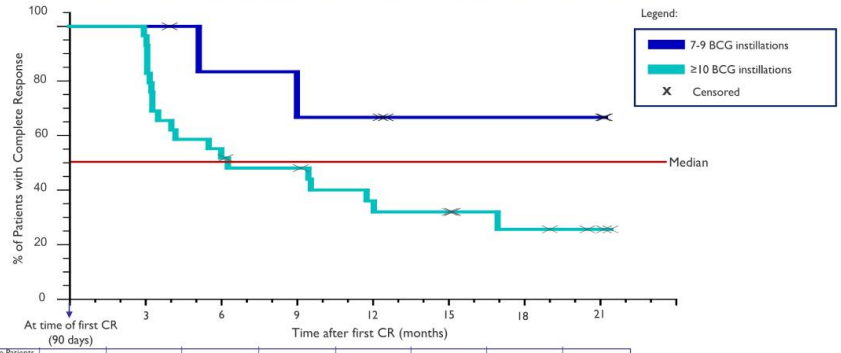
Duration of Response: The longer you have a complete response, the higher the probability of remaining cancer-free



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

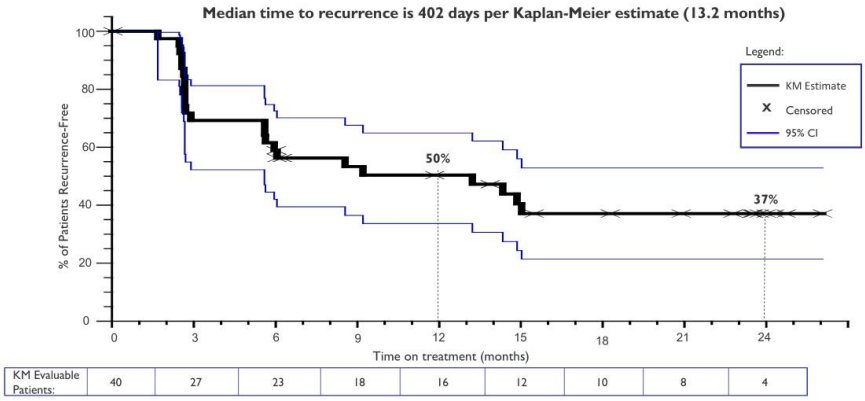
The BCG shortage may cause a new normal wherein patients receive less BCG



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.

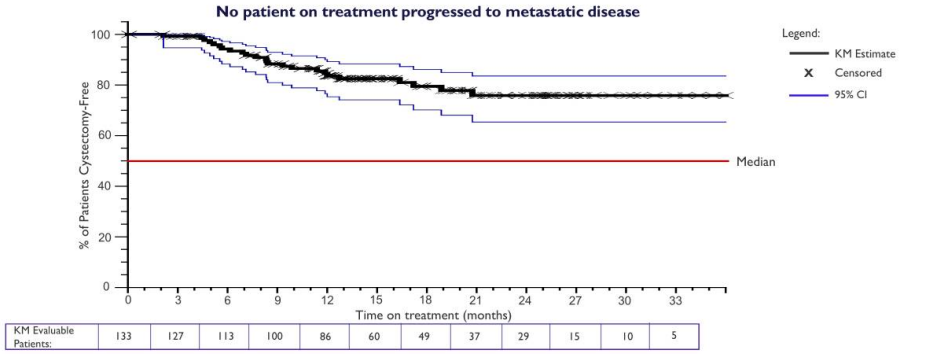
Recurrence-free Rate: 42% of high-risk papillary patients remain disease-free after one year

Recurrence-free 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



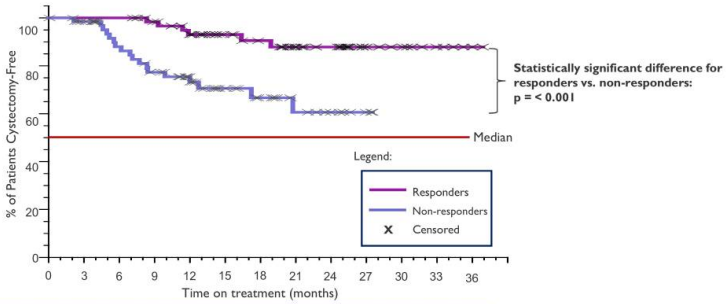
KM Evaluable Patients:	133	127	113	100	86	60	49	37	29	15	10	5

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).

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[1]
1 year	98%	97%
2 years	96%	94%

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

Safety and Tolerability: Our Phase II and Phase III clinical trials are highly consistent for safety and tolerability

Increased dosing and duration of exposure does not appear to lead to an increase in incidence or severity of AEs

Treatment-related serious adverse events reported:

- Phase II Clinical Trial: 6 SAEs reported, none determined to be related to treatment by the investigator.
- Phase III Clinical Trial: 3 patients reported 4 events including grade 4 cholestatic hepatitis, grade 5 renal failure[1], grade 3 acute kidney injury[2], and grade 2 pyrexia.

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

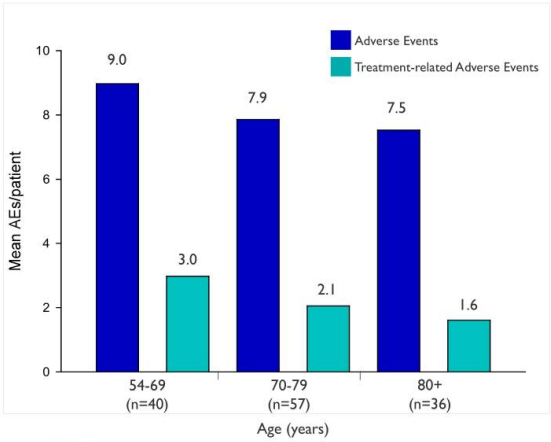
Vicineum Treatment Exposure:

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

[1]90-year-old man started the trial Mar. 2016. In May 2016, admitted for renal failure and started dialysis. Two weeks later, patient opted to discontinue dialysis, entered hospice and died in June 2016. Case reported to DSMB, FDA and Health Canada. [2]74-year-old man started the trial Nov. 2016. In Dec. 2016, admitted for acute kidney injury. In 2017, protocol amended to enhance monitoring, and educated investigators. No new serious related renal events since.

Safety and Tolerability: No age-related increase in adverse events in our Phase III trial

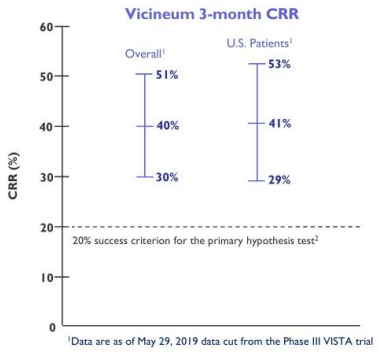
The average patient in the VISTA trial was ~74 years old



Note: Data consist of patients from all cohorts 1, 2 & 3 (n=133).
Mean AEs for all patients: 8.1 (range 0-54), Mean treatment-related AEs for all patients: 2.2 (range 0-51).

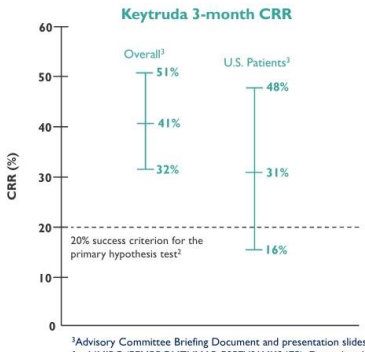
3-month complete response rate data from different clinical trials

Please use caution when drawing comparisons across different clinical trials



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

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



[3]Advisory Committee Briefing Document and presentation slides for 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)

Pipeline of Targeted Therapies

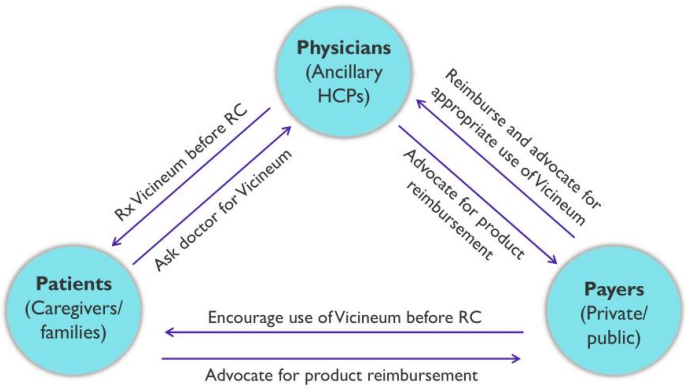
We believe there is strong scientific rationale for Vicineum in combination with checkpoint inhibitors. Vicineum in combination with AstraZeneca's anti-PD-L1, Imfinzi (durvalumab), is being evaluated in a Phase 1 trial run by the National Cancer Institute.

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 our resources on our ongoing development of Vicineum for the treatment of high-risk NMIBC. We are also exploring collaborations for Vicineum, for the treatment of SCCHN, and VB6-845d.
ETA, exotoxin A; IO, immuno-oncology agent

Appendix

Commercial Opportunity

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



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

Note: RC= Radical Cystectomy

Large Global Commercial Opportunity

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

- We have CMO partners capable of reliably meeting that demand

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

Compelling intent to prescribe research

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

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

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	✓	✓	X
Directed by Urologist	✓	✓	X
Administration by Urology nurse	✓	✓	X
Bladder infusion via urinary catheter	✓	✓	X
2-hour infusion, hold, and rotation	✓	✓	X

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

Market Research Input
Clinical Data from Emerging Treatments for NMIBC

	Vicineum (Phase III Data)	Tecentriq (Phase II Data)
Characteristics		
Median Patient Age **Median # of BCG Instillations**	73 12	73 12
Efficacy	N=89	N=73
• **At 3 Months** • **At 6 Months**	40% 28%	41% 28%
Safety	N=133	N=73
Treatment-Related Grade 3-5 AEs	4%	12%
Mode of Administration	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
- Company has informed customers of delay

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

Appendix

1Q 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
Mechanism of Action	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 cell-mediated immune responses to attack the tumor
Indication	• Carcinoma *in situ* • High-risk papillary (Ta/T1)	• Carcinoma *in situ*
	2nd line use for patients who have failed following at least 2 courses of BCG (minimum 7 doses), and still have evidence of disease	2nd line use for patients who have failed following at 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
Mode of Administration	Intravesical	Intravenous
Dosing Regimen	Induction Weeks 1-6: twice weekly Weeks 7-12: once weekly Maintenance Every 2 weeks	Every 3 weeks
Generally Administered By	Urologist	Medical Oncologist

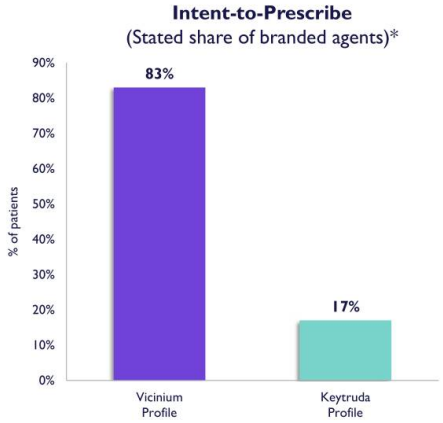
Source: Dec. 2019 FDA briefing book for Keytruda profile; Dec. 2019 BLA submission for Vicineum profile.
This slide is intended for market research purposes only and is not intended for marketing purposes.

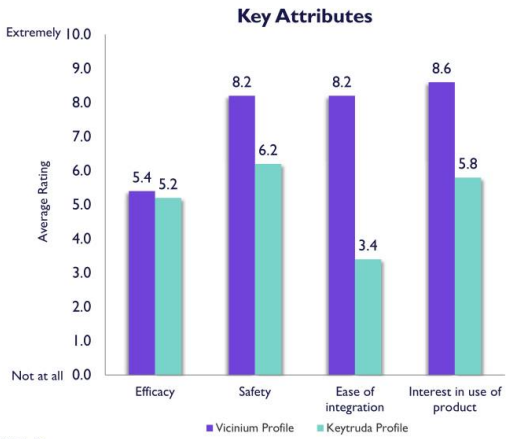
Market Research Input
Clinical Data from Emerging Treatments for NMIBC

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

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

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





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

1Q 2020 Market Research Results
Reasons Urologists Prefer 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

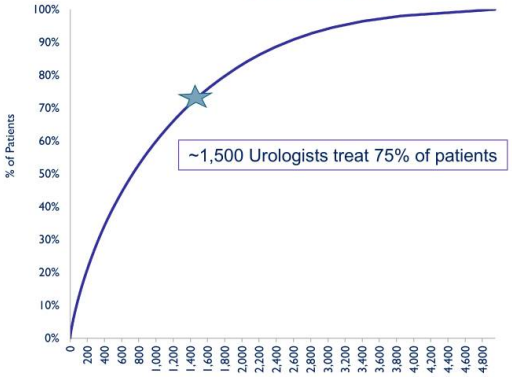
- **Urologists perceive negative psychological effects of intravenous chemotherapy on patients**
  - Stigma of seeing an Oncologist/going to large academic medical center
  - Patient perception of more advanced disease (e.g. terminal patients)

Source: Emerging treatment IDIs with high BCG-treating Urologists, 1Q 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[1]

BCG Prescribers[2]



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

At treatment decision points, caregivers often play an influential role

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

Digital

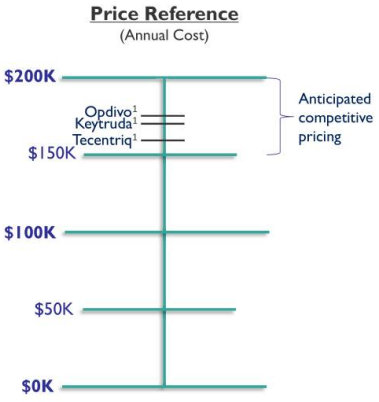
- Paid search
- Organic search
- Videos
- Banners
- Website (branded or unbranded)

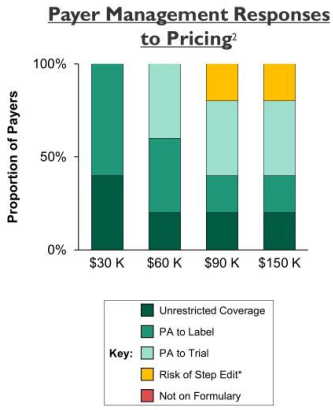
Social

- Facebook community groups
- Twitter
- Lead gen/CRM

Lead gen = lead generation
CRM = customer relationship management

Pricing and Reimbursement US Benchmarks





Sources: [1]Center for Medicare and Medicaid Services (CMS) Average Selling Price (ASP) Price List as of 1Q 2020.
[2]Payer Interviews, ClearView Analysis, n=10, March 2019.
*Note: Payers cited a possibility of using a step edit, but could not be certain, as the ability to use a step edit is new to their organization's Medicare Advantage medical benefit. PA = Prior Authorization

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 manufacturers

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

FUJIFILM Diosynth biotechnologies

- Licensed for commercial production of 8 approved products
- 25+ years developing and manufacturing biologics
- 310+ protein-based therapeutics in development and/or manufacturing
- Proven track record with FDA and worldwide regulatory agencies

Baxter

Baxter's BioPharma Solutions Business:

- 160 clinical and commercial programs
- 60+ years of experience in manufacturing of oncology products
- ISPE 2016 Facility of the Year Award at site of Vicineum manufacture
- Proven track record with FDA and worldwide regulatory agencies

Vicineum Commercial Manufacturing Strategy

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

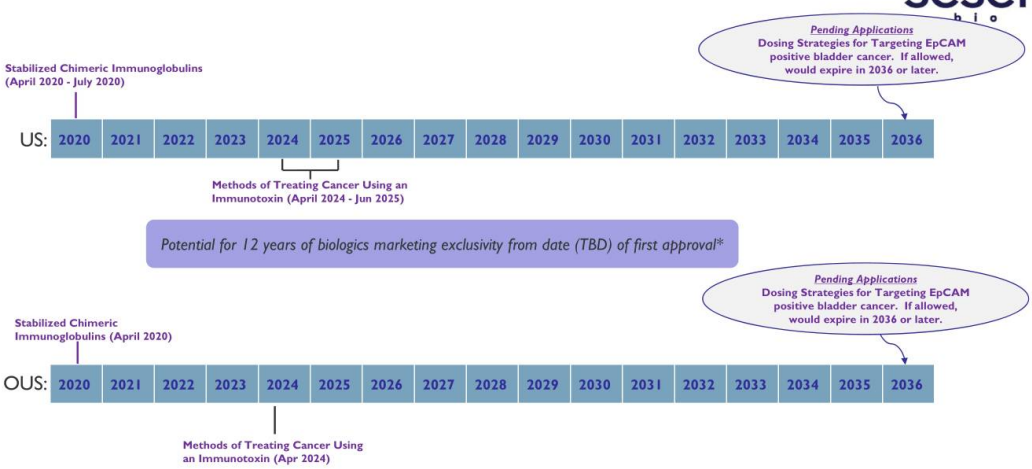
The analytical comparability plan is comprised of 4 key elements:

1. Analytical Release Testing
   - Assesses the purity, biological activity and general characteristics of the protein (e.g. purity by HPLC, endotoxin content)
2. Biophysical Characterization
   - Assesses the structural characteristics of the protein (e.g. Peptide Mapping, Differential Scanning Calorimetry)
3. Forced Degradation Studies
   - Assesses the degradation pathway of the protein when exposed to stress conditions (e.g. purity by HPLC after temperature extremes)
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



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))