Sesen Bio Reports First Quarter 2019 Financial Results and Updated, Preliminary Primary and Additional Secondary Endpoint Data from Phase 3 VISTA Trial for High-Risk Non-Muscle Invasive Bladder Cancer

May 13, 2019

Company Announces Confirmed Meetings with the U.S. Food and Drug Administrationin May and June 2019 to Review Registration Strategy for Vicinium®

Management to Host a Business Update Call Today at 8:00 a.m. EDT

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 13, 2019-- **Sesen Bio** (Nasdaq:SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, today reported operating results for the first quarter ended March 31, 2019. The Company also reported updated, preliminary primary and additional secondary endpoint data from the Company's Phase 3 VISTA trial further supporting the strong benefit-risk profile of Viciniumfor the potential treatment in patients with high-risk,bacillus Calmette-Guérin(BCG) unresponsive, non-muscle invasive bladder cancer (NMIBC). The updated preliminary Phase 3 clinical data, along with the Phase 2 clinical trial data, will serve as the basis for upcoming meetings with the U.S. Food and Drug Administration (FDA).

"We are very encouraged by the most recent analysis of our 12-month Phase 3 VISTA trial data, which will be the basis for our meetings with the FDA in May and June," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "We believe these preliminary data, along with a closely matched Phase 2 data set, support a compelling benefit-risk profile, and give us confidence in the regulatory approvability and strong commercial viability of Vicinium. The huge unmet need for patients with NMIBC is widely acknowledged and has been exacerbated by the recurring global shortage of BCG. We will continue to work closely with the FDA in our effort to expeditiously bring a product to market that has the potential to save and improve the lives of patients with NMIBC."

Phase 3 VISTA Trial Progress and Updates

- **Updated, Preliminary VISTA Trial Data Reported in BCG-unresponsive NMIBC:** In March, Sesen Bio announced updated preliminary data from its ongoing Phase 3 VISTA trial, a single-arm, multi-center clinical trial designed to support the approval of Vicinium for the treatment of patients with high-risk, BCG-unresponsive NMIBC. The trial completed registration in the second quarter of 2018, with a total of 133 patients across three cohorts based on histology and time to disease recurrence after adequate BCG treatment (at least two courses of BCG with at least five doses in the first course and two doses in the second course). Primary endpoints include complete response rate and duration of response for patients in Cohort 1. Secondary endpoints include time to disease recurrence for patients in Cohort 3, and time to cystectomy, progression-free survival, event-free survival, and overall survival for all patients across cohorts. As of the March 1, 2019 data cutoff, updated preliminary primary and secondary efficacy data for each of the trial cohorts were as follows:

Cohort 1 (n=86) Complete Response Rate

Time point	Evaluable Patients	Complete Response Rate
3-months	n=86	37%
6-months	n=86	26%
9-months	n=85	19%
12-months	n=84	15%

Patients with Carcinoma *in situ* with or without papillary disease that was determined to be refractory or recurred within six months of their last course of adequate BCG

Cohort 2 (n=7) Complete Response Rate

Time point	Evaluable Patients	Complete Response Rate
3-months	n=7	57%

6-months	n=7	57%
9-months	n=7	43%
12-months	n=7	14%

Patients with Carcinoma *in situ* with or without papillary disease that was determined to be refractory or recurred after six months, but less than 11 months, after their last course of adequate BCG

Pooled Cohorts 1 and 2 (n=93) Complete Response Rate

Time point	Evaluable Patients	Complete Response Rate (95% Confidence Interval)
3-months	n=93	39% (29%- 49%)
6-months	n=93	28% (19%-38%)
9-months	n=92	21% (13%-30%)
12-months	n=91	15% (9%-24%)

Patients with Carcinoma *in situ* with or without papillary disease that was determined to be refractory or recurred less than 11 months, after their last course of adequate BCG

- **Duration of Response:** The median duration of response for patients in Cohort 1 (n=86) is 287 days (95% CI, 127-NA), using the Kaplan-Meier method. Additional ad hoc analysis of pooled data for all patients with Carcinoma *in situ* (Cohorts 1 and 2, n=93) shows that among patients who achieved a complete response at 3 months, 54% had a complete response for a total of 12 months or longer after starting therapy, using the Kaplan-Meier method.
- **Time to Disease Recurrence:** High-risk papillary (Ta or T1) NMIBC is associated with higher rates of progression and recurrence. Therefore, time to disease recurrence is a key secondary endpoint for patients with high-risk papillary-only NMIBC. The median time to disease recurrence for patients in Cohort 3 (n=40) is 402 days (95% CI, 170-NA), using the Kaplan-Meier method.
- **Time to Cystectomy:** The FDA guidance states that the goal of therapy in patients with BCG-unresponsive NMIBC is to avoid cystectomy. Therefore, time to cystectomy is a key secondary endpoint in the VISTA trial. Across all 133 patients treated with Vicinium, >75% of patients are estimated to remain cystectomy-free at 2.5 years, using the Kaplan-Meier method. Additional ad hoc analysis of responders and non-responders for all patients shows that responders are approximately 15 times more likely to remain cystectomy-free at 2.5 years compared to non-responders.
- **Additional Secondary Endpoint Data from Phase 3 VISTA Trial Support a Growing Body of Evidence Demonstrating the Durable Anti-tumor Activity of Vicinium:** Since the last data update reported in March, Sesen Bio has completed preliminary analyses of the remaining secondary endpoints in the VISTA trial, including progression-free survival, overall survival, and event-free survival, as measured across all patient cohorts. Reported data is as of the March 1, 2019 cutoff:
    - **Progression-Free Survival:** >85% of all 133 patients treated with Vicinium are estimated to remain progression-free at 2 years, using the Kaplan-Meier method. Progression-free is 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.
    - **Event-Free Survival:** 30% of all 133 patients treated with Vicinium are estimated to remain event-free at 12 months, using the Kaplan-Meier method. Event-free survival is defined as the time from the date of first dose of study treatment to disease recurrence, progression, or death as a first event.
    - **Overall Survival:** 91% of all 133 patients treated with Vicinium have an overall survival of >2.5 years, using the Kaplan-Meier method. Overall survival is defined as the time from the date of first dose of study treatment to death from any cause.
- **Vicinium Continues to be Well-tolerated by Patients Treated in the Phase 3 VISTA Trial**: As of the March 1, 2019 data cut off, in patients across all cohorts (n=133), 78% of adverse events were Grade 1 or 2. The most commonly reported treatment-related adverse events were dysuria (13%), hematuria (12%) and urinary tract infection (11%) – all of which are consistent with the profile of bladder cancer patients and the use of catheterization for treatment delivery. These adverse events were determined by the clinical investigators to be manageable and reversible, and only five patients (4%) discontinued treatment due to an adverse event. Serious adverse events, regardless of treatment attribution, were reported in 14% of patients. There were four treatment-related SAEs reported in three patients including acute kidney injury (Grade 3), pyrexia (Grade 2), cholestatic hepatitis (Grade 4) and renal failure (Grade 5). There were no age-related increases in adverse events observed in the Phase 3 VISTA trial.
- **Positive Data and Safety Monitoring Board (DSMB) Review of Phase 3 VISTA Trial Data**: In March, the independent DSMB completed its ninth planned safety review for the Phase 3 VISTA trial and recommended the trial continue without modification.
- **Completion of Full-Scale GMP Manufacturing Run at FUJIFILMProvides Encouraging Preliminary Results, Supporting Analytical Comparability Plan to be Reviewed with the FDA**: In October 2018, Sesen Bio entered into an agreement for the manufacturing process and technology transfer of Vicinium production with FUJIFILM Diosynth

Biotechnologies U.S.A., Inc. (FUJIFILM). In April 2019, the first full, commercial-scale GMP run was completed at FUJIFILM. Preliminary indicators of success, including the bacterial growth and purification profiles, support FUJIFILM'S ability to produce the bulk drug substance form of Vicinium for commercial purposes if Sesen Bio receives regulatory approval to market Vicinium. Full quality release testing is underway, and results are expected to be completed in May 2019.

- **Updated Phase 3 VISTA Trial Data Along with Closely Matched Phase 2 Clinical Trial Data to Serve as Basis for Upcoming FDA Meetings**:
  - **Type C CMC Meeting Scheduled for May 20, 2019.** In conjunction with the technology transfer of Vicinium production with FUJIFILM, the Company will seek alignment with the FDA on an analytical comparability plan that can be used to assess comparability between the supply used in clinical trials and the potential commercial supply produced by FUJIFILM.
  - **Pre-BLA Meeting Scheduled for June 6, 2019:** In concurrence with the FDA's recommendation that the Company schedule a meeting in mid-2019, Sesen Bio has confirmed a meeting date with the FDA in June to discuss its intended registration strategy for Vicinium for the treatment of high-risk NMIBC.

First Quarter 2019 Financial Results

- **Cash Position:** Cash and cash equivalents were $42.4 million as of March 31, 2019, compared to $50.4 million as of December 31, 2018, and $19.7 million as of March 31, 2018, the comparable period one year ago.
- **Revenue:** No revenue was recorded for the three months ended March 31, 2019, nor for the same period in 2018.
- **R&D Expenses:** Research and development (R&D) expenses for the first quarter of 2019 were $4.7 million compared to $3.3 million in R&D expenses for the same period in 2018. The increase was primarily due to $1.7 million in costs related to the ongoing manufacturing process and technology transfer with FUJIFILM, and increased internal and external staffing costs, partially offset by reduced expenses related to the Phase 3 VISTA trial.
- **G&A Expenses:** General and administrative expenses for the first quarter of 2019 were $3.1 million compared to $2.0 million for the same period in 2018. The increase was primarily due to higher legal costs, an increase in professional fees and market research costs.
- **Net Loss:** Net loss was $6.5 million, or $0.08 per share, for the first quarter of 2019, compared to $4.0 million, or $0.11 per share, for the first quarter of 2018.
- **Financial Guidance:** Based on its current operating plans, Sesen Bio believes it will have capital sufficient to fund its current operating plan into 2020.

Conference Call Information

To participate in the conference call, please dial (844) 831-3025 (domestic) or (315) 625-6887 (international) and refer to conference ID 7176228. The webcast can be accessed in the Investor Relations section of the company's website at www.sesenbio.com. The replay of the webcast will be available in the investor section of the company's website at www.sesenbio.com for 60 days following the call.

About the VISTA Clinical Trial

The VISTA trial is an open-label, multicenter, single-arm Phase 3 clinical trial evaluating the efficacy and tolerability of Vicinium® as a monotherapy in patients with high-risk, bacillus Calmette-Guérin, or BCG, unresponsive non-muscle invasive bladder cancer (NMIBC). The primary endpoints of the trial are the complete response rate and the duration of response in patients with Carcinoma in situ with or without papillary disease. Patients in the trial receive locally administered Vicinium twice a week for six weeks, followed by once-weekly treatment for another six weeks, then treatment every other week for up to two years. To learn more about the Phase 3 VISTA trial, please visit www.clinicaltrials.gov and search the identifier NCT02449239.

About Vicinium®

Vicinium, a locally-administered fusion protein, is Sesen Bio's lead product candidate being developed for the treatment of high-risk non-muscle invasive bladder cancer (NMIBC). Vicinium is comprised of a recombinant fusion protein that targets epithelial cell adhesion molecule (EpCAM) antigens on the surface of tumor cells to deliver a potent protein payload, *Pseudomonas Exotoxin A*. Vicinium is constructed with a stable, genetically engineered peptide tether to ensure the payload remains attached until it is internalized by the cancer cell, which is believed to decrease the risk of toxicity to healthy tissues, thereby improving its safety. In prior clinical trials conducted by Sesen Bio, EpCAM has been shown to be overexpressed in NMIBC cells with minimal to no EpCAM expression observed on normal bladder cells. Sesen Bio is currently conducting the Phase 3 VISTA trial, designed to support the registration of Vicinium for the treatment of high-risk NMIBC in patients who have previously received a minimum of two courses of bacillus Calmette-Guérin (BCG) and whose disease is now BCG-unresponsive. Additionally, Sesen Bio believes that Vicinium's cancer cell-killing properties promote an anti-tumor immune response that may potentially combine well with immuno-oncology drugs, such as checkpoint inhibitors. The activity of Vicinium in BCG-unresponsive NMIBC is also being explored at the US National Cancer Institute in combination with AstraZeneca's immune checkpoint inhibitor durvalumab.

About Sesen Bio

Sesen Bio, Inc. is a late-stage clinical company advancing targeted fusion protein therapeutics for the treatment of patients with cancer. The company's lead program, Vicinium ®, also known as VB4-845, is currently in a Phase 3 registration trial, the VISTA trial, for the treatment of high-risk, BCG-unresponsive non-muscle invasive bladder cancer (NMIBC). Vicinium is a locally-administered targeted fusion protein composed of an anti-EPCAM antibody fragment tethered to a truncated form of *Pseudomonas Exotoxin A* for the treatment of high-risk NMIBC. For more information, please visit the company's website at www.sesenbio.com.

Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, the Company's strategy, future operations, and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties inherent in the initiation and conduct of clinical trials, the possibility that the preliminary data of the Phase 3 VISTA trial are not indicative of final clinical results and final clinical trial results may not be positive with regard to the safety or efficacy of Vicinium, our ability to successfully develop our product candidates and complete our planned clinical programs, expectations regarding our upcoming FDA meetings, our ability to obtain marketing approvals for our product candidates, expectations regarding our ongoing clinical trials, availability and timing of data from clinical trials, whether interim results from a clinical trial will be predictive of the final results of the trial or results of early clinical studies will be indicative of the results of future studies, the adequacy of any clinical models, expectations regarding the manufacturing process and technology transfer with FUJIFILM Diosynth Biotechnologies U.S.A., Inc., expectations regarding regulatory approvals, expectations regarding the adequacy of our existing capital resources to fund our operating plan into 2020 and other factors discussed in the "Risk Factors" section of the Company's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and other reports filed with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

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

	Three Months Ended March 31,	
	2019	**2018**
Total revenue	$ -	$ -
Operating expenses:		
Research and development	4,686	3,255
General and administrative	3,055	1,952
Gain from change in fair value of contingent consideration	(1,000)	(1,200)
Total operating expenses	6,741	4,007
Loss from operations	(6,741)	(4,007)
Other income, net	261	44
Net loss and comprehensive loss	$ (6,480)	$ (3,963)
Net loss per share —basic and diluted	$ (0.08)	$ (0.11)
Weighted-average number of common shares used in net loss per share —basic and diluted	77,458	35,674

SESEN BIO, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	(Unaudited) March 31, 2019	**December 31, 2018**
Assets		
Current assets:		
Cash and cash equivalents	$ 42,437	$ 50,422
Prepaid expenses and other current assets	3,014	1,334
Total current assets	45,451	51,756
Property and equipment, net	272	321
Restricted cash	20	20
Intangible assets	46,400	46,400
Goodwill	13,064	13,064
Other assets	232	-
Total assets	$ 105,439	$ 111,561

Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,683	$ 1,367
Accrued expenses	$ 5,234	$ 4,746
Other current liabilities	136	-
Total current liabilities	7,053	6,113
Other liabilities	398	313
Deferred tax liability	12,528	12,528
Contingent consideration	47,400	48,400
Stockholders' equity:		
Common stock	77	77
Additional paid-in capital	230,487	230,154
Accumulated deficit	(192,504)	(186,024)
Total stockholders' equity	38,060	44,207
Total liabilities and stockholders' equity	$ 105,439	$ 111,561

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Source: Sesen Bio

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