Sesen Bio Reports Fourth Quarter and Full-Year 2018 Financial Results and Additional Preliminary Data from Phase 3 VISTA Trial

March 4, 2019

Company Announces Additional Key Primary and Secondary Endpoints Further Supporting Vicinium® Treatment Potential in High-Risk Non-Muscle Invasive Bladder Cancer

Company on Track to Report Updated 12-Month Data from Phase 3 VISTA Trial of Vicinium in Mid-2019

Management to Host a Business Update Call on March 4, 2019 at 8:00 a.m. EST

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Mar. 4, 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 fourth quarter and full year ended December 31, 2018. The Company also reported new, preliminary analyses from the Company's Phase 3 VISTA trial further demonstrating the activity of Vicinium treatment in patients with high-risk non-muscle invasive bladder cancer (NMIBC).

"2018 was a year of tremendous progress towards our goal of bringing Vicinium to patients with BCG-unresponsive NMIBC, setting us up for a transformational 2019," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "We are well underway with our Phase 3 VISTA trial designed to support the full approval of Vicinium for patients with NMIBC. The totality of the efficacy and safety data generated to date in our Phase 3 VISTA trial, and the compelling benefit-risk profile, give us confidence in the approvability of Vicinium for this indication. Due to the limited treatment options, once patients become BCG-unresponsive, their choice is to either undergo a life-altering, complicated surgery of complete bladder removal or live with a highly-progressive cancer. We believe Vicinium can have a substantial impact on how patients with NMIBC are treated, translating into a significant commercial opportunity, as we endeavor to achieve our mission of saving and renewing the lives of patients with cancer."

VISTA Trial Progress

- **Positive Preliminary VISTA Trial Data Reported in BCG-unresponsive NMIBC:** In January, Sesen Bio announced positive 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 enrollment 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. Cohort 1 enrolled 86 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 enrolled seven patients with Carcinoma *in situ* with or without papillary disease that was determined to be refractory or recurred after six months, but less than 12 months, after their last course of adequate BCG. Cohort 3 enrolled 40 patients with high-risk papillary disease without Carcinoma *in situ* that was determined to be refractory or recurred within six months of their last course of adequate BCG. As of a December 3, 2018 data cutoff data, preliminary efficacy data for each of the trial cohorts were as follows:

Cohort 1 CRRs (n=86)

Time point	Evaluable Patients	Complete Response Rate (95% Confidence Interval)
3-months	n=86	37% (27%-48%)
6-months	n=85	25% (16%-35%)
9-months	n=84	18% (10%-28%)
12-months	n=81	14% (7%-23%)

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 CRRs (n=7)

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%)

Patients with Carcinoma in *situ* with or without papillary disease that was determined to be refractory or recurred after six months, but less than 12 months, after their last course of adequate BCG

Pooled Cohorts 1 and 2 CRRs (n=93)

Time point	Evaluable Patients	Complete Response Rate (95% Confidence Interval)
3-months	n=93	39% (29%-49%)
6-months	n=92	27% (18%-37%)
9-months	n=91	20% (12%-29%)
12-months	n=88	14% (7%-23%)

Patients with Carcinoma in *situ* with or without papillary disease that was determined to be refractory or recurred less than 12 months, after their last course of adequate BCG

Cohort 3 Recurrence-Free Rate (n=40)*

Time point	Evaluable Patients	Recurrence-Free Rate (95% Confidence Interval)
3-months	n=40	68% (51%-81%)
6-months	n=39	56% (40%-72%)
9-months	n=38	42% (26%-59%)
12-months	n=36	36% (21%-54%)

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

***As of the December 3, 2018 data cut off, but not previously reported in January 2019**

- **Additional Preliminary VISTA Analyses Further Support Vicinium Treatment Potential for NMIBC:** Since the first preliminary data were reported in January, Sesen Bio conducted additional analyses, including duration of response in patients with Carcinoma *in situ* with or without papillary disease, time to cystectomy across all patient types with Carcinoma *in situ* or papillary disease, and time to disease recurrence and recurrence-free rate in patients with papillary disease without Carcinoma *in situ* as of an assessment date of December 3, 2018. These additional preliminary data, in addition to the data reported in January, support a growing body of evidence demonstrating the anti-tumor activity of Vicinium.
    - **Duration of Response:** In addition to the complete response rate in Cohort 1, duration of response in Cohort 1 is a primary endpoint measure.The median duration of complete response for patients in Cohort 1 (n=86) is 227 days (95% CI, 127-516), 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, 69% had a complete response of 6 months or longer after starting therapy.
    - **Time to Cystectomy:** The U.S. Food and Drug Administration (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, patients are projected to be cystectomy-free for approximately 519 days (95% CI, 361-523), or 18 months.
    - **Time to Disease Recurrence:** High-grade 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-grade papillary-only (Ta and T1) NMIBC. The median time to disease recurrence for patients in Cohort 3 (n=40) is 270 days (95% CI, 169-452).

    - **Recurrence-free Rate:**Sesen Bio conducted an ad hoc analysis on disease recurrence, a standard criterion to evaluate treatment response for patients with high-grade papillary-only (Ta and T1) NMIBC. The analysis showed that for patients in Cohort 3 (n=40), Vicinium treatment demonstrated favorable efficacy with 56% (95% CI, 40%-72%) of patients remaining recurrence-free at 6 months, and 36% (95% CI, 21%-54%) of patients remaining recurrence-free at 12 months.
- **Vicinium Demonstrated to be Well-tolerated in the VISTA Trial**: As of the December 3, 2018 data cut off, in patients across all cohorts (n=133), 78% 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 to be manageable and reversible, and only five patients 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 renal injury (Grade 3), pyrexia (Grade 2), cholestatic hepatitis (Grade 4) and renal failure (Grade 5). No patient developed metastatic disease during the Phase 2 clinical trial for Vicinium or the Phase 3 VISTA trial (through the December 3, 2018 data cut off).
- **Updated VISTA Trial Data on Track to be Reported in Mid-2019**: The Phase 3 VISTA trial remains ongoing and the company anticipates reporting updated primary and secondary endpoint data from the VISTA trial in mid-2019. In August 2018, Vicinium was granted Fast Track Designation by the FDA for the treatment of patients with high-risk NMIBC who have previously received two courses of BCG and whose disease is now BCG-unresponsive. In connection with this designation, the Company is planning to further engage with the FDA in the first half of 2019 to discuss its intended registration strategy for Vicinium for the treatment of high-risk NMIBC.

Additional Vicinium Progress

- **Manufacturing Readiness Underway with FUJIFILM**:In October 2018, the Company entered into an agreement for the manufacturing process and technologytransfer of Vicinium production with FUJIFILM Diosynth Biotechnologies U.S.A., Inc. (FUJIFILM). Preparations are underway for full-scale GMP manufacturing at FUJIFILM in the second quarter of 2019 to assess FUJIFILM'S ability to produce the bulk drug substance form of Vicinium for commercial purposes if Sesen Bio receives regulatory approval to market Vicinium for the treatment of high-risk NMIBC.
- **Continued Support of Vicinium Combination Trial in NMIBC:** Sesen Bio has continued support of the National Cancer Institute's ongoing clinical assessment of Vicinium in combination with AstraZeneca's immune checkpoint inhibitor, durvalumab, for the treatment of patients with high-risk, BCG-unresponsive NMIBC. Sesen Bio believes the Phase 1 trial is based on strong scientific rationale, as well as both clinical and preclinical data, on combining Vicinium with a checkpoint inhibitor. The Company expects biomarker data from this Phase 1 trial to be reported in the second half of 2019.

Fourth Quarter and Full-Year 2018 Financial Results

- **Cash Position:** Cash and cash equivalents were $50.4 million as of December 31, 2018, compared to $14.7 million as of December 31, 2017.
- **Revenue:** No revenue was recorded for the three months ended December 31, 2018, nor for the same period in 2017. For the twelve months ended December 31, 2018, Sesen Bio did not record any revenue, compared to $0.4 million in revenue for the same period in 2017. This decrease was due to revenue recognized in 2017 from the License Agreement with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc related to EBI-031 and all other IL-6 antagonist antibody technology, which was a part of the Company's prior technology platform before the Company acquired Viventia Bio, Inc. in 2016.
- **R&D Expenses:** Research and development (R&D) expenses for the fourth quarter of 2018 were $4.7 million, compared to $3.1 million in R&D expenses for the same period in 2017. For the twelve months ended December 31, 2018, research and development expenses were $14.1 million compared to $12.5 million for the same period in 2017. The fourth quarter and annual increases were both driven by expenses related to the ongoing manufacturing process and technology transfer with FUJIFILM which initiated in mid-2018.
- **G&A Expenses:** General and administrative expenses for the fourth quarter of 2018 were $3.5 million compared to $2.0 million for the same period in 2017. The increase was due primarily to higher staffing, and consulting costs as well as higher legal and intellectual property related costs in 2018. For the twelve months ended December 31, 2018, general and administrative expenses were $11.6 million and $8.1 million for the same period in 2017. The increase was due primarily to an increase in professional fees, one-time personnel-related expenses and increased market research consulting costs.
- **Net Loss:** Net loss was $6.8 million, or $0.09 per share, for the fourth quarter of 2018 and $33.7 million, or $0.55 per share, for the twelve months ended December 31, 2018, compared to $6.5 million, or $0.22 per share, for the fourth quarter of 2017 and $29.0 million, or $1.11 per share, for the full year ended December 31, 2017.
- **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 2179668. 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 duration of complete 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. Updated twelve-month data for the VISTA trial are anticipated in mid-2019. 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 (ETA). 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 two courses of bacillus Calmette-Guérin (BCG) and whose disease is now BCG-unresponsive. Updated twelve-month data from the trial are anticipated in mid-2019. 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 un-responsive non-muscle invasive bladder cancer. Updated twelve-month data from the trial are anticipated in mid-2019. Vicinium incorporates a tumor-targeting antibody fragment and a protein cytotoxic payload into a single protein molecule designed to selectively and effectively kill cancer cells, while minimizing toxicity to non-cancerous bladder cells. 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, 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.
CONSOLIDATED BALANCE SHEETS

(in thousands)

	December 31, 2018	2017
Assets		
Current assets:		
Cash and cash equivalents	$ 50,422	$ 14,680
Prepaid expenses and other current assets	1,334	301
Total current assets	51,756	14,981
Property and equipment, net	321	522
Restricted cash	20	10
Intangible assets	46,400	46,400
Goodwill	13,064	13,064
Other assets	-	120

Total assets	$ 111,561	$ 75,097
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,367	$ 907
Accrued expenses	4,746	3,813
Total current liabilities	6,113	4,720
Other liabilities	313	215
Deferred tax liability	12,528	12,528
Contingent consideration	48,400	39,600
Stockholders' equity:		
Common stock	77	35
Additional paid-in capital	230,154	170,330
Accumulated deficit	(186,024)	(152,331)
Total stockholders' equity	44,207	18,034
Total liabilities and stockholders' equity	$ 111,561	$ 75,097

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

	(unaudited)			
	Three Months Ended December 31,		**Twelve Months Ended December 31,**	
	2018	**2017**	**2018**	**2017**
Total revenue	$ -	$ -	$ -	$ 425
Operating expenses:				
Research and development	4,671	3,108	14,077	12,510
General and administrative	3,495	1,985	11,623	8,070
Loss (gain) from change in fair value of contingent consideration	(1,100)	1,500	8,800	9,100
Total operating expenses	7,066	6,593	34,500	29,680
Loss from operations	(7,066)	(6,593)	(34,500)	(29,255)
Other income, net	309	46	807	226
Net loss before income taxes	(6,757)	(6,547)	(33,693)	(29,029)
Provision for income taxes	-	-	-	-
Net loss and comprehensive loss	$ (6,757)	$ (6,547)	$ (33,693)	$ (29,029)
Net loss per share —basic	$ (0.09)	$ (0.22)	$ (0.55)	$ (1.11)
Weighted-average number of common shares used in net loss per share —basic	77,345	30,385	61,774	26,105
Net loss per share —diluted	$ (0.09)	$ (0.22)	$ (0.55)	$ (1.11)
Weighted-average number of common shares used in net loss per share —diluted	77,345	30,385	61,774	26,105

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