Sesen Bio Reports Positive, Preliminary Data Update from Phase 3 VISTA Trial for High-Risk Non-Muscle Invasive Bladder Cancer

August 8, 2019

Updated 12-month Phase 3 Data will Serve as the Basis for Submission of the BLA

On Track for Anticipated Initiation of BLA Submission in 4Q 2019

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Aug. 8, 2019-- **Sesen Bio** (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, today reported updated, preliminary primary and secondary endpoint data from the Company's Phase 3 VISTA trial further supporting the strong benefit-risk profile of Vicinium for the potential treatment of patients with high-risk,bacillus Calmette-Guérin(BCG) unresponsive, non-muscle invasive bladder cancer (NMIBC). The updated preliminary Phase 3 clinical data will serve as the basis for the anticipated initiation of the Company's BLA submission in 4Q 2019.

"After two very positive meetings with the FDA in the second quarter, we are now focused on initiating the BLA submission for Vicinium in the fourth quarter under an Accelerated Approval pathway with Rolling Review," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "We believe this regulatory pathway and o ur strong 12-month Phase 3 data could potentially expedite patient access to Vicinium, which is particularly important in light of the ongoing BCG shortage. We look forward to our two additional face-to-face meetings with the FDA in the fourth quarter as we work to bring Vicinium to market to help save and improve the lives of patients with NMIBC."

Phase 3 VISTA Trial Progress

- **Updated Primary and Secondary Endpoint Data from Phase 3 VISTA Trial Support a Growing Body of Evidence Demonstrating the Clinically Meaningful Anti-tumor Activity of Vicinium:** In May, Sesen Bio announced updated preliminary data from its ongoing Phase 3 VISTA trial, a single-arm, 24-month, 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 efficacy endpoints consist of complete response rate and duration of response for patients in Cohort 1. Secondary efficacy 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 patients across all cohorts. As of the May 29, 2019 data cut, updated preliminary primary and secondary efficacy data for each of the trial cohorts were as follows:

Cohort 1 Complete Response Rate, Evaluable Population

Time point	Evaluable Patients*	Complete Response Rate
3-months	n=82	39%
6-months	n=82	26%
9-months	n=82	20%
12-months	n=82	17%

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.

*Response-evaluable population includes any modified intention to treat (mITT) subject who completed the induction phase.

Cohort 2 Complete Response Rate, Evaluable Population

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 or equal to 11 months, after their last course of adequate BCG.

*Response-evaluable population includes any mITT subject who completed the induction phase.

Pooled Cohorts 1 and 2 Complete Response Rate, Evaluable Population

Time point	Evaluable Patients*	Complete Response Rate (95% Confidence Interval)
3-months	n=89	40% (30%- 51%)
6-months	n=89	28% (19%-39%)
9-months	n=89	21% (13%-31%)
12-months	n=89	17% (10%-26%)

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.

*Response-evaluable population includes any mITT subject who completed the induction phase.

- **Duration of Response:** The median duration of response for patients in Cohort 1 (n=86) is 273 days (95% CI, 122-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, 52% 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 approximately 88% of responders are estimated to remain cystectomy-free at 3 years.
- **Progression-Free Survival:** 90% of all 133 patients treated with Vicinium are estimated to remain progression-free for 2 years or greater, 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:** 29% 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:** 96% of all 133 patients treated with Vicinium are estimated to have an overall survival of 2 years or greater, 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 in the Phase 3 VISTA Trial:** As of the May 29, 2019 data cut, in patients across all cohorts (n=133), 95% of adverse events were Grade 1 or 2. The most commonly reported treatment-related adverse events were dysuria (14%), hematuria (13%) and urinary tract infection (12%) – all of which are consistent with the profile of bladder cancer patients and the use of catheterization for treatment administration. These adverse events were determined by the clinical investigators to be manageable and reversible, and only four patients (3%) discontinued treatment due to an adverse event. Serious adverse events (SAEs), 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.

Vicinium Regulatory Pathway Updates

- **Bulk Drug Substance from the Full-Scale GMP Manufacturing Run at FUJIFILM Met all Phase 3 Quality Release Specifications:** In April 2019, the first full, commercial-scale GMP run was completed at FUJIFILM Diosynth Biotechnologies U.S.A., Inc (FUJIFILM). Release testing of the bulk drug substance has been completed and all Phase 3 release specifications were met, further de-risking the Company's manufacturing technology transfer to FUJIFILM and the Company's Analytical Comparability Plan.
- **Recent positive interactions with the FDA reaffirm the Company's confidence in the regulatory and commercial pathway for Vicinium**
    - **Type C CMC Meeting held on May 20, 2019.** In conjunction with the technology transfer of Vicinium production to FUJIFILM, the Company has reached agreement with the FDA on the Analytical Comparability Plan, and that, subject to final comparability data to be provided in the BLA submission, no additional clinical trials to establish comparability are deemed necessary at this time.
    - **Pre-BLA Meeting held on June 6, 2019.** The Company has reached alignment with the FDA on the regulatory approval pathway for Vicinium:
        - The clinical, nonclinical and clinical pharmacology data, as well as the safety database, are sufficient to support a BLA submission, and no additional clinical trials are necessary for a BLA submission.
        - FDA recommended submission under an Accelerated Approval Pathway and Rolling Review.
        - Per the official FDA minutes received post-meeting, the FDA stated that the pre-approval inspection (PAI) may be completed at the time of PPQ manufacturing, which the Company believes will further de-risk the CMC review timeline.
        - Expected Advisory Committee (ODAC) meeting post-BLA submission to review the benefit-risk profile of Vicinium, given there have been no product approvals in this indication in the past twenty years.

Key Upcoming Corporate Milestones:

- Type B CMC meeting to align on the submission strategy of CMC Module 3.
- Type C meeting to discuss the details of a post-marketing confirmatory trial in support of the Accelerated Approval Pathway for Vicinium.
- Initiation of BLA submission including nonclinical and clinical modules 1, 2, 4 and 5.

Second Quarter 2019 Financial Results

- **Cash Position:** Cash and cash equivalents were $64.9 million as of June 30, 2019, compared to $50.4 million as of December 31, 2018.
- **Revenue:** No revenue was recorded for the three months ended June 30, 2019, nor for the comparable period in 2018.
- **R&D Expenses:** Research and development (R&D) expenses for the second quarter of 2019 were $7.9 million compared to $2.8 million in R&D expenses for the same period in 2018. The increase of $5.1 million was due primarily to 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 second quarter of 2019 were $2.6 million compared to $2.4 million for the same period in 2018. The increase was due primarily to higher professional fees and internal staffing costs.
- **Net Loss:** Net loss was $54.3 million, or $0.67 per share, for the second quarter of 2019, compared to $9.0 million, or $0.16 per share, for the second quarter of 2018. Included in the 2019 net loss is a charge for $44.0 million to increase the Company's contingent consideration liability for higher estimated commercial sales volumes of Vicinium.

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 cancer cell-killing properties of Vicinium 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 future meetings with the FDA, our ability to obtain marketing approvals for our product candidates, expectations regarding our ongoing clinical trials, availability and timing of data from clinical trials, 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 submissions and approvals, expectations regarding the adequacy of our existing capital resources to fund our operating plan into 2021 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 BALANCE SHEETS
(in thousands)

	(unaudited) June 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 64,931	$ 50,422
Prepaid expenses and other current assets	2,598	1,334
Total current assets	67,529	51,756
Property and equipment, net	376	321
Restricted cash	20	20
Intangible assets	46,400	46,400
Goodwill	13,064	13,064

Other assets	223	-
Total assets	$ 127,612	$ 111,561
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,176	$ 1,367
Accrued expenses	$ 5,630	$ 4,746
Other current liabilities	142	-
Total current liabilities	7,948	6,113
Other liabilities	367	313
Deferred tax liability	12,528	12,528
Contingent consideration	91,400	48,400
Stockholders' equity:		
Common stock	101	77
Additional paid-in capital	262,107	230,154
Accumulated deficit	(246,839)	(186,024)
Total stockholders' equity	15,369	44,207
Total liabilities and stockholders' equity	$ 127,612	$ 111,561

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
Operating expenses:				
Research and development	7,944	2,779	12,630	6,034
General and administrative	2,617	2,351	5,672	4,303
Loss from change in fair value of contingent consideration	44,000	3,900	43,000	2,700
Total operating expenses	54,561	9,030	61,302	13,037
Loss from operations	(54,561)	(9,030)	(61,302)	(13,037)
Other income, net	226	72	487	116

Net loss and comprehensive loss	$ (54,335)	$ (8,958)	$ (60,815)	$ (12,921)
Net loss per share —basic and diluted	$ (0.67)	$ (0.16)	$ (0.77)	$ (0.28)
Weighted-average number of common shares used in net loss per share —basic and diluted	80,739	56,421	79,107	46,105

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