Sesen Bio Reports Third Quarter 2019 Financial Results and Update on Regulatory Activities Related to Vicinium

November 12, 2019

On Track for Anticipated Initiation of BLA Submission in December, 2019

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 12, 2019-- **Sesen Bio** (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, today reported financial results for the third quarter of 2019 and provided an update on regulatory activities related to Vicinium.

"The third quarter of 2019 marked a pivotal period for the Company, as we began preparations to transition from a development stage to a commercial stage organization," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "We believe Vicinium has demonstrated compelling and clinically meaningful efficacy, and we look forward to submitting these data to the FDA as part of the initiation of our BLA submission in December. This key value inflection point sets up 2020 to be a transformational year for us and we are excited to continue working expeditiously to potentially bring Vicinium to market to help save and improve the lives of patients with NMIBC."

Vicinium Regulatory Pathway Update

- **Recent positive interactions with the FDA support the Company's confidence in the regulatory and commercial pathway for Vicinium**
  - **On November 4, 2019, the Company met with the FDA for a Type C meeting to discuss the details of a post-marketing confirmatory trial for Vicinium.** The Company reached agreement with the FDA that the trial will enroll BCG-refractory patients who have received less-than-adequate BCG. This represents a broader patient population than the BCG-intolerant population originally proposed and it is anticipated that, if Vicinium is approved by the FDA and the post-marketing confirmatory trial is successful, labeling will be expanded to include this additional patient population. This trial is expected to be powered to demonstrate the superior efficacy of Vicinium compared to currently utilized therapies for the primary endpoints, which are expected to include the complete response rate and duration of response in CIS patients. These data, along with the secondary endpoints, which are expected to include a number of quality of life, survival and safety endpoints, are anticipated to position Vicinium for favorable reimbursement with payers.

Key Fourth Quarter 2019 Events

- FDA meeting on December 4, 2019 to discuss the submission strategy for CMC Module 3
- Anticipated initiation of BLA submission under a Rolling Review in December 2019
- Sesen Bio Regulatory Update in December 2019

Third Quarter 2019 Financial Results

- **Cash Position:** Cash and cash equivalents were $57.9 million as of September 30, 2019, compared to $50.4 million as of December 31, 2018.
- **R&D Expenses:** Research and development expenses for the third quarter of 2019 were $6.6 million compared to $3.4 million for the same period in 2018. The increase of $3.2 million was due primarily to costs related to the ongoing technology transfer process as we scale-up for commercial manufacturing and increased regulatory, 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 third quarter of 2019 were $3.2 million compared to $3.8 million for the same period in 2018. The decrease was due primarily to lower legal, commercial and internal employee staffing costs, offset by higher professional fees.
- **Net Loss:** Net loss was $13.1 million, or $0.13 per share, for the third quarter of 2019, compared to $14.0 million, or $0.18 per share, for the third quarter of 2018. The decrease was due primarily to a lesser non-cash change in the fair value of contingent consideration, offset by the higher research and development expenses described above.

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 (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 received 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 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 conduct of clinical trials, 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, the adequacy of any clinical models, expectations regarding regulatory submissions, labeling, and approvals 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 September 30,		Nine Months ended September 30,	
	2019	**2018**	**2019**	**2018**
Operating expenses:				
Research and development	$ 6,613	$ 3,372	$ 19,243	$ 9,406
General and administrative	3,238	3,825	8,910	8,128
Change in fair value of contingent consideration	3,600	7,200	46,600	9,900
Total operating expenses	13,451	14,397	74,753	27,434
Loss from Operations	(13,451)	(14,397)	(74,753)	(27,434)
Other income (expense):				
Other income, net	319	382	806	498
Net Loss and Comprehensive Loss	**$ (13,132)**	**$ (14,015)**	**$ (73,947)**	**$ (26,936)**

Net loss per common share - basic and diluted	$ (0.13)	$ (0.18)	$ (0.85)	$ (0.48)
Weighted-average common shares outstanding - basic and diluted	101,266	77,030	86,575	56,526

SESEN BIO, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited; In thousands, except share and per share data)

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 57,865	$ 50,422
Prepaid expense and other current assets	1,547	1,334
Total current assets	59,412	51,756
Restricted cash	20	20
Property and equipment, net of accumulated depreciation of $4,519 and $4,355, respectively	294	321
Intangible assets	46,400	46,400
Goodwill	13,064	13,064
Other assets	208	-
Total Assets	**$ 119,398**	**$ 111,561**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,583	$ 1,367
Accrued expenses	6,350	4,746
Other current liabilities	159	-
Total current liabilities	9,092	6,113
Contingent consideration	95,000	48,400
Deferred tax liability	12,528	12,528
Other liabilities	311	313
Total Liabilities	116,931	67,354
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, $0.001 par value per share; 5,000,000 shares authorized at September 30, 2019 and December 31, 2018; no shares issued and outstanding at September 30, 2019 and December 31, 2018	-	-

Common stock. $0.001 par value per share; 200,000,000 shares authorized at September 30, 2019 and December 31, 2018; 101,267,578 and 77,456,180 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	101	77
Additional paid-in capital	262,337	230,154
Accumulated deficit	(259,971)	(186,024)
Total Stockholders' Equity	2,467	44,207
Total Liabilities and Stockholders' Equity	**$ 119,398**	**$ 111,561**

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Source: Sesen Bio

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