Sesen Bio Announces Positive Preliminary 12-Month Data from Registration Phase 3 VISTA Trial of Vicinium for Non-Muscle Invasive Bladder Cancer

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Complete Response Rates from All Four Time Points in Carcinoma in Situ Patients In-line with Phase 2 Data

Company to Host Conference Call Today, January 3, at 8:30 a.m. ET

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jan. 3, 2019-- Sesen Bio, Inc. (Nasdaq: SESN), a late-stage clinical company advancing targeted fusion protein therapeutics for the treatment of cancer, today reported positive preliminary efficacy data for the primary endpoint of its ongoing Phase 3 registration trial, the VISTA Trial, of Vicinium® for the treatment of patients with high-grade non-muscle invasive bladder cancer (NMIBC) who have been previously treated with bacillus Calmette-Guérin (BCG) and deemed BCG-unresponsive. The data reported show clinically meaningful complete response rates in evaluable Carcinoma *in situ* patients at three, six, nine and 12 months of follow-up in the trial consistent with the data in the completed Phase 1 and Phase 2 clinical trials. Importantly, Vicinium continues to be generally well-tolerated in treated patients.

“Non-muscle invasive bladder cancer is a very prevalent cancer that can progress to become incurable. The usual treatment for patients who relapse or become refractory to BCG, today’s standard-of-care, is complete bladder removal or radical cystectomy,” said Michael A.S. Jewett, M.D., Professor of Surgery, Division of Urology, University of Toronto. “Removing the bladder is a potentially morbid and complex surgery with potential for side effects that can drastically reduce a patient’s quality of life. In fact, many patients choose not to undergo bladder removal. I am very encouraged by the data generated to-date with intravesical Vicinium as an alternative after BCG failure. Based on the strength of the clinical activity observed, and the consistently favorable safety and tolerability, I believe that Vicinium has the potential to change the treatment outcome for patients.”

VISTATrial Design
The Phase 3 VISTA Trial is a single-arm, multi-center clinical trial designed to support the approval of Vicinium for the treatment of patients with high-grade, BCG-unresponsive NMIBC. The trial enrolled a total of 133 patients across three cohorts based on histology and time to disease recurrence after adequate BCG:

- Cohort 1 (n=86): Carcinoma *in situ* patients with or without papillary disease whose cancer was determined to be refractory or recurred within six months of their last course of adequate BCG
- Cohort 2 (n=7): Carcinoma *in situ* patients with or without papillary disease whose cancer was determined to be refractory or recurred after six months, but less than 12 months, after their last course of adequate BCG
- Cohort 3 (n=40): patients with papillary disease without Carcinoma *in situ* whose cancer was determined to be refractory or recurred within six months of their last course of adequate BCG

The data reported build upon preliminary three-month data presented from a subset of patients in May 2018 and are for the primary endpoint of the VISTA Trial, which is the complete response rate and duration of response in patients in Cohort 1. The company also reported data from Cohort 2, separately and pooled with Cohort 1, based on final U.S. Food and Drug Administration guidance on treatment of BCG-unresponsive Carcinoma *in situ* patients (defined as patients with recurrent Carcinoma *in situ* within 12 months of adequate BCG therapy)[1].

The patient population in Cohort 3 represents an opportunity for future label expansion, and the company plans to report efficacy data from this cohort, as well as the secondary endpoints in the VISTA Trial, in mid-2019.

Preliminary Efficacy Results in Carcinoma *in situ* Patients

Cohort 1 (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%)

Cohort 2 (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%)

Pooled Cohorts 1 and 2 (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%)

Notably, the interim Phase 3 complete response rates in pooled patients from Cohorts 1 and 2 are in-line with the complete response rates in pooled patients in the completed Phase 2 clinical trial.

Preliminary Phase 3 CRR vs Phase 2 CRR

Time point	Phase 3 Pooled CRR (95% Confidence Intervals)	Phase 2 Pooled CRR (95% Confidence Interval)
3-months	39% (29%, 49%)	40% (26%, 56%)
6-months	27% (18%, 37%)	27% (15%, 42%)
9-months	20% (12%, 29%)	18% (8%, 32%)
12-months	14% (7%, 23%)	16% (7%, 30%)

The company also reported an update on the durability of responses in the VISTA Trial. While the median has not yet been reached, the preliminary data show that Vicinium treatment resulted in a prolonged duration of response in many patients. This is particularly notable given that, in order for patients to remain on study, they have to have achieved a complete response at each assessment time period. These findings suggest that Vicinium has the potential to benefit patients by delaying the time to a radical cystectomy, a secondary endpoint that will be measured and reported in mid-2019.

Preliminary Safety Results

Vicinium continues to be well-tolerated by patients treated in the VISTA Trial. As of the December 3, 2018 data cut off, in patients across all three cohorts (n=133), 78 percent 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 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 percent 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).

"We are very pleased with these preliminary data, which are consistent with the data in our completed Phase 2 clinical trial of Vicinium for the treatment of high-grade NMIBC, and further support our belief that Vicinium has the potential to change how patients are treated after BCG," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "The design of the VISTA Trial aligns with FDA's guidance for NMIBC drug development, and the findings are highly encouraging, demonstrating that treatment with Vicinium results in clinically meaningful efficacy and favorable safety and tolerability. Overall, the data reinforce our belief that Vicinium is positioned to provide a valuable benefit to patients by treating their disease with long-term responses and extending their time to face such a decision as removing their bladder. 2019 is set to be a transformational year for Sesen Bio, and we look forward to advancing the VISTA Trial and assessing the full 12-month data from all patients later this year."

The VISTA Trial completed enrollment in the second quarter of 2018, and complete 12-month efficacy data from all patients in the clinical trial are expected to be reported at a medical meeting in mid-2019.

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 4263106. 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® in patients with high-grade non-muscle invasive bladder cancer (NMIBC) that is Carcinoma *in situ*, which is cancer found on the inner lining of the bladder that has not spread into muscle or other tissue and/or papillary, which is cancer that has grown from the bladder lining out into the bladder but has not spread into muscle or other tissue, who have been previously treated with bacillus Calmette-Guérin (BCG). The primary endpoint of the trial is the complete response rate 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. Twelve-month data from all patients in 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-grade 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-grade NMIBC in patients who have previously received two courses of bacillus Calmette-Guérin (BCG) and whose disease is now BCG-unresponsive. Complete 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 Non-Muscle Invasive Bladder Cancer
Bladder cancer is the sixth most commonly diagnosed cancer in the United States, and approximately 80 percent of patients have non-muscle invasive bladder cancer (NMIBC). In NMIBC, cancer cells are in the lining of the bladder or have grown into the lumen of the bladder but have not spread into muscle or other tissue. NMIBC primarily affects men and is associated with carcinogen exposure. Initial treatment includes surgical resection; however, there is a high rate of recurrence and more than 60 percent of all patients diagnosed with NMIBC will receive bacillus Calmette-Guérin (BCG) immunotherapy. While BCG is effective in many patients, challenges with tolerability have been observed and many patients will experience recurrence of disease. If BCG is not effective or a patient can longer receive BCG, the recommended option for treatment is radical cystectomy, the complete removal of the bladder.

About Sesen Bio
Sesen Bio, Inc. is a late-stage clinical company advancing targeted fusion protein therapeutics for the treatment of 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-grade, BCG-unresponsive non-muscle invasive bladder cancer. Twelve-month data from all patients in the VISTA 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 sparing healthy 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 available preliminary data of the Phase 3 VISTA Trial are not indicative of final data from all patients in Phase 3 VISTA Trial and final data 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, the adequacy of any clinical models, expectations regarding regulatory 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.

[1]United States Food and Drug Administration, BCG-Unresponsive Nonmuscle Invasive Bladder Cancer: Developing Drugs and Biologics for Treatment Guidance for Industry, February 2018

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Source: Sesen Bio, Inc.

Monique Allaire, THRUST Strategic Communications
monique@thrustsc.com
617-895-9511

Chelcie Lister, THRUST Strategic Communications
chelcie@thrustsc.com
910-777-3049