



Sesen Bio to Present Three-month VISTA Trial Data at Global Congress on Bladder Cancer 2018

September 20, 2018

Biomarker Data Show that Molecular Target of Vicinium™, EpCAM, Expressed in Nearly All High-Grade NMIBC Patients

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Sep. 20, 2018-- Sesen Bio, Inc. (Nasdaq: SESN), a late-stage clinical company developing fusion protein therapies for the treatment of cancer, today announced that the company will present its three-month Phase 3 VISTA Trial data during a poster session at the Global Congress on Bladder Cancer 2018. The congress is being held Sept. 20-21, 2018 in Madrid. The ongoing VISTA registration trial is evaluating Vicinium™, Sesen Bio's lead product candidate, for the treatment of people with high-grade non-muscle invasive bladder cancer (NMIBC) who have been previously treated with bacillus Calmette-Guérin (BCG).

The data, which were [presented](#) during a plenary session at the American Urological Association Annual Meeting in May 2018, include a biomarker update showing that nearly all screened patient samples expressed EpCAM, the molecular target of Vicinium.

"We are delighted to present the three-month VISTA Trial data at the Global Congress on Bladder Cancer and further showcase the promise of Vicinium in treating people with NMIBC," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "Today, patients who are unresponsive or become refractory to BCG therapy have virtually one option: complete removal of their bladder. This is a long, challenging and life-altering procedure with a high rate of mortality that nearly half of people who face it choose not to undergo. It is critically important that such people are provided an effective and tolerable option that spares them from having to make such a difficult decision and saves their bladder. We believe that Vicinium holds significant potential as a targeted treatment that could renew the lives of these underserved patients."

As announced in May, the three-month data are from 111 patients in the VISTA Trial with high-grade NMIBC that is either carcinoma in situ (CIS), which is cancer found on the inner lining of the bladder that has not spread into muscle or other tissue, with or without papillary disease, or from patients with papillary disease without CIS, which is cancer that has grown from the bladder lining out into the bladder, but has not spread into muscle or other tissue. In an analysis assessing pooled CIS patients (n=77), based on final U.S. Food and Drug Administration guidance on treatment of BCG-unresponsive CIS NMIBC patients (defined as patients with recurrent CIS within 12 months of adequate BCG therapy)¹, Vicinium treatment resulted in a complete response rate of 42 percent at three months. In patients with papillary disease without CIS, treatment with Vicinium demonstrated a 68 percent recurrence-free rate at three months.

In addition, Vicinium has been well-tolerated in the VISTA Trial. Of the treatment-related adverse events in the three-month analysis, four percent were Grade 3 or 4, with no Grade 5 treatment-related adverse events. Four treatment-related serious adverse events were reported, including acute kidney injury or renal failure and cholestatic hepatitis.

About Vicinium™

Vicinium™ (also known as VB4-845), Sesen Bio's lead product candidate, is a fusion protein 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 linker 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 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. 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 fusion protein therapies for the treatment of cancer based on the company's Targeted Protein Therapeutics platform. 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 non-muscle invasive bladder cancer. 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 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 three-month 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 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.

¹United 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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