Sesen Bio Announces Vicinium Granted Fast Track Designation by FDA for Treatment of Non-Muscle Invasive Bladder Cancer

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CAMBRIDGE, Mass.--(BUSINESS WIRE)--Aug. 9, 2018-- Sesen Bio, Inc. (Nasdaq: SESN), a late-stage clinical company developing next-generation antibody-drug conjugate (ADC) therapies for the treatment of cancer, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to Vicinium™ for the treatment of BCG-unresponsive high-grade non-muscle invasive bladder cancer (NMIBC). Vicinium, Sesen Bio's lead product candidate, is currently being evaluated in a Phase 3 registration trial, the VISTA Trial, for the treatment of patients with high-grade NMIBC who have previously received two courses of bacillus Calmette-Guérin (BCG) and whose disease is now BCG-unresponsive.

"The granting of this designation is an important milestone for Sesen Bio, and we believe it exemplifies the urgent need for a new treatment option for people with NMIBC for whom bladder removal is the recommended course after BCG," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "We are highly encouraged by the differentiated product profile of Vicinium in NMIBC, with a unique mechanism of action, positive three-month data presented earlier this year and favorable tolerability in patients treated to-date. With Fast Track designation, we look forward to determining the optimal registration path and assessing the opportunity for accelerated approval to bring Vicinium to patients as quickly as possible."

The FDA's Fast Track process is designed to expedite the development and review of drugs used to treat serious or life-threatening conditions and fill an unmet medical need. Fast Track designation allows for frequent communication and interactions with the review team at the FDA throughout the drug development and review process, with the goal of providing faster drug approval and greater patient access.

Enrollment is complete in the Phase 3 VISTA Trial and the company expects to report 12-month efficacy results in mid-2019.

About Vicinium™
Vicinium™, also known as VB4-845, is Sesen Bio's lead product candidate and is a next-generation antibody-drug conjugate (ADC), developed using the company's proprietary Targeted Protein Therapeutics platform, 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 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. 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 next-generation antibody-drug conjugate 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 potential benefits of the Fast Track designation of Vicinium, 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.

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