Sesen Bio Initiates Rolling Submission of BLA for Vicinium to FDA

December 9, 2019

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Dec. 9, 2019-- **Sesen Bio** (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, today announced that on December 6, 2019, the Company initiated the submission of its Biologics License Application (BLA) for Vicinium for the treatment of BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) under Rolling Review to the U.S. Food and Drug Administration (FDA). Vicinium was granted Fast-Track Designation by the FDA in 2018.

"There remains a significant unmet medical need in NMIBC that has also been further complicated by the ongoing BCG shortage," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "T he initiation of the rolling BLA for Vicinium marks a tremendous achievement for Sesen Bio and an important step forward in our efforts to help save and renew the lives of patients with cancer."

The Company has submitted completed non-clinical and clinical modules, and a partially completed Chemistry, Manufacturing and Controls (CMC) module. The Company anticipates completing the BLA submission with the finalization of the CMC module in 2020. If the FDA accepts the BLA filing, the Company plans to request a Priority Review.

In addition, Dr. Cannell will host a conference call and webcast on Monday, December 16th at 8 AM ET to provide a regulatory update for Vicinium.

To participate in the conference call, please dial (844) 831-3025 (domestic) or (315) 625-6887 (international) and refer to conference ID 5285284. The webcast can be accessed from the Investor Relations section of the Company's website at www.sesenbio.com. The replay of the webcast will be available in the Investor Relations section of the Company's website at www.sesenbio.com for 60 days following the call.

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: expectations regarding the timing of our BLA submissions, expectations about our plans to request Priority Review, our ability to successfully finalize the CMC module 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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Source: Sesen Bio, Inc.

Chad Myskiw, Senior Director, Strategic Planning
ir@sesenbio.com