# Sesen Bio Announces Acceptance of Analytical Comparability Plan by the U.S. Food and Drug Administration to Support the BLA and Commercialization of Its Lead Asset, Vicinium® for Non-Muscle Invasive Bladder Cancer

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CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 21, 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 the Company has completed its Type C CMC meeting and has reached agreement with the U.S. Food and Drug Administration (FDA) on the Analytical Comparability Plan, and that, subject to final comparability data to be provided in the BLA submission, no additional clinical trials to establish comparability are deemed necessary at this time.

In its Phase 2 and 3 clinical trials, Sesen Bio manufactured Vicinium in its facility in Winnipeg, Manitoba. Based on the Company's assessment of the global demand potential for Vicinium, Sesen Bio sought a commercial manufacturer with outstanding manufacturing quality, a proven track record with regulatory agencies, and the capacity to meet global demand forecasts.

In October 2018, Sesen Bio entered into an agreement for the manufacturing process and technology transfer of Vicinium production with FUJIFILM Diosynth Biotechnologies U.S.A., Inc. (FUJIFILM). In April 2019, the first in a series of full-scale, commercial GMP runs was successfully completed at FUJIFILM. The final bulk drug substance produced in this first run met all release specifications.

"Because we are changing manufacturing sites, it was important to agree on an approach to establish product comparability, which will be part of the BLA submission for Vicinium," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "Gaining FDA agreement with our proposed Analytical Comparability Plan was the primary objective for yesterday's meeting with the FDA. This is a very positive outcome and brings us one step closer to regulatory approval of Vicinium, and our ability to help save and improve the lives of patients."

On June 6, 2019, Sesen Bio will meet with the FDA for its second scheduled meeting, a Type B Pre-BLA meeting, to discuss the registration strategy for Vicinium. Due to the wide-range of topics to be discussed at the Pre-BLA meeting, the Company plans to provide an update on the outcome of that meeting upon receipt of the final meeting minutes, which is typically within 30 days.

**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 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 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, the VISTA 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 the Company's Analytical Comparability Plan, expectations regarding the Company's final comparability data, the Company's ability to successfully develop its product candidates and complete its planned clinical programs, the Company's ability to obtain marketing approvals for is product candidates, expectations regarding the manufacturing process and technology transfer with FUJIFILM Diosynth Biotechnologies U.S.A., Inc., 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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