# Sesen Bio Announces Successful Type C Meeting with FDA for Vicinium

November 5, 2019

*Alignment reached with FDA on post-marketing confirmatory trial design*

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 5, 2019-- **Sesen Bio** (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, today reported alignment with the FDA on the design of its post-marketing confirmatory trial for Vicinium.

Sesen Bio reached agreement with the FDA that the post-marketing confirmatory trial for Vicinium will enroll BCG-refractory patients who have received less-than-adequate BCG*, which is especially important in light of the ongoing BCG shortage. This represents a broader patient population than the originally proposed BCG-intolerant population. It is anticipated that, if Vicinium is approved by the FDA, the initial indication will be for BCG-unresponsive patients who have received adequate BCG. However, assuming the post-marketing confirmatory trial is successful, it is expected that labeling will be expanded to include this additional population of patients who have received less-than-adequate BCG.

"This was our third face-to-face meeting with the FDA in the past 6 months, and we continue to have very positive and constructive interactions, which help us advance Vicinium toward regulatory review and approval," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "Our long-term relationship with the Agency has allowed us to shape our clinical program in alignment with FDA guidance. It has also helped to ensure that we are able to address the broadest possible segment of appropriate patients, and is expected to provide payers with the superiority data that will help to ensure product reimbursement. We look forward to our next FDA meeting in December."

The trial is expected to be powered to demonstrate the superior efficacy of Vicinium compared to currently utilized therapies for the primary endpoints, which are expected to include the complete response (CR) rate and duration of response in CIS patients. Secondary endpoints are expected to include a number of quality of life, survival and safety endpoints, with the objective of demonstrating the superiority of Vicinium relative to currently utilized therapies. In addition, after a discussion of favorable Phase 3 post-hoc analyses with the FDA, the trial is expected to be designed to detect a delayed CR in patients who were non-CRs at the initial 3-month assessment.

**Key Fourth Quarter 2019 Events**

- FDA meeting on December 4, 2019 to discuss the submission strategy for CMC Module 3
- Anticipated initiation of BLA submission under a Rolling Review in December 2019
- Sesen Bio Regulatory Update in December 2019

***** *As per the 2018 FDA guidance on NMIBC, adequate BCG is defined as at least 5 doses in an initial induction course, plus at least 2 doses in a second course.*

**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® as a monotherapy in patients with high-risk, bacillus Calmette-Guérin (BCG) unresponsive non-muscle invasive bladder cancer (NMIBC). The primary endpoints of the trial are the complete response rate and the duration of response in patients with carcinoma in situ with or without papillary disease. Patients in the trial received 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. 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-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: the uncertainties inherent in the conduct of clinical trials, our ability to successfully develop our product candidates and complete our planned clinical programs, expectations regarding future meetings with the FDA, our ability to obtain marketing approvals for our product candidates, the adequacy of any clinical models, expectations regarding regulatory submissions, labelling, and 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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