Sesen Bio Announces Successful Application Orientation Meeting (AOM) with the FDA for Vicineum™

February 1, 2021

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Feb. 1, 2021-- **Sesen Bio** (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, today reported that on January 29, 2021 the Company participated in a productive Application Orientation Meeting with the FDA regarding its Biologic License Application (BLA) for Vicineum, for the treatment of BCG-unresponsive non-muscle invasive bladder cancer (NMIBC).

After the Company submitted its BLA to the FDA in December 2020, Sesen Bio was invited to participate in an Application Orientation Meeting, which is available in certain Center for Drug Evaluation and Research (CDER) review divisions, at the review team's discretion, for priority applications where early action is expected and/or desired. The objectives of an Application Orientation Meeting include familiarizing the FDA with application datasets, discussing scientific aspects including clinical risk-benefit, and establishing early communication between applicants and the FDA.

"We are very pleased with the outcome of Friday's 90-minute meeting with the FDA," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "We continue to believe Vicineum has a favorable risk-benefit profile which positions it to be best-in-class, and we are encouraged by the high level of time and engagement the FDA has demonstrated toward our review. We look forward to continuing to work with the FDA to expeditiously bring Vicineum to the market."

The Company expects to learn if the BLA is accepted for filing by the FDA on February 16, 2021. If the file is accepted, in the following two to four weeks, the Company expects to receive a decision on the following three items:

- Priority vs. Standard review
- Target PDUFA date for approval
- Necessity of an FDA Advisory Committee meeting

About Vicineum™

Vicineum, 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). Vicineum 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. Vicineum 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 in the follow-up stage of a Phase 3 registration trial in the US 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. In December 2020, Sesen Bio completed the BLA submission for Vicineum to the FDA. Additionally, Sesen Bio believes that cancer cell-killing properties of Vicineum promote an anti-tumor immune response that may potentially combine well with immuno-oncology drugs, such as checkpoint inhibitors. The activity of Vicineum 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, Vicineum™, also known as VB4-845, is currently in the follow-up stage of a Phase 3 registration trial for the treatment of high-risk, BCG-unresponsive non-muscle invasive bladder cancer (NMIBC). In December 2020, the Company completed the BLA submission for Vicineum to the FDA. Sesen Bio retains worldwide rights to Vicineum with the exception of Greater China and the Middle East and North Africa (MENA), for which the Company has partnered with Qilu Pharmaceutical and Hikma Pharmaceuticals, respectively, for commercialization. Vicineum 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.

COVID-19 Pandemic Potential Impact

Sesen Bio continues to monitor the rapidly evolving environment regarding the potential impact of the COVID-19 pandemic on our Company. The Company has not yet experienced any disruptions to our operations as a result of COVID-19, however, we are not able to quantify or predict with certainty the overall scope of potential impacts to our business, including, but not limited to, our ability to raise capital and, if approved, commercialize Vicineum. Sesen Bio remains committed to the health and safety of patients, caregivers and employees.

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 Company's ability to successfully develop its product candidates and complete its planned clinical programs, expectations regarding the outcome of the Company's BLA for Vicineum, the Company's belief in the favorability of Vicineum's risk-benefit profile, the Company's ability to bring Vicineum to market in the United States, the Company's expectations for learning whether its BLA for Vicineum will be accepted for filing by the FDA and whether priority review of Vicineum will be granted 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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