Sesen Bio Reports Positive Interactions with EMA on Regulatory Pathway for Vicinium®

No additional clinical trials were requested by the CHMP for submission of Vicinium marketing authorization application

Anticipated submission of marketing authorization application in early 2021

CAMBRIDGE, Mass., May 7, 2020 – Sesen Bio (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, today reported that the Company has received positive Scientific Advice from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) related to the regulatory pathway for Vicinium in Europe. The Company's lead program, Vicinium, 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 2019, the Company initiated the BLA submission for Vicinium to the United States Food and Drug Administration (FDA) under Rolling Review.

"We are very pleased to have received positive guidance from the CHMP on the regulatory approval pathway for Vicinium," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "We strongly believe that Vicinium is a highly differentiated product candidate that is well positioned to address the considerable unmet need in NMIBC. This encouraging progress reinforces our confidence in bringing Vicinium to market in Europe, which represents a tremendous opportunity for the company. We will continue working collaboratively with the EMA to move Vicinium through the approval process as expeditiously as possible."

Key Elements of CHMP Scientific Advice

- The CHMP agreed that the Company's nonclinical, clinical pharmacology and safety database are all sufficient to support a marketing authorization application (MAA). Furthermore, additional clinical trials were not requested by the CHMP in support of the MAA submission for Vicinium.
- The CHMP agreed that due to the well-known impact of cystectomy on morbidity and quality of life of patients, a new local treatment that enables patients to avoid radical cystectomy would be meaningful, especially for patients who are contraindicated for cystectomy.
- The CHMP provided guidance on additional data analyses they expect to be included in the MAA, and the Company is confident that these can be fully addressed with the completed Phase 3 dataset.
- Based on the guidance received, the Company expects to submit the MAA for Vicinium to the EMA in early 2021, with potential approval anticipated in early 2022.
- The Company expects to receive Scientific Advice from the CHMP on the Chemistry, Manufacturing and Controls (CMC) program for Vicinium at a later date.

The Company believes there is a significant commercial opportunity in Europe and projects European peak sales to be substantially greater than US peak sales, driven by the significantly higher incidence rates and strong pricing benchmarks in the region.

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). In December 2019, the Company initiated the BLA submission for Vicinium to the FDA under Rolling Review. 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: our ability to successfully develop our product candidates and complete our planned clinical programs, expectations regarding the timing of the submission of our MAA for Vicinium to the EMA, expectations regarding the timing of potential approval of our MAA submission by the EMA, expectations regarding the projected market opportunity for Vicinium, our ability to obtain marketing

approvals for our product candidates, 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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