Sesen Bio Announces Successful Pre-BLA Meeting with FDA for Vicinium®

June 10, 2019

FDA Recommends Accelerated Approval Pathway

FDA Indicated No Additional Clinical Trials Necessary for BLA Submission

Company Expects to Initiate Submission of the BLA in 4Q 2019 Under Rolling Review

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jun. 10, 2019-- **Sesen Bio** (Nasdaq:SESN), a late-stage clinical company developing targeted fusion protein therapeutics for patients with cancer, today announced that it has completed a successful Type B Pre-Biologics License Application (BLA) meeting regarding the approval path for Vicinium for the treatment of patients with high-risk,Bacillus Calmette-Guérin(BCG) unresponsive, non-muscle invasive bladder cancer (NMIBC). The Company has reached alignment with the U.S. Food and Drug Administration (FDA) on an Accelerated Approval Pathway for Vicinium along with Rolling Review, and the Company expects to initiate submission of the BLA in the fourth quarter of 2019. The FDA also indicated that the nonclinical data, the clinical pharmacology data, and the safety database are sufficient to support a BLA submission, and that no additional clinical trials are necessary for a BLA submission.

Rolling Review of the BLA enables individual modules to be submitted and reviewed on an ongoing basis, rather than waiting for all sections to be completed before submission. The final module submission for the BLA will be CMC, and Sesen Bio plans to meet with the FDA in the second half of 2019 to discuss the content and timing of that module.

"We have now had two successful meetings with the FDA over the last three weeks, which build on our long-term relationship with the Agency and make our regulatory path forward for Vicinium even more clear," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "Gaining alignment with the FDA on an Accelerated Approval Pathway, in addition to a rolling review of the BLA, significantly increases our confidence in our regulatory pathway and our ability to bring a product to market that has the potential to save and improve the lives of patients."

On May 21, 2019Sesen Bio announced a positive outcome from its previous meeting with the FDA, a Type C CMC meeting, where Sesen Bio reached agreement with the FDA on the Analytical Comparability Plan, and confirmed, subject to final comparability data to be provided in the BLA submission, that no additional clinical trials were deemed necessary for comparability.

Sesen Bio plans to schedule two additional meetings with the FDA in the second half of 2019, a Type C meeting to discuss the details of a post-marketing confirmatory trial in support of the Accelerated Approval Pathway for Vicinium, and a Type B CMC meeting to discuss the submission strategy of the CMC module.

Conference Call Information

To participate in the conference call, please dial (844) 831-3025 (domestic) or (315) 625-6887 (international) and refer to conference ID 2958515. The webcast can be accessed in the Investor Relations section of the company's website at www.sesenbio.com. The replay of the webcast will be available in the investor 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 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 risks and uncertainties, including with respect to the regulatory pathway for Vicinium, the timing of the Company's BLA submission for Vicinium, the outcome of the FDA's review of the BLA submission and the data contained therein, the timing and outcome of future meetings with the FDA, the Company's ability to successfully develop its product candidates and complete its planned clinical programs, the Company's ability to achieve regulatory approvals for its 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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