Sesen Bio Announces Anticipated Regulatory Path Forward for Vicineum™

December 9, 2021

Company plans to conduct an additional clinical trial for potential resubmission of BLA

Company expects to hold a Type C meeting with the FDA in early 2022 to discuss the clinical trial protocol

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Dec. 9, 2021-- Sesen Bio (Nasdaq:SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, today announced its anticipated regulatory path forward for Vicineum™ for the treatment of BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) following its Clinical Type A meeting with the US Food and Drug Administration (FDA), which occurred on December 8, 2021 (Clinical Type A Meeting).

Following the productive Clinical Type A Meeting, the Company believes it has greater clarity regarding the requirements for resubmission of the BLA and the trial design, which may include these elements:

- A randomized clinical trial assessing the safety and efficacy of Vicineum compared to investigators' choice of intravesical chemotherapy;
- Trial may include both patients who have received adequate BCG[1] and patients who have received less-than-adequate BCG;
- Company encouraged to submit the final VISTA trial results with the resubmission; and
- Anticipated randomized trial design is aligned with guidance the Company has received from the European Medicines Agency, which may help to coordinate the regulatory paths forward for Vicineum in the US and the European Union.

The Company expects to hold a Type C meeting with the FDA in early 2022 to discuss the protocol for the additional clinical trial.

"We are pleased to have greater clarity on the regulatory path forward to resubmit the BLA and ultimately bring Vicineum to market if approved," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "Our team looks forward to working productively with regulators as we continue to focus on our mission of saving and improving the lives of patients."

About Vicineum™

Vicineum, a locally administered fusion protein, is Sesen Bio's lead product candidate being developed for the treatment of BCG-unresponsive 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 to the antibody binding fragment until it is internalized by the cancer cell. This fusion protein design 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 clinical trial in the US for the treatment of BCG-unresponsive NMIBC. In February 2021, the FDA accepted the Company's Biologics License Application (BLA) file for Vicineum for the treatment of BCG-unresponsive NMIBC, granted Priority Review for the BLA and set a Prescription Drug User Fee Act (PDUFA) date of August 18, 2021. On August 13, 2021, the Company received a Complete Response Letter (CRL) from the FDA regarding its BLA for Vicineum. 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. For this reason, 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 oportuzumab monatox, is currently in the follow-up stage of a Phase 3 clinical trial for the treatment of BCG-unresponsive NMIBC. In February 2021, the FDA accepted the Company's BLA file

for Vicineum for the treatment of BCG-unresponsive NMIBC, granted Priority Review for the BLA and set a PDUFA date of August 18, 2021. On August 13, 2021, the Company received a CRL from the FDA regarding its BLA for Vicineum. Sesen Bio retains worldwide rights to Vicineum with the exception of Greater China, the Middle East and North Africa (MENA) and Turkey, for which the Company has partnered with Qilu Pharmaceutical, Hikma Pharmaceuticals and Eczacibasi Pharmaceuticals Marketing (EIP), 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, which is being developed for the treatment of BCG-unresponsive 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 the Company. The Company has not yet experienced any disruptions to its operations as a result of COVID-19, however, the Company is not able to quantify or predict with certainty the overall scope of potential impacts to its business, including, but not limited to, its 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," "expect," "intend," "may," "plan," "predict," "target," "potential," "will," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. For example, statements regarding the anticipated regulatory path forward for Vicineum following the Clinical Type A Meeting, the Company's plans to conduct an additional clinical trial for potential resubmission of the BLA for Vicineum, the Company's expectation to hold a Type C meeting with the FDA in early 2022 to discuss the clinical trial protocol, the Company's belief that it has greater clarity of the requirements for resubmission of the BLA and trial design, which may include the following elements: a randomized clinical trial assessing the safety and efficacy of Vicineum compared to investigators' choice of intravesical chemotherapy, inclusion of both patients who have received adequate BCG and patients who have received less-than-adequate BCG and submission of the final VISTA trial results, the Company's expectation that the anticipated randomized trial design is aligned with guidance the Company has received from the European Medicines Agency (EMA), which may help to coordinate the regulatory paths forward for Vicineum in the US and the European Union, the impact of COVID-19 on the Company, including its ability to raise capital, and, if approved, its ability to commercialize Vicineum for the treatment of BCG-unresponsive NMIBC. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the risk that the Company may not resume its plans to pursue regulatory approval for Vicineum in the US or the European Union, the risk that clinical trials of Vicineum for the treatment of BCG-unresponsive NMIBC, including the additional clinical trial needed to address issues raised in the CRL, may fail to demonstrate safety and efficacy to the satisfaction of the FDA or the EMA, or otherwise produce favorable results, the risk that the FDA may not approve the BLA for Vicineum for the treatment of BCG-unresponsive NMIBC if the Company resubmits the BLA at a future time, the risk that the European Commission may not approve the marketing authorization application (MAA) for Vicineum for the treatment of BCG-unresponsive NMIBC if the Company resubmits the MAA at a future time, the risk that Vicineum for the treatment of BCG-unresponsive NMIBC may cause undesirable side effects, serious adverse events or have other properties that could delay or halt clinical trials, delay or prevent its regulatory approval by the FDA or the European Commission, limit the commercial profile of its labeling, if approved, or result in significant negative consequences following any marketing approval, 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.

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

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