Sesen Bio Announces Strategic Decision to Pause Clinical Development of Vicineum™ in the US

July 18, 2022

Company intends to seek a partner for further development of Vicineum

Sesen Bio continues to focus on the assessment of potential strategic alternatives

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jul. 18, 2022-- **Sesen Bio** (Nasdaq: SESN) today announced that it has made the strategic decision to voluntarily pause further development in the US of its lead asset, Vicineum. The decision was based on a thorough reassessment of Vicineum, which included the incremental development timeline and associated costs for an additional Phase 3 clinical trial for the treatment of non-muscle invasive bladder cancer (NMIBC), following recent discussions with the US Food & Drug Administration (FDA). This decision enables Sesen Bio to conserve cash while it continues to assess potential strategic alternatives with the goal of maximizing shareholder value. Additionally, the Company intends to seek a partner for the further development of Vicineum.

"We have had four productive meetings with the FDA since August 2021 and we believe we have a full understanding of the FDA's evolving position and guidance on the following variables: accelerated versus standard approval, single-arm versus randomized controlled trials, comparative versus non-comparative efficacy endpoints, and adequate versus less-than-adequate BCG patient populations," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "We have also recently observed an evolution of the current treatment paradigm in NMIBC, with substantial uptake of intravesical chemotherapy (monotherapy and combination therapy) during the ongoing BCG shortage. In assessing the impact of the regulatory and commercial landscape, we have made the decision to pause the clinical development of Vicineum."

Dr. Cannell continued, "We continue to believe that Vicineum has benefits for patients and healthcare providers that can be maximized through a company with larger infrastructure, and as such, we intend to find a partner that can execute further development to realize the full potential of Vicineum. We now turn our primary focus to the careful assessment of strategic alternatives, which we hope to have complete by the end of the year."

As of June 30, 2022, the Company had $161.2 million in cash and cash equivalents, no outstanding debt and fewer than 0.2 million outstanding warrants. These amounts are preliminary and are subject to change upon completion of the Company's financial statements for the quarterly period ended June 30, 2022.

About Vicineum™
Vicineum, a locally administered fusion protein, is Sesen Bio's lead product candidate for the treatment of 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 has completed 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. The Company intends to seek a partner for further development of Vicineum while it continues to assess potential strategic alternatives with the goal of maximizing shareholder value. 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 therapies, 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 focused on targeted fusion protein therapeutics for the treatment of patients with

cancer. The Company's lead program, Vicineum™, also known as oportuzumab monatox, has completed 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. The Company intends to seek a partner for further development of Vicineum while it continues to assess potential strategic alternatives with the goal of maximizing shareholder value. 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. 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 identify and assess potential strategic alternatives, seek a partner for the further development of Vicineum or raise capital. 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," "would," "should," "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 Company's ability to conserve cash while it continues to assess potential strategic alternatives with the goal of maximizing shareholder value, the Company's intentions to seek a partner for the further development of Vicineum, the Company's belief that Vicineum has benefits for patients and healthcare providers that can be maximized through a company with larger infrastructure, the Company's expectation that it will complete its assessment of potential strategic alternatives by the end of the year, and the impact of COVID-19 on the Company, including its ability to identify and assess potential strategic alternatives, seek a partner for the further development of Vicineum or raise capital. 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 be successful in identifying one or more strategic alternatives or a partner for the further development of Vicineum, the risk that the Company may not ultimately be successful in seeking such a partner or pursuing a strategic alternative that delivers the anticipated benefits or enhances shareholder value within the anticipated timeframe or at all, the risk that the Company's assessment of strategic alternatives or its intentions to seek a partner for the further development of Vicineum may be disruptive to the Company's business operations or cause the Company's stock price to fluctuate significantly, the risk that the Company's assessment of strategic alternatives or its intentions to seek a partner for the further development of Vicineum may be time consuming and involve the dedication of significant resources and may require the Company to incur significant costs and expenses, the risk that the Company's assessment of strategic alternatives or its intentions to seek a partner for the further development of Vicineum could negatively impact the Company's ability to attract, retain and motivate key employees and expose the Company to potential litigation in connection with such intentions to seek a partner or the process of assessing strategic alternatives or any resulting transaction, 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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