



Sesen Bio Provides Strategic Update

May 3, 2022

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 3, 2022-- **Sesen Bio** (Nasdaq: [SESN](#)), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, today announced that it has initiated a process to review strategic alternatives with the goal of maximizing shareholder value. Potential strategic alternatives to be explored and evaluated during the review process may include the sale of the Company, a merger, acquisition or other business combination, a strategic partnership with one or more parties, or the licensing, sale or divestiture of some of the Company's proprietary technologies. Pending any decision to undertake any strategic alternative, the Company is continuing its development activities in accordance with its existing business strategy.

"Our strong cash position provides us the opportunity to carefully consider a wide range of potential strategic alternatives designed to maximize shareholder value," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "As we assess potential external strategic alternatives, we continue to seek to create value through the development of Vicineum for the treatment of non-muscle invasive bladder cancer. We plan to request a meeting with the FDA in the coming weeks to align on the remaining outstanding items related to an additional Phase 3 clinical trial."

As of March 31, 2022, the Company had \$169.8 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 March 31, 2022.

About Vicineum™

Vicineum, a locally administered fusion protein, is Sesen Bio's lead product candidate being developed 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 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. After meeting with the FDA, the Company plans to conduct an additional Phase 3 clinical trial for Vicineum for the treatment of NMIBC in connection with the potential resubmission of a BLA. The Company plans to request a meeting with the FDA in the coming weeks to align on the remaining outstanding items related to the additional Phase 3 clinical trial. 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. After meeting with the FDA, the Company plans to conduct an additional Phase 3 clinical trial for Vicineum for the treatment of NMIBC in connection with the potential resubmission of a BLA. The Company plans to request a meeting with the FDA in the coming weeks to align on the remaining outstanding items related to the additional Phase 3 clinical trial. 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 Eczacıbaşı 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 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 conduct an additional Phase 3 clinical trial for Vicineum for the treatment of NMIBC, its ability to raise capital and, if approved, its ability to 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," "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 plans to explore and evaluate potential strategic alternatives, which may include the sale of the Company, a merger, acquisition or other business combination, a strategic partnership with one or more parties, or the licensing, sale or divestiture of some of the Company's proprietary technologies, the Company's plans to continue its development activities with its existing business strategy, the Company's plans to carefully consider a wide range of potential strategic alternatives designed to maximize shareholder value, the Company's plans to continue to seek to create value through the development of Vicineum for the treatment of NMIBC as it assesses potential external strategic alternatives, the impact of COVID-19 on the Company, including its ability to conduct an additional Phase 3 clinical trial for Vicineum for the treatment of NMIBC, its ability to raise capital, and, if approved, its ability to commercialize Vicineum. 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 ultimately pursuing a strategic alternative that delivers the anticipated benefits or enhances shareholder value, the risk that the Company's exploration and evaluation of strategic alternatives or the public announcement thereof 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 exploration and evaluation of strategic alternatives 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 exploration and evaluation of strategic alternatives could divert the attention of the Company's management and its board of directors from the existing business operations, negatively impact the Company's ability to attract, retain and motivate key employees, and expose the Company to potential litigation in connection with the process of exploring strategic alternatives or any resulting transaction, the risk that the Company may not resume its plans to pursue regulatory approval for Vicineum for the treatment of NMIBC, the risk that the Company may not be able to align with the FDA on the remaining outstanding items related to the additional Phase 3 clinical trial for Vicineum for the treatment of NMIBC, or other issues related to preparing for the additional Phase 3 clinical trial for Vicineum, including difficulties with clinical trial site selection and obtaining clinical trial materials and supplies, the risk that clinical trials of Vicineum for the treatment of 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 European Medicines Agency, or otherwise produce favorable results, 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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