



Sesen Bio Strengthens Medical Team

November 29, 2021

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 29, 2021-- **Sesen Bio** (Nasdaq: [SESN](#)), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, today announced the strengthening of its medical team with the hiring of Dominika Kowalski as Senior Director of Global Drug Safety. Ms. Kowalski's hiring demonstrates Sesen Bio's strong commitment to and continued focus on the development of Vicineum™ for the treatment of BCG-unresponsive non-muscle invasive bladder cancer.

"We are excited for Dominika to join our team as we continue to engage with the FDA and work toward advancing our lead product candidate," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "Dominika has the right experience to support our mission of saving and improving the lives of patients, and her hiring further demonstrates our commitment to working to bring new treatment options to market."

Ms. Kowalski brings over 14 years of drug safety experience in the pharmaceutical industry supporting both marketed and investigational products. She previously worked at Horizon Therapeutics, Abbott and AbbVie, where she managed safety surveillance, preparation of periodic safety reports and adherence to local and global authority requirements. Over the course of her career, Ms. Kowalski has worked on evaluation of the overall safety profile for products in clinical development, products approved by the US Food and Drug Administration (FDA) and products marketed under foreign regulatory authorities.

Ms. Kowalski holds a Master of Science degree in Public Health Nursing and a Post-Master Degree for Pediatric Nurse Practitioners from Rush University and a Bachelor of Science in Nursing from University of Illinois. She holds active licensure as a Pediatric Nurse Practitioner, and prior to joining the pharmaceutical industry, Ms. Kowalski worked as a study coordinator on HIV clinical trials and as a Pediatric Nurse Practitioner.

As previously disclosed, on October 29, 2021, Sesen Bio participated in a productive Type A meeting with the FDA to discuss questions related to chemistry, manufacturing and controls (CMC) raised in the FDA's Complete Response Letter (CRL) regarding the Company's Biologics License Application (BLA) for Vicineum. The Company believes it has a clear understanding of what additional information regarding CMC is required for resubmission of the BLA. Additionally, as disclosed on November 18, 2021, a separate Type A meeting to discuss recommendations specific to additional clinical/statistical data and analyses raised in the CRL is scheduled for December 8, 2021.

In connection with the hiring of Ms. Kowalski, a non-statutory stock option will be granted. Under the grant of the non-statutory stock option, up to 70,000 shares of Sesen Bio common stock will be purchasable upon vesting of the stock option within its ten-year term. The stock option will vest over a four-year period, with one quarter of the underlying shares of common stock vesting on the first anniversary of the date of grant, and an additional 6.25% of the underlying shares of common stock vesting at the end of each successive three-month period following the one-year anniversary of the date of grant, subject to Ms. Kowalski's continued service with Sesen Bio.

The non-statutory stock option will be granted on November 29, 2021 at an exercise price equal to the closing price per share of Sesen Bio's common stock on The Nasdaq Global Market on November 29, 2021. The stock option will be granted outside of the Company's 2014 Stock Incentive Plan and will be granted as a material inducement to employment in accordance with Nasdaq Listing Rule 5635(c)(4).

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 registration 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 registration 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 our operations as a result of COVID-19, however, we are not able to quantify or predict with certainty the overall scope of potential impacts to our business, including, but not limited to, our 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 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 those 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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