



## Sesen Bio Expands CMC and Clinical Teams

October 12, 2021

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Oct. 12, 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 expansion of its chemistry, manufacturing, and control (CMC) and clinical development teams with the hiring of Eun Jang as Senior Director, Analytical Sciences, and Chèrie Kaefring as Director, Clinical Operations. The addition of these new team members 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 (NMIBC).

"I am delighted to welcome Eun and Chèrie to Sesen Bio to further strengthen our capabilities across our CMC and clinical teams," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "Their deep clinical and analytical expertise is the right match for our CMC and clinical needs as we chart our path forward in consultation with regulators. I am confident Eun and Chèrie will each make valuable contributions to Sesen Bio and to our mission of saving and improving the lives of patients."

These hirings come as Sesen Bio is preparing for CMC and clinical Type A meetings with the US Food and Drug Administration (FDA) for Vicineum™. The Company has submitted a request for the CMC Type A meeting, which is anticipated to occur at the end of October, and expects the clinical Type A meeting to occur later in the fourth quarter of 2021.

In connection with these hirings, non-statutory stock options were or will be granted. Under such grants, a combined total of up to 122,500 shares of Sesen Bio common stock are purchasable upon vesting of the stock options within each option's ten-year term. Each of the stock options vests over a four-year period, with one quarter of the underlying shares vesting on the first anniversary of the date of grant, and an additional 6.25% of the underlying shares vesting at the end of each successive three-month period following the one-year anniversary of the date of grant, subject in each case to the employee's continued service with Sesen Bio.

Ms. Jang's non-statutory stock option was granted on October 11, 2021 and Ms. Kaefring's non-statutory stock option will be granted on October 25, 2021, and each such stock option has an exercise price equal to the closing price per share of Sesen Bio's common stock on The Nasdaq Global Market on the date of the grant. These options are being granted outside of the Company's 2014 Stock Incentive Plan and 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 BLA file for Vicineum for the treatment of BCG-unresponsive NMIBC and granted the application Priority Review with a target 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 immunooncology 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 non-muscle invasive bladder cancer (NMIBC). In February 2021, the FDA accepted the Company's BLA file for Vicineum for the treatment of BCG-unresponsive NMIBC and granted the application Priority Review with a target 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. 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](http://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 Company's expectations, commitment to and continued focus on development of Vicineum for the treatment of BCG-unresponsive NMIBC, the Company's preparations for CMC and clinical Type A meetings with the FDA to discuss next steps for Vicineum for the treatment of BCG-unresponsive NMIBC, the Company's expectations regarding the timing of the CMC Type A meeting, the Company's expectations regarding the timing of the clinical Type A meeting with the FDA to discuss Vicineum for the treatment of BCG-unresponsive NMIBC, 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 FDA may not schedule Type A meetings with the Company within the currently expected timing, or at all, the risk that the Company may not resume its plans to pursue regulatory approval for Vicineum in the US or Europe, the risk that clinical trials of Vicineum for the treatment of BCG-unresponsive NMIBC may fail to demonstrate safety and efficacy to the satisfaction of the FDA or the European Medicines Agency (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 EMA may not approve the Company's 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 EMA, 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.

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