Sesen Bio Announces Global Supply Partnership with Qilu Pharmaceutical

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Technology transfer to Qilu Pharmaceutical on track for completion in 2021

Sesen Bio to receive $2M milestone payment upon completion of technology transfer

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jun. 2, 2021-- **Sesen Bio** (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, today announced that on Tuesday, June 1, 2021 the Company entered into a global supply agreement for Vicineum™ drug substance and drug product with the Company's partner in China, Qilu Pharmaceutical.

Under the terms of the global supply agreement, Qilu Pharmaceutical will be part of the manufacturing network for global commercial supply of Vicineum drug substance and drug product. In February 2021, the U.S. Food and Drug Administration (FDA) accepted for filing the Company's Biologics License Application (BLA) for Vicineum for the treatment of BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) and granted the application Priority Review, with a target Prescription Drug User Fee Act (PDUFA) date of August 18, 2021. The Company anticipates initiating promotion to physicians and patients in the US upon approval, with commercial product supply broadly available to urology clinics by the fourth quarter of 2021.

In December 2020, Sesen Bio entered into a commercial manufacturing and supply framework agreement with Qilu Pharmaceutical in which both parties aligned on key components of the structure of a global supply partnership. The new global supply agreement with Qilu Pharmaceutical builds on the Company's existing partnership by setting specific terms such as capacity, forecasts, pricing and product delivery. The completion of the global supply agreement expands the Company's network of world-class partners committed to providing reliable supply of Vicineum worldwide. Sesen Bio is entitled to a $2 million milestone payment upon completion of technology transfer to Qilu Pharmaceutical, which the Company believes is on track for completion in 2021.

"Given the chronic product shortage issues that exist for patients with NMIBC, we have thoughtfully developed what we believe to be a very reliable and robust supply chain with world-class manufacturing partners," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "Qilu Pharmaceutical has extensive biomanufacturing expertise and experience supplying products for commercial sale around the world, which positions them well to support the anticipated significant global demand for Vicineum."

Sesen Bio also continues to support Qilu Pharmaceutical in the development and commercialization of Vicineum in China. In March 2021, the Investigational New Drug (IND) application for Vicineum was approved by the Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA) thereby triggering a $3 million milestone payment to Sesen Bio, which the Company received, net of taxes, on May 24, 2021. The approval of the IND enables Qilu Pharmaceutical to conduct the proposed clinical trial to assess the efficacy and safety of Vicineum for patients in China. It is anticipated that the first patient will be dosed in the trial within the next month. Assuming a successful trial, Qilu Pharmaceutical anticipates submission of the product market application for Vicineum in 2022 with potential approval in China expected in 2023.

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 until it is internalized by the cancer cell, which 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 for filing the Company's BLA for Vicineum for the treatment of BCG-unresponsive NMIBC and granted the application Priority Review

with a target PDUFA date of August 18, 2021. 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 non-muscle invasive bladder cancer (NMIBC). In February 2021, the FDA accepted for filing the Company's BLA for Vicineum for the treatment of BCG-unresponsive NMIBC and granted the application Priority Review with a target PDUFA date of August 18, 2021. Sesen Bio retains worldwide rights to Vicineum with the exception of Greater China and the Middle East and North Africa (MENA), for which the Company has partnered with Qilu Pharmaceutical and Hikma Pharmaceuticals, 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 the treatment of BCG-unresponsive NMIBC. For more information, please visit the Company's website at www.sesenbio.com.

About Qilu Pharmaceutical

Qilu Pharmaceutical is a leading vertically integrated pharmaceutical company focused on discovering, developing, manufacturing and commercializing innovative medicines. With a diverse pipeline of novel therapeutics, 10 manufacturing sites and more than 23,000 employees worldwide, Qilu Pharmaceutical is dedicated to transforming scientific innovation by internal R&D across 5 R&D platforms based in the US (Seattle WA, Boston MA, San Francisco CA) and China (Shanghai, Jinan), and external partnership globally into healthcare solutions to address unmet medical needs. To date, Qilu Pharmaceutical has launched 200+ products with 30+ products "First to launch" in China and 3 products "D181 launch" in US.

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," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: dependence on third parties for the Company's supply chain for Vicineum, requirements to demonstrate product manufactured by third parties is comparable to that used in the Company's clinical trials, the timing and receipt by the Company of any milestone payments from Qilu Pharmaceutical, the timing for completion of the manufacturing technology transfer with Qilu Pharmaceutical, the timing for the FDA's decision on the Company's BLA for Vicineum for the treatment of BCG-unresponsive NMIBC based on the FDA granting the BLA Priority Review and the target PDUFA date of August 18, 2021, 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, the timing and results of any clinical trial for Vicineum in China, the timing for submission and potential approval of the product market application for Vicineum for the treatment of BCG-unresponsive NMIBC to the National Medical Products Administration, 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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