Sesen Bio announces an exclusive license agreement with Qilu Pharmaceutical for the development and commercialization of Vicineum™ in Greater China

July 31, 2020

Sesen to receive $12 million upfront and $23 million in potential regulatory and tech transfer milestone payments

Sesen eligible to receive royalties on net sales in China

Sesen to host conference call Friday, July 31st at 8:00 a.m. EDT

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jul. 31, 2020-- Sesen Bio (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, and Qilu Pharmaceutical, a leading vertically integrated pharmaceutical company in China specializing in the manufacturing and marketing of active pharmaceutical ingredients and drug products, today announced that the companies have entered into an exclusive licensing agreement for the manufacture, development and commercialization of Vicineum for the treatment of BCG-unresponsive non-muscle invasive bladder cancer (“NMIBC”) and other types of cancer in China, Hong Kong, Macau and Taiwan (“Greater China”).

“As a leader in the Chinese pharmaceutical industry, we believe there is no better company than Qilu suited to support the expansion of our development and commercialization efforts for Vicineum,” said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. “Qilu is well-respected for their commercialization and manufacturing expertise, and this partnership marks an important milestone not only in realizing what we believe to be a significant market opportunity for Vicineum, but in strengthening our balance sheet through nondilutive capital while we remain focused on pursuing regulatory approval in the United States and the European Union. Additionally, we are thrilled to have completed this agreement completely virtually, despite the current COVID-19 pandemic, which speaks volumes to the strong execution capabilities of the Sesen team. This reinforces our focus on continuing to pursue additional business development opportunities for Vicineum outside the US in this manner.”

“Sesen is the ideal partner for us, given their expertise in NMIBC and our complementary skillsets and the different geographic focus between our two companies,” said Yan Li, chief executive officer of Qilu Pharmaceutical. “We look forward to working with Sesen and The National Medical Products Administration to bring Vicineum to patients who urgently need better therapies for BCG unresponsive non-muscle invasive bladder cancer in China.”

“Vicineum is a potential first-in-class, highly differentiated product candidate that can address a significant unmet need in China,” said Oliver Kong, M.D. chief medical officer, corporate vice president of Qilu Pharmaceutical. “The unique mechanism of action of Vicineum and associated strong clinical data position Vicineum to make a meaningful impact on the lives of patients.”

Under the terms of the agreement, Sesen granted Qilu Pharmaceutical an exclusive license to develop and commercialize Vicineum in Greater China. Sesen will receive an upfront payment of $12 million and is eligible to receive up to an additional $23 million in technology transfer and regulatory milestone payments. Upon commercialization in Greater China, Sesen is also entitled to receive royalties on net sales in Greater China. Sesen retains full development and commercialization rights for Vicineum for the treatment of NMIBC in the US and the rest of the world excluding Greater China. The terms of the agreement also include the transfer of the Vicineum manufacturing technology to Qilu Pharmaceutical, whose world-class manufacturing expertise represents a future opportunity for production expansion to meet the anticipated significant global demand for Vicineum for the treatment of NMIBC.

Torreya acted as a financial advisor and Hogan Lovells acted as a legal advisor to Sesen for this transaction.

Conference Call Information

Members of the Sesen management team will host a conference call and webcast Friday, July 31, 2020 at 8:00 AM EDT to provide an overview of the partnership with Qilu Pharmaceutical. To participate in the conference call, please dial (844) 831-3025 (domestic) or (315) 625-6887 (international) and refer to conference ID 2177393. The webcast can be accessed in the Investor Relations section of the company’s website at www.sesenbio.com. The replay of the webcast will be available in the investor section of the company’s website at www.sesenbio.com for 60 days following the call.

About Vicineum™

Vicineum, a locally administered fusion protein, is Sesen Bio’s lead product candidate currently in the follow-up stage of a Phase 3 registration trial for the treatment of high-risk, BCG-unresponsive NMIBC. In December 2019, the Company initiated the BLA submission for Vicineum to the FDA under Rolling Review. 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 conducting the Phase 3 VISTA trial, designed to support the registration of Vicineum for the treatment of high-risk NMIBC in patients who have previously received a minimum of two courses of bacillus Calmette-Guérin (BCG) and whose disease is now BCG-unresponsive. 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. 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 the VISTA Clinical Trial

The VISTA trial is an open-label, multicenter, single-arm Phase 3 clinical trial evaluating the efficacy and tolerability of Vicineum™ as a monotherapy in patients with high-risk, bacillus Calmette-Guérin (BCG) unresponsive non-muscle invasive bladder cancer (NMIBC). The primary endpoints of the trial are the complete response rate and the duration of response in patients with carcinoma in situ with or without papillary disease. Patients in the trial received locally administered Vicineum twice a week for six weeks, followed by once-weekly treatment for another six weeks, then treatment every other week for up to two years. To learn more about the Phase 3 VISTA trial, please visit www.clinicaltrials.gov and search the identifier NCT02449239.

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 VB4-845, is currently in a Phase 3 registration trial for the treatment of high-risk, BCG-unresponsive non-muscle invasive bladder cancer (NMIBC). In December 2019, the Company initiated the BLA submission for Vicineum to the FDA under Rolling Review. 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 high-risk NMIBC. For more information, please visit the company’s website at www.sesenbio.com.

About Qilu Pharmaceutical

Qilu Pharmaceutical is one of the leading vertically integrated pharmaceutical companies in China focusing on the development, manufacturing and marketing of active pharmaceutical ingredients (APIs) & finished formulations. Qilu currently has 12 subsidiaries, 10 manufacturing sites and over 23,000 employees worldwide. Qilu ranks No.8 in Chinese pharmaceutical industry by sales revenue in 2019. Dedicated to offering more affordable medicines to the world and improving people’s well-being, Qilu has exported its products to over 70 countries. Qilu has always maintained an innovative development strategy guided by the market demand and is achieving its organic growth strategy utilizing a strong pool of 2000+ scientists spread across 5 R&D platforms based in the US (Seattle WA, Boston MA, San Francisco CA) and China (Shanghai, Jinan). To date, Qilu has launched 200+ products with 30+ products “First to launch” in China and 3 products “D181 launch” in US. The company also has a robust pipeline, including 200+ generic products, 20+ biosimilar products and 50+ innovative products. Qilu’s finished formulations and APIs have been approved by US FDA, European Medicines Agency (EMA), Therapeutic Goods Administration (TGA) of Australia, Medicines and Healthcare products Regulatory Agency (MHRA) of UK, PMDA of Japan and other national regulatory authorities.

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: our ability to successfully develop our product candidates and complete our planned clinical programs, expectations regarding the safety and efficacy of Vicineum, expectations regarding possible milestone and royalty payments under the license agreement with Qilu, expectations regarding Qilu’s ability to manufacture, develop and commercialize Vicineum in Greater China, expectations regarding potential partnerships to develop and commercialize Vicineum outside of the US, 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.