

## Hikma Pharmaceuticals and Sesen Bio announce exclusive partnership to commercialise Vicineum™ in MENA

**Amman, December 1, 2020** - Hikma Pharmaceuticals PLC (Hikma), the multinational pharmaceutical company, today announced an exclusive licensing and distribution agreement with Sesen Bio (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer.

The licensing agreement provides Hikma with exclusive rights to commercialise and distribute Vicineum in the MENA region for the treatment of BCG-unresponsive non-muscle invasive bladder cancer (“NMIBC”) and other types of cancer.

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.

“At Hikma, we believe that partnerships with innovative pharma companies are a key contributor to the success of our business. We are very pleased to enter into an exclusive partnership with Sesen given their expertise in NMIBC and the strong clinical profile of Vicineum,” said Mazen Darwazah, Hikma’s Executive Vice Chairman and President of MENA. “As a company whose mission is to put better health within reach every day, we regard being the partner of choice to Sesen in MENA as a key collaboration that augments Hikma’s biotechnology and oncology portfolio to deliver on our strategy of bringing innovative products to patients in the region. Vicineum™ - our first innovative fusion protein - is a highly differentiated product candidate and is positioned to make a meaningful impact on the lives of bladder cancer patients.”

“Sesen is committed to saving and improving the lives of patients, and Hikma is an ideal partner to deliver Vicineum to patients with NMIBC in the MENA region,” said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. “As we continue to work toward regulatory approval in the US and Europe, we also continue to execute partnerships outside of the US as part of our mission to deliver this important medicine to patients around the world. Hikma has strong expertise in commercialising innovative products in the MENA region and a successful track record of serving patients world-wide. This partnership represents a further step in realizing the significant global opportunity for Vicineum.”

Under the terms of the agreement, Sesen Bio granted Hikma an exclusive license to register and commercialise Vicineum in all 19 MENA markets in an arrangement anticipated to deliver equal value share to both parties. Financial terms of the agreement are confidential and include an upfront payment to Sesen Bio, sales related milestone payments and royalties on net sales in the region for the term of the agreement.

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### **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 Non-Muscle Invasive Bladder Cancer**

Bladder cancer is the sixth most commonly diagnosed cancer in the United States, and approximately 80 percent of patients have non-muscle invasive bladder cancer (NMIBC). In NMIBC, cancer cells are in the lining of the bladder or have grown into the lumen of the bladder but have not spread into muscle or other tissue. NMIBC primarily affects men and is associated with carcinogen exposure. Initial treatment includes surgical resection; however, there is a high rate of recurrence and more than 60 percent of all patients diagnosed with NMIBC will receive bacillus Calmette-Guérin (BCG) immunotherapy. While BCG is effective in many patients, challenges with tolerability have been observed and many patients will experience recurrence of disease. If BCG is not effective or a patient can no longer receive BCG, the recommended option for treatment is radical cystectomy, the complete removal of the bladder.

### **About Hikma**

(LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (rated BBB-/stable S&P, BBB-/stable Fitch and Ba1/stable Moody's)

Hikma helps put better health within reach every day for millions of people in more than 50 countries around the world. For more than 40 years, we've been creating high-quality medicines and making them accessible to the people who need them. Headquartered in the UK, we are a global company with a local presence across the United States (US), the Middle East and North Africa (MENA) and Europe, and we use our unique insight and expertise to transform cutting-edge science into innovative solutions that transform people's lives. We're committed to our customers, and the people they care for, and by thinking creatively and acting practically, we provide them with a broad range of branded and non-branded generic medicines. Together, our 8,600 colleagues are helping to shape a healthier world that enriches all our communities. We are a leading licensing partner, and through our venture capital arm, are helping bring innovative health technologies to people around the world. For more information, please visit: [www.hikma.com](http://www.hikma.com)

### **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](http://www.sesenbio.com)