Seagen and RemeGen Announce Exclusive Worldwide License and Co-Development Agreement for Disitamab Vedotin

– Seagen Licenses Disitamab Vedotin, a Novel HER2-targeted Antibody-Drug Conjugate (ADC) from RemeGen –

– Disitamab Vedotin has Shown Potential as a Differentiated ADC Across a Range of HER2 Expressing Tumors and is Being Developed as Monotherapy and in Combination with PD-1 Inhibitors, Further Expanding and Complementing Seagen's Deep and Diverse Pipeline –

– Agreement Leverages Seagen and RemeGen's Leadership and Expertise in Developing ADCs as well as Seagen's Global Development and Commercialization Capabilities –

BOTHELL, Wash. and YANTAI, China —(August 9, 2021)—Seagen Inc. (Nasdaq: SGEN), a world leader and pioneer in antibody-drug conjugate (ADC) therapies and RemeGen Co., Ltd. (9995.HK), a leading innovative biopharmaceutical company in China, today announced that the two companies have entered into an exclusive worldwide licensing agreement to develop and commercialize disitamab vedotin, a novel HER2-targeted ADC.

Disitamab vedotin combines the drug-linker technology originally developed by Seagen with RemeGen's novel HER2 antibody exhibiting higher affinity and an increased internalization rate as compared to trastuzumab in preclinical models.[1, 2] As monotherapy, disitamab vedotin has demonstrated antitumor activity in clinical trials in several solid tumor types, including urothelial, gastric and breast cancer, as well as across a spectrum of HER2 expression levels. In addition, promising combination activity was demonstrated with a PD-1 inhibitor in urothelial cancer.[3] It is believed that vedotin-based immunogenic cell death (ICD) may differentiate this class of ADC's when combined with checkpoint inhibitors.

"This collaboration leverages Seagen's world-class expertise and knowledge of ADC development, manufacturing and commercialization to maximize the potential of disitamab vedotin. It also complements our existing franchises and our deep and diverse portfolio of innovative anti-cancer therapies for patients in need," said Clay Siegall, Ph.D., President and CEO, Seagen. "The addition of disitamab vedotin as a late-stage asset with multiple development opportunities aligns strategically with our plans to continue expanding our global footprint and deliver meaningful therapies to patients around the world."

Disitamab vedotin received U.S. Food and Drug Administration (FDA) Breakthrough Therapy designation in 2020 for use in second-line treatment of patients with HER2-expressing, locally advanced or metastatic urothelial cancer (mUC) who have previously received platinum-containing chemotherapy. In the same year, RemeGen announced FDA's clearance of an Investigational New Drug (IND) application for a Phase II clinical trial in mUC. Disitamab vedotin is conditionally approved for treating locally advanced metastatic gastric cancer in China, and in July 2021 the National Medical Products Administration (NMPA) of China also accepted a New Drug Application for disitamab vedotin in mUC.

"Disitamab vedotin has demonstrated robust antitumor activity in multiple advanced cancers where no effective therapy is available," said Jianmin Fang, Ph.D., Co-founder, CEO and CSO, RemeGen. "Seagen is a well-known global biotechnology company recognized for its capabilities in the field of oncology and ADC therapies. We are delighted to partner with Seagen to maximize the potential of disitamab vedotin and to make it available to patients worldwide. We believe this license agreement highlights the global potential of disitamab vedotin in the ADC arena and is a major milestone for us as we begin the journey to transform from a domestic to a global biopharmaceutical company."

Under the terms of the agreement, Seagen will make a $200 million upfront payment to exclusively license rights to disitamab vedotin for global development and commercialization, outside of RemeGen's territory. RemeGen will retain development and commercialization rights for Asia, excluding Japan and Singapore. Seagen will lead global development and RemeGen will fund and operationalize the portion of global clinical trials attributable to its territory. RemeGen will also be responsible for all clinical development and regulatory submissions specific to its territory.

Seagen will pay RemeGen up to $2.4 billion in potential total milestone payments based upon the achievement of specified development, regulatory and commercialization goals across multiple indications and products. RemeGen will be entitled to a tiered, high single digit to mid-teen percentage royalty based on net sales of disitamab vedotin in Seagen's territory.

About Disitamab Vedotin (RC48)

Disitamab vedotin is a novel ADC that selectively delivers the anti-cancer agent monomethyl auristatin E (MMAE) into HER2-expressing tumor cells. The novel antibody component of the ADC exhibits a higher affinity and increased internalization rate as compared to trastuzumab in preclinical models, and in animal models, demonstrates promising antitumor activity. It is the first domestically developed ADC in China to receive marketing approval. In June 2021, disitamab vedotin received conditional approval by the NMPA of China to treat locally advanced or metastatic gastric cancer (GEJ carcinoma). In July 2021, the NMPA accepted the New Drug Application for disitamab vedotin in locally advanced or metastatic urothelial carcinoma. In addition, disitamab vedotin has shown significant antitumor activity in clinical trials of a number of HER2-expressing cancers, including those with low HER2 expression. It is currently being studied in multiple late-stage clinical trials across several solid tumor types.

About RemeGen

RemeGen Co., Ltd. (RemeGen) is a leading fully integrated biopharmaceutical company in China committed to the discovery, development and commercialization of innovative and differentiated biologics for the treatment of autoimmune, oncology and ophthalmic diseases with unmet medical needs in China and globally. RemeGen's main focus is research and development, manufacturing and commercialization of novel biologics, most notably monoclonal antibodies (mAb) and antibody-drug conjugates (ADCs). Headquartered in Yantai, Shandong Province, China, RemeGen has labs/offices in Beijing, Shanghai, California and Maryland. Since its inception in 2008, RemeGen has created more than 10 novel drug molecules that are in various stages of development. Currently, there are two products that have been approved and marketed in China to treat autoimmune and oncology indications. For more information about RemeGen, please visit: www.remegen.com.

About Seagen

Seagen is a global biotechnology company that discovers, develops and commercializes transformative cancer medicines to make a meaningful difference in people's lives. Seagen is headquartered in the Seattle, Washington area, and has locations in California, Canada, Switzerland and the European Union. For more information on the company's marketed products and robust pipeline, visit www.seagen.com and follow @SeagenGlobal on Twitter.

Seagen Forward-Looking Statements

Certain of the statements made in this press release are forward looking, such as those, among others, relating to the therapeutic potential of disitamab vedotin and the potential development and commercialization of disitamab vedotin in regions outside Greater China; and other statements that are not historical facts. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. Factors that may cause such a difference include, but are not limited to, risks associated with licensing transactions, such as the risks that disitamab vedotin will not be integrated into Seagen's pipeline successfully or will not perform as anticipated, in which case, Seagen may not recover its investment in disitamab vedotin; and risks related to the development and commercialization of disitamab vedotin, including the risk that Seagen or RemeGen may be delayed or unsuccessful in planned clinical trial initiations, enrollment in and conduct of clinical trials, obtaining data from clinical trials, regulatory submissions, and regulatory approvals in the U.S. and in other countries in each case for a variety of reasons including the difficulty and uncertainty of pharmaceutical product development, negative or disappointing clinical trial results, unexpected adverse events or regulatory actions and the inherent uncertainty associated with the regulatory approval process; and risks related to the duration and severity of the COVID-19 pandemic and resulting global economic, financial and healthcare system disruptions More information about the risks and uncertainties faced by Seagen is contained in the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2021, filed with the Securities and Exchange Commission. Seagen disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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REFERENCES:

1. Yao et al., Breast Cancer Res Treat (2015) 153:123-133, company data.
2. Data on file at Seagen.
3. PD1 combo solid tumor basket study is ongoing in HER2 1+expressing patients in China (breast, gastric, urothelial). A separate urothelial trial is also ongoing in China, HER2 allcomers.