RemeGen, Ltd. Announces Positive Results from RC48 Clinical Trial in HER2 Positive Metastatic or Unresectable Urothelial Cancer

Results, presented at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting, demonstrated clinically meaningful response in patients with urothelial carcinoma whose treatment previously failed, a population with high unmet medical need

YANTAI, China, June 4, 2019 – RemeGen, Ltd. today announced positive topline results for a Phase II clinical trial of RC48. The HER2-targeting antibody-drug conjugate (ADC) and potential new medicine was evaluated in patients with HER2-positive metastatic or unresectable urothelial cancer who have received previous treatment with chemotherapies and had visceral metastasis.

Results showed a 51 percent confirmed objective response rate (cORR) per independent central review. The most common treatment-related adverse events included hypoesthesia, alopecia and hemotoxicity. These results are expected to support a global late stage clinical trial, including an Investigational New Drug Application (IND), with the US Food and Drug Administration (FDA) anticipated in the second half of 2019.

“We are encouraged to see positive data from the RC48 trial now reinforcing what earlier data have shown,” said Jianmin Fang, Ph.D., founder and CEO of RemeGen, Ltd. “Urothelial carcinoma is a common cancer worldwide and we believe RC48 has the potential to redefine the treatment for these patients, as well as for patients with HER2-expressing cancers who continue to have high unmet medical need.”

Urothelial carcinoma, also known as transitional cell carcinoma, is the most common type of bladder cancer (90 percent of cases).[i] Globally, approximately 549,000 people were diagnosed with bladder cancer in 2018 and there were about 200,000 deaths.[ii] Unfortunately, no breakthrough treatments for metastatic urothelial carcinoma have emerged in over two decades. The current therapeutic options, which include cisplatin-based combination chemotherapy, have subpar efficacy, as reflected in high rates of recurrence and mortality.[iii]

“For HER2-positive urothelial carcinoma patients with previously-treated locally advanced or metastatic urothelial cancer, there's no targeted treatment available,” said Fang. “These results for RC48 indicate it may be able to help patients whose cancer has progressed following treatment with standard chemotherapy and immuno-oncology agents and we look forward to discussing the data with relevant health authorities.”

About RC48

RC48, a novel antibody-drug conjugate (ADC), was developed to treat HER2-positive solid tumors. It is comprised of a novel HER2-monoclonal antibody, a cathepsin cleavable linker and monomethyl auristatin E (MMAE), as the cytotoxic payload. The HER2-targeted antibody has a higher affinity for HER2 compared to standard of care, and superior anti-tumor activity compared to other treatments in animal models. RC48 was the first ADC drug approved for human clinical trials in China and an excellent safety profile has been observed in clinical trials. It is currently being studied in multiple late-stage clinical trials across solid tumor types.

About RemeGen, Ltd.

RemeGen, Ltd. is a leading biopharmaceutical company in China dedicated to fulfilling unmet medical needs for patients with life-threatening conditions. RemeGen Ltd.'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, RemeGen, Ltd. has laboratory research facilities and offices in Beijing, Shanghai and California. It has an extensive collaboration with Tongji University, one of the top universities in China. Since its inception in 2008, RemeGen, Ltd. has created more than 10 novel drug molecules that are in various stages of development. Currently, there are two products in Phase III clinical development to treat autoimmune and oncology indications: RC18 and RC48.

Forward-Looking Statements

Certain of the statements made in this press release are forward-looking, such as those, among others, relating to the possible utility or application of the Company's technologies to develop therapeutic agents, therapeutic potential of investigational agents, and future development activities including clinical trials. 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 the difficulty and uncertainty of pharmaceutical product development, including the risks that RemeGen, Ltd. may experience delays in its planned clinical trial initiations or otherwise experience failures or setbacks in its preclinical and clinical development programs due to the potential lack of efficacy or risk of adverse events as RemeGen, Ltd.'s product candidates advance in development or other factors. These factors include those discussed in RemeGen, Ltd.'s public reports are available by contacting Dan Ross at danross@remegen.cn. RemeGen, Ltd. disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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[i] American Society of Clinical Oncology. Bladder Cancer: Introduction (10-2017). https://www.cancer.net/cancer-types/bladder-cancer/introduction.

[ii] World Health Organization. Global Health Observatory. Geneva: World Health Organization; 2018. who.int/gho/database/en. Accessed May 21, 2019.

[iii] Vlachostergios PJ, Jakubowski CD, Niaz MJ, et al. Antibody-Drug Conjugates in Bladder Cancer. Bladder Cancer. 2018;4(3):247–259. Published 2018 Jul 30.