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Positive results from RC48 Clinical Trial in HER2-Positive Metastatic or Unresectable Urothelial Cancer

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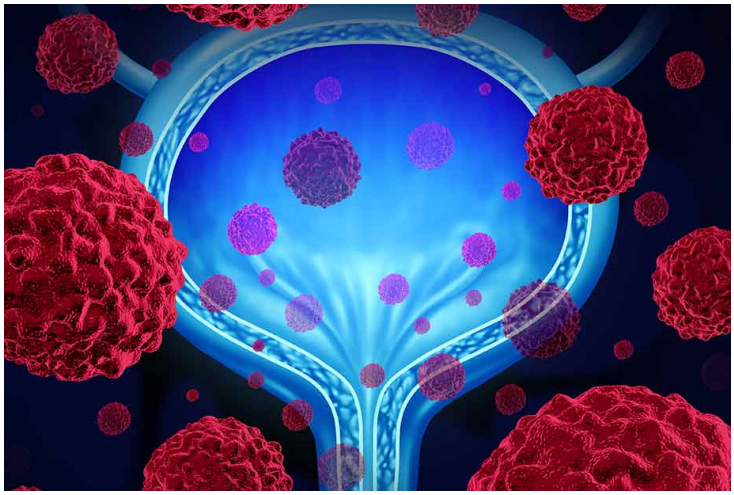
RC48, a novel antibody-drug conjugate (ADC) targeting HER2-positive solid tumours showed a 51% confirmed objective response rate (cORR)



RemeGen, Ltd. announced positive promising results for a Phase II clinical trial of RC48 on 4 June 2019, in Yantai, China. 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 a high unmet medical need.

The HER2-targeting antibody-drug conjugate (ADC) and potential new medicine were 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% 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.

Urothelial carcinoma, also known as transitional cell carcinoma, is the most common type of bladder cancer. 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.

RC48, a novel antibody-drug conjugate (ADC), was developed to treat HER2-positive solid tumours. 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-tumour 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 tumour types.

Jianmin Fang, Ph.D., founder and CEO of RemeGen, Ltd., said: "Urothelial carcinoma is 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 a high unmet medical need."

He added, "For HER2-positive urothelial carcinoma patients with previously treated locally advanced or metastatic urothelial cancer, there's no targeted treatment available. 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."