RemeGen Announces US FDA Has Granted Breakthrough Therapy Designation for Disitamab Vedotin (RC48) in Urothelial Cancer

The Breakthrough Therapy designation marks an important milestone for RemeGen's leading ADC treatment for urothelial cancer

YANTAI, China, (September 25, 2020) – RemeGen Co., Ltd. ("RemeGen") today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation for disitamab vedotin (RC48), a novel humanized anti-HER2 antibody drug conjugate (ADC), for the second-line treatment of patients with HER2 positive locally advanced or metastatic urothelial cancer (UC) who have also previously received platinum-containing chemotherapy treatment. Earlier this year, RemeGen announced the FDA's clearance of an Investigational New Drug (IND) application for a Phase II clinical study in the United States and the grant of Fast Track designation for disitamab vedotin.

A drug development program with Breakthrough Therapy designation is eligible for all Fast Track designation features, intensive guidance on an efficient drug development program beginning as early as Phase I, and organizational commitment involving senior managers. This process is designed to expedite the development and review process.

"An estimated 81,400 new cases of urothelial cancer and 17,980 deaths are predicted in the United States in 2020,[i]" said Jianmin Fang, Ph.D., founder, CEO and CSO of RemeGen. "The high prevalence of metastatic urothelial cancer underscores the need for effective and accessible treatment methods for patients. This Breakthrough Therapy designation will bring RemeGen one step closer to finding a safe and effective treatment for this devastating disease. We look forward to working with the FDA to advance the clinical development of disitamab vedotin."

Urothelial cancer represents the ninth most common cancer worldwide and the fourth most common cancer in men in the United States.[ii]

About RC48

RC48 was developed to treat HER2 expressing solid tumors. It has a novel antibody with a higher affinity to 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 favorable 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

About RemeGen

RemeGen Co., Ltd. (“RemeGen”) is a leading biopharmaceutical company in China dedicated to fulfilling unmet medical needs for patients with life-threatening conditions. 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 in late stage clinical development in China to treat autoimmune and oncology indications.

For more information about RemeGen, please visit: www.remegen.com

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 Co., 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 Co., Ltd.'s product candidates advance in development or other factors. These factors include those discussed in RemeGen Co., Ltd.'s public reports are available by contacting Dan Ross at danross@remegen.cn. RemeGen Co., 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.

Contacts

Media:

Bryan Blatstein
917.714.2609
bblatstein@spectrumscience.com

Investor:

Dan Ross
619.208.8439
danross@remegen.cn

_____

References

i National Cancer Institute. Cancer Stat Facts: Bladder Cancer. 2020. Available at https://seer.cancer.gov/statfacts/html/urinb.html
ii Nature.com. Scientific Reports. The Global Epidemiology of Bladder Cancer. 2018. Available at https://www.nature.com/articles/s41598-018-19199-z.pdf?origin=ppub