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Merck KGaA, Darmstadt, Germany, Discontinues Clinical Development Program of Tecemotide as a Monotherapy in Stage III Non-Small Cell Lung Cancer

Darmstadt, Germany, September 12, 2014 – Merck KGaA, Darmstadt, Germany, announced today that its biopharmaceutical division will discontinue the clinical development program of its investigational MUC1 antigen-specific cancer immunotherapy tecemotide (also known as L-BLP25) as a monotherapy in Stage III non-small cell lung cancer (NSCLC).

Luciano Rossetti, Global Head of Research & Development at the biopharmaceutical division, said: "While the data from the exploratory subgroup analysis in the START trial[1] generated a reasonable hypothesis to warrant additional study, the results of the recent trial in Japanese patients decreased the probability of current studies to reach their goals. Therefore, we have decided to discontinue the development of tecemotide as a monotherapy in NSCLC in order to refocus our efforts on other promising candidates in our pipeline, like our anti-PD-L1 antibody MSB0010718C. We remain committed to developing new treatment options for patients with difficult-to-treat cancers."

The company's decision to discontinue the current clinical program in NSCLC, which includes the Phase III START2 and INSPIRE studies, follows recent results from a planned analysis of EMR 63325-009, a randomized, double-blind, placebo-controlled Phase I/II study in Japanese patients with Stage III unresectable, locally advanced NSCLC who had received concurrent or sequential chemoradiotherapy (CRT), with a

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minimum of two cycles of platinum-based chemotherapy and radiation dose ≥50 Gy. Of the patients included in the Phase II part of the study, the majority had received concurrent CRT. The results indicate that no effect has been observed for either the primary endpoint, overall survival (OS), or for any of the secondary endpoints (progression-free survival [PFS], time to progression [TTP] and time to treatment failure). An analysis of the reported adverse events has not identified a clinically meaningful difference in the frequency between treatment groups. Although the trial was not powered to demonstrate a statistically significant difference in benefit between the two arms, the company's biopharmaceutical division made the recommendation to stop the investigational treatment for patients in the EMR 63325-009 study in Japan.

Merck KGaA, Darmstadt, Germany, has made the decision to discontinue all other clinical trials with tecemotide in NSCLC worldwide sponsored by its biopharmaceutical division. Those patients on active treatment with tecemotide can undergo an individual assessment by their treating physician and apply to receive further treatment outside of the studies. The company will continue to supply tecemotide for ongoing investigator-sponsored trials in other indications in accordance with the company's agreements with the sponsors of these studies.

The biopharmaceutical division of Merck KGaA, Darmstadt, Germany, continues to evaluate a number of investigational compounds for difficult-to-treat cancers, and remains committed to improving the lives of cancer patients and their families.

References

1. Butts C, et al. Lancet Oncol 2014;15(1):59-68.

About tecemotide

Tecemotide is an investigational MUC1 antigen-specific cancer immunotherapy that is designed to stimulate the body's immune system to identify and target cells expressing the cell-surface glycoprotein MUC1. MUC1 is expressed in many cancers, including NSCLC, and has multiple roles in tumor growth and survival. Tecemotide was being investigated in the Phase III START2, START and INSPIRE trials for the treatment of unresectable, locally advanced Stage III NSCLC.

Merck KGaA, Darmstadt, Germany, obtained the exclusive worldwide rights for development and commercialization of tecemotide from Oncothyreon Inc., Seattle, Washington, U.S., in 2007, in an agreement replacing prior collaboration and supply agreements originally entered in 2001. In Japan, Merck

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KGaA, Darmstadt, Germany, entered into a co-development and co-marketing agreement for tecemotide with Ono Pharmaceutical Co., Ltd., Osaka, Japan.
The START2 study is a Phase III, multicenter, 1:1 randomized, double-blind, placebo-controlled clinical trial designed to assess the efficacy, safety and tolerability of tecemotide in patients suffering from unresectable, locally advanced (Stage IIIA or IIIB) NSCLC who have had a response or stable disease after at least two cycles of platinum-based concurrent CRT. Concurrent CRT – a combination of chemotherapy and radiotherapy given at the same time – is the current standard of care for most of these patients. The study, which began in April 2014, expected to recruit about 1,000 patients. The study's primary endpoint is OS. Secondary endpoints include time to symptom progression, PFS and TTP.
The basis for the START2 trial was the outcome of the initial START study. START did not meet the primary endpoint of demonstrating an improved OS with tecemotide compared with placebo in the overall patient population (n=1,239). Median OS was 25.6 months for patients in the tecemotide group compared with 22.3 months for those in the placebo group (adjusted hazard ratio [HR]: 0.88; 95% confidence interval [CI]: 0.75–1.03; p=0.123). However, data from an exploratory analysis of a pre-defined subgroup of patients in the START trial, who received tecemotide after concurrent CRT, showed that these patients achieved a median OS of 30.8 months versus 20.6 months in patients treated with placebo (n=806; HR: 0.78; 95% CI: 0.64–0.95; p=0.016).
INSPIRE is a Phase III, multicenter, randomized, double-blind, placebo-controlled clinical trial designed to evaluate the efficacy, safety and tolerability of tecemotide in patients suffering from unresectable, locally advanced Stage IIIA or IIIB NSCLC who have had a response or stable disease after at least two cycles of platinum-based concurrent CRT. INSPIRE expected to recruit approximately 500 Stage III NSCLC patients across China, Hong Kong, Korea, Singapore and Taiwan.

About Merck KGaA, Darmstadt, Germany

Merck KGaA of Darmstadt, Germany, is a leading company for innovative and top-quality high-tech products in the pharmaceutical and chemical sectors. Its subsidiaries in Canada and the United States operate under the umbrella brand EMD. Around 39,000 employees work in 66 countries to improve the quality of life for patients, to further the success of customers and to help meet global challenges. The company generated total revenues of € 11.1 billion in 2013 with its four divisions: Biopharmaceuticals, Consumer Health, Performance Materials and Life Science Tools. Merck KGaA of Darmstadt, Germany is the world's oldest pharmaceutical and chemical company – since 1668, the name has stood for innovation,

business success and responsible entrepreneurship. Holding an approximately 70 percent interest, the founding family remains the majority owner of the company to this day.