Press Release

Celltrion Receives Positive CHMP Opinion For Herzuma® For Trastuzumab Biosimilar

Celltrion's Herzuma® (trastuzumab biosimilar) receives positive opinion from EMA's CHMP for early breast cancer, metastatic breast cancer, and metastatic gastric cancer.

[Incheon, Dec 17th, 2018] Celltrion announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) issued a positive opinion recommending that Herzuma® (trastuzumab biosimilar) be granted marketing authorization in the European Union (EU) for the treatment of patients with early breast cancer, metastatic breast cancer, or metastatic gastric cancer whose tumors have either HER2 overexpression or HER2 gene amplification. The CHMP's opinion will now be sent to the European Commission (EC) for final review.

Herzuma® is a biosimilar to Herceptin®[i], a breast cancer and gastric cancer treatment antibody biologic drug developed by Genentech and marketed by Roche. Herceptin® is a blockbuster drug which had worldwide sales of CHF 6.8 billion[ii] (US$6.8 billion) in 2016, of which CHF 2.1 billion[iii] (US$2.1 billion) was in European sales.

"We welcome the CHMP's recommendation. By providing more treatment options, biosimilars open more opportunities for greater affordability and improve access to wider use of biotherapeutics. Herzuma® could become a cost-effective alternative to biologics for treatment of breast cancer and gastric cancer, since biologics, which cost much more than conventional anticancer drugs, place undue financial burden on patients and the general healthcare system." said Woo Sung Kee, Chief Executive Officer of Celltrion.

About Herzuma®

Herzuma® is an anticancer monoclonal antibody (mAb) biosimilar used to treat breast cancer and gastric cancer. Similarity of Herzuma® to the reference product, Herceptin®, was demonstrated in terms of pharmacokinetic, pharmacodynamics, efficacy and safety through multiple global clinical trials covering various indications such as HER2-positive early breast cancer, HER2-positive metastatic breast cancer, and HER2-positive metastatic gastric cancer. Celltrion also submitted the Biologics License Application (BLA) to the US Food and Drug Administration (FDA). In 2017, Celltrion launched Herzuma® in Korea.

About Celltrion

Headquartered in Incheon, Korea, Celltrion is a leading biopharmaceutical company, specializing in research, development and manufacture of biosimilar and innovative drugs. Celltrion strives to provide more affordable biosimilar mAbs to patients who previously had limited access to advanced therapeutics. Celltrion received FDA and EMA approval for Inflectra® and Remsima®, respectively, which is the world's first mAb biosimilar to receive approval from a regulatory agency in a developed country. Celltrion also received EMA approval for Truxima® (CT-P10, a mAb biosimilar to MabThera®[iv] (rituximab)) in February 2017. For more information, visit www.celltion.com.

[i] Herceptin® is a registered trademark of Genentech Inc.

[ii] Roche Financial Report 2016

[iii] Roche Financial Report 2016

[iv] MabThera® is a registered trademark of Genentech, Inc

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