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ASIA EDITION

EirGenix's proposed Biosimilar 'Trastuzumab' shows positive Ph 3 results

March 25, 2021 | News

Breast cancer biosimilar, EG12014 will proceed with the preparations for submissions of Biologics license application (BLA) to the U.S. FDA, MAA, EMA, and TFDA



EirGenix, Inc. announced that the Phase III clinical trial (Trial No.: EGC002, NCT03433313) of its breast cancer biosimilar, EG12014 (proposed trastuzumab biosimilar, also called EGI014), has met its primary endpoint. EG12014 has shown equivalent efficacy to Herceptin® in regards to its clinical response (pathologic complete response, pCR), in addition to demonstrating a comparable safety profile. EirGenix will proceed with the preparations for submissions of Biologics License Application (BLA) to the U.S. FDA, Market Approval Application (MAA) to European Medicines Agency (EMA) and New Drug Application to TFDA, exact timings remain confidential.

This phase III clinical trial is a multi-national, multi-center, randomized, double-blinded study involving female with early, HER2-positive breast cancer. The purpose of the trial was to demonstrate the therapeutic equivalence in terms of efficacy between EG12014 to Herceptin®, and to compare the safety, immunogenicity and PK between the two trastuzumab products. The topline results demonstrated that EG12014 met equivalence to Herceptin® in terms of clinical response in both analysis populations (per-protocol and full-analysis sets).

According to Roche's annual report, global sales of Herceptin® totaled 3.73 billion CHF in 2020. The US and EU market are 1.36 billion CHF and 0.67 billion CHF respectively. Herceptin® sales were 34% lower than in 2019, driven by biosimilar competition, which was introduced in the second half of 2019 in the US and mid-2018 in Japan and Europe. Upon approval Sandoz AG, a global leader in generics and biosimilars will sell EG12014 globally in all markets except for Taiwan and Mainland China, as per the licensing agreement signed with EirGenix in April 2019. In 2019, Taiwan's National Health Insurance (NHI) paid approximately 1.657 billion New Taiwan Dollars (NTD) for Herceptin®.

EirGenix is currently the first and only biopharmaceutical company in Taiwan to have successfully signed a licensing agreement with a global pharmaceutical company for a biosimilar. EirGenix is also one of only a handful of Taiwanese biopharmaceutical companies to have independently developed a biosimilar product into Phase III clinical trials and successfully demonstrating its equivalent efficacy. With such developmental achievements. EirGenix is rightfully worthy of investors' attention and expectations.