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EirGenix inks commercialization agreement with Sandoz

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EirGenix, Inc. has entered into a license agreement with global generic and biosimilar drug manufacturer Sandoz AG, granting an exclusive license to Sandoz for right of commercialization of EirGenix 's breast cancer biosimilar drug, EG12014 (Trastuzumab Biosimilar to Roche / Genentech's Herceptin) globally with the exception of Taiwan and mainland China.

According to the terms of the agreement, EirGenix will receive an upfront payment, milestone payments, and is entitled to receive profit share payments for sales in the territory. The signing of this agreement is one of the most significant achievements for EirGenix's product development business since the company's establishment, and represents an exciting moment for Taiwan's biotech industry.

Sandoz is a Novartis division, and a global leader in generic pharmaceuticals and biosimilars and a pioneer in the emerging field of prescription digital therapeutics. Sandoz has a long history and extensive experience in the development and commercialization of biosimilar and cancer drugs in markets such as Europe and the United States. The collaboration between EirGenix and Sandoz will leverage the combined strength of EirGenix 's R&D of biosimilar drugs, with Sandoz's substantial experience in global drug sales and advantages in market access.

This collaboration will be conducive to EirGenix 's market development and expansion in the pharmaceutical market and will be extremely positive for EirGenix 's financial and business development as the collaboration will enhance the visibility and competitiveness of its products in the global market, which would thereby improve the company's overall operating scale and profitability. With the successful market entry of EG12014, HER2-positive breast cancer patients will benefit from more treatment options.

EG12014 (Trastuzumab biosimilar) has entered a global Phase 3 clinical trial (Study No.: EGC002) which has been to date approved to conduct such trial by ten regulatory authorities including the U.S. FDA, Taiwan TFDA, as well as the authorities in Russia, Belarus, Ukraine, South Africa, Georgia, South Korea, India and Chile. A total of 800 breast cancer patients will be enrolled for this Phase 3 clinical trial, and the primary endpoint analysis is expected to be completed in the second half of 2020 to support the product registration. According to Roche's 2018 annual report, Herceptin's global sales amounted to 6.982 billion Swiss Francs. Herceptin tops the list in drug spending by Taiwan's National Health Insurance, with an annual expenditure of nearly NT$3 billion.

EirGenix, Inc. has utilized reverse engineering technology in developing its four biosimilar products. In addition to the two

antibody biosimilars for the treatment of HER2-positive breast cancers, there are two other anti-angiogenesis biosimilar drugs in development.

EirGenix recently opened its commercial mass production facility in Zhubei, Taiwan, and aims to complete multiple batches of commercial-scale productions in 2019. In terms of CDMO business, it already reached break-even point in the first-half of 2016 and the revenue grew more than 35 fold since 2013 and is expected to steadily drive its revenue growth in the coming year. It is without a doubt that through its diligent pursuit of rapid business innovation, EirGenix has become one of the fastest growing companies in Taiwan's biotech/pharmaceutical industry.