

Taiwan's EirGenix partners with Sandoz for breast cancer biosimilar in \$152 M deal

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Taiwan-based EirGenix Inc. has entered into a second global exclusive licensing agreement with international biosimilar leader Sandoz AG for the commercialisation of its independently developed breast cancer biosimilar, EG1206A (Pertuzumab Biosimilar to Roche Perjeta®), covering all territories except Taiwan, Mainland China, Macau, South Korea, Mongolia, Brunei, Cambodia, Indonesia, Laos, Myanmar, the Philippines, and Japan.

The agreement further strengthens the two companies' collaborative development of the HER2 biosimilar product. Under the terms of the agreement, EirGenix will receive a total up to \$152 million of upfront and milestone payments. In addition, EirGenix will also be entitled to a profit share once the product is launched in the licensed territory plus potential sales incentives based on market performance. EirGenix will be responsible for product development, manufacturing, and supply.

EG1206A has completed its pharmacokinetic (PK) clinical study, and last month received positive feedback from both the US FDA and the European Medicines Agency (EMA), confirming that the product qualifies for an abbreviated development pathway, allowing for the waiver of Phase III comparative efficacy trials.

This agreement marks another major milestone and breakthrough in EirGenix's biosimilar development efforts. This partnership further strengthens the existing collaboration between Sandoz and EirGenix. The two companies previously signed a global commercialisation agreement for EG12014 (Trastuzumab Biosimilar in both 150 mg and 420 mg formulations). EG12014 has already been approved by the European Commission and is currently under BLA review by the US FDA.

EirGenix has successfully utilised reverse engineering technologies to develop multiple biosimilar products. With regulatory trends increasingly favorable, EirGenix is accelerating the development of four HER2-targeted antibody programs, expanding its in-house product pipeline as well as CDMO services for additional biosimilar projects.