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Formosa Pharma files European trial application for Kadcyla biosimilar TSY-110

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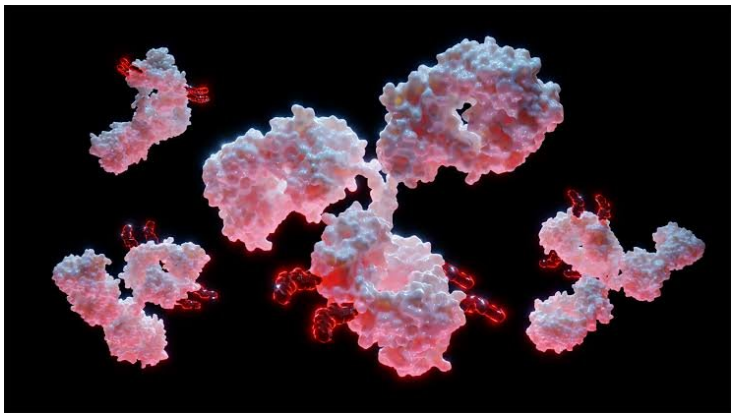
The pivotal study will compare the HER2-targeting ADC biosimilar with reference ado-trastuzumab emtansine across safety, pharmacokinetics and immunogenicity.



Taiwan-based Formosa Pharmaceuticals has submitted a Clinical Trial Application to European regulators for a pivotal study of TSY-110, its biosimilar candidate referencing the HER2-targeting antibody-drug conjugate ado-trastuzumab emtansine.

TSY-110 is being co-developed by Formosa Pharmaceuticals and EirGenix as a biosimilar to Roche's Kadcyla.

The reference therapy is used in HER2-positive metastatic and early-stage breast cancer.

The planned pivotal study has been designed following regulatory guidance from authorities in both the United States and Europe.

It will compare TSY-110 with the reference product across safety, tolerability, pharmacokinetics and immunogenicity.

Formosa Pharmaceuticals is seeking to position TSY-110 as the first biosimilar alternative to Kadcyla in major regulated markets.

The programme combines EirGenix's antibody capabilities with Formosa Laboratories' antibody-drug conjugate bioconjugation platform.

Formosa Pharma said the integrated development and manufacturing structure provides the programme with an end-to-end ADC research, development and manufacturing supply chain in Taiwan.

The company has also completed a Biosimilar Biological Product Development Type II meeting with the US Food and Drug Administration in 2026.

The meeting provided alignment on the clinical trial design and chemistry, manufacturing and controls strategy for TSY-110.

Biosimilar development in the ADC field introduces additional complexity compared with conventional monoclonal antibodies because developers must establish similarity across the antibody, cytotoxic payload, linker and conjugated final product.

Formosa Pharma and EirGenix are developing TSY-110 with the aim of providing a lower-cost HER2-directed ADC option while maintaining comparable quality and clinical performance to the reference therapy.

The programme forms part of a broader ADC pipeline at Formosa Pharmaceuticals.

The company is also developing TSY-120, an Enhertu-referencing ADC biosimilar, and TSY-310, a next-generation bispecific ADC targeting EGFR and ROR1.

Submission of the European CTA moves TSY-110 closer to pivotal clinical evaluation and represents another step towards the potential arrival of biosimilar competition in the antibody-drug conjugate market.