

# Investigation Report on Trastuzumab in China, 2018-2022

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## Abstracts

### DESCRIPTION

Trastuzumab was developed by GENE GENTECH and approved in Sept. 1998 by the FDA for clinical use. Its trade name is Herceptin and it is now a major product of Roche. In 2017, trastuzumab was sold for around USD 7 billion worldwide. It is a standard medicine recommended by the international medical community for HER2 positive breast cancer and gastric cancer.

In 2002, trastuzumab entered the Chinese market and was mainly used to treat HER2 metastatic breast cancer. After entering China, trastuzumab developed rapidly. Its annual sales increased from less than CNY 70 million in 2007 to CNY 887 million in 2017, and the CAGR reached 30.4% during 2007 to 2017. Before 2017, trastuzumab was produced by GENENTECH and Roche. Since 2017, it has been monopolized by the latter in the Chinese market. Currently, Roche is the single product in the market

Trastuzumab was first approved to market by the FDA in Sept. 1998 and was admitted to China in 2002. The patent for trastuzumab in the EU expired in Jul. 2014 and will expire in the U.S. in Jun. 2019. Many pharmaceutical companies have taken part in the research and development of biosimilar drugs. Three biomedical companies, Fuhong Hanlin, Anke Bio and Jiahe Bio, are now producing biosimilar of Trastuzumab in clinical Phase III. According to the approval requirements of CDE, Fuhong Hanlin and Anke Bio are expected to be the first to hold licenses. Fuhong Hanlin is even ahead of the other and is expected to get sales permits in 2019, which makes it the first case of domestic biosimilar of trastuzumab.

In Jul. 2017, Trastuzumab was incorporated in China's National Health Insurance

Directory, which caused a surge in market demand and shortages in many parts of the country. In Jun. 2018, the CFDA issued a notice to allow Trastuzumab be sold on market when being inspected through ports, which can save 2 to 3 months.

CRI expects that from 2018 to 2020 Roche's Herceptin will continue to monopolize the Chinese market. In 2020, domestic trastuzumab will be successively launched and grab market shares at a low price. Besides, the incidence of breast cancer and gastric diseases in China keeps rising, so the demand for trastuzumab will also continue to increase.

## **TOPICS COVERED**

Development environment of Trastuzumab

Development of Trastuzumab in China

Chinese Market Size of Trastuzumab

Sale Price of Trastuzumab in China

Competition Landscape of Trastuzumab in China

Prospects of Chinese trastuzumab market

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### **COMPANIES MENTIONED**

1 GENENTECH

2 Shanghai Roche Pharmaceuticals Ltd.

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