

China Monoclonal Antibody Industry Report, 2010-2011

https://marketpublishers.com/r/C8A696072C6EN.html

Date: July 2011 Pages: 64 Price: US\$ 1,700.00 (Single User License) ID: C8A696072C6EN

Abstracts

China has been engaging in the R&D of monoclonal antibody industry for a long time, but still lags far behind the European and American countries in terms of industrialization. In 2010, the market scale of monoclonal antibody drugs in China was no more than around USD340million, while the global sales in the same period hit USD44billion.

Restricted by high technical threshold and the need of huge capital, only a few Chinese enterprises can realize industrialized production of monoclonal antibody drugs. Presently, there are around 10 monoclonal antibody drug manufacturers that have carried clinical trials in China, but only some including Shanghai CP Guojian Pharmaceutical, Beijing Biotech Pharmaceutical Company, Chengdu Huasun Group and Shanghai Meien Biotechnology have launched their products into the market. As of May 2011, a total of 17 monoclonal antibody drugs were approved by SFDA and rolled out into the market, among which, nearly 60% were the imported products.

Currently, the monoclonal antibody product with the highest value of drug use is Roche's Rituximab which was introduced to China in 2000, and its market shares in the first three quarters of 2009 reached 36.6%. Another leading monoclonal antibody drug of Roche, Trastuzumab accessed into Chinese market late, but its market share keeps rising in the recent years, and it swept a 22.7% market share in the first three quarters of 2009. In addition, Merck's monoclonal antibody drug Cetuximab gets used for curing colorectal cancer, and the market shares of this drug got to 22.2%.

The monoclonal antibody market is mainly dominated by the imports, but China's monoclonal antibody drug sales grows significantly as Shanghai CP Guojian Pharmaceutical and Biotech Pharma have launched its own humanized products with



price superiority. For instance, Biotech Pharma's Nimotuzumab, rolled out into the market only in two years, obtained the sale of over RMB100 million in the second year after being launched in the market.

Since monoclonal antibody drugs are supported by national policies, Chinese pharmaceutical companies such as Fosun Pharma, Shanghai Fudan-Zhangjiang Bio-Pharmaceutical, Hisun Pharmaceutical, SL Pharmaceutical, Kanghong Pharmaceutical, Shenzhen Accord Pharmaceutical, Livzon Pharmaceutical Group, etc are also planning to make more projections into the R&D of monoclonal products. In July of 2010, Fosun Pharma announced in Shanghai its joint funding with the international pharmaceutical corporation Chemo to build up the monoclonal antibody drug project, with the total investments approximating RMB500 million as estimated. Livzon Pharmaceutical plans to associate with its shareholder JoinCare to make joint funding for establishing a monoclonal antibody bio-technology company.



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