



**China Monoclonal Antibody Industry  
Report, 2010-2011**

**July 2011**

## ***This report***

- ◆ **Analyzes the status quo of China Monoclonal Antibody Industry market.**
- ◆ **Focuses on the market segments of monoclonal antibody in China**
- ◆ **Highlights the operation of major monoclonal antibody manufacturers worldwide and China.**

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## Abstract

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.

## Monoclonal Antibody Drugs Approved for being Launched in Chinese Market as of 2011

NO.	Drug	Company	Type of Antibody	Date of Listing	Application
1	Mouse Monoclonal Antibody against Human CD3 Antigen of T Lymphocyte	Cuba CIMAB S.A.	Murine	1999	Organ transplant anti-rejection therapy
2	Rituximab	Roche/ Genentech	Chimeric	2000	Non-Hodgkin's lymphoma
3	Daclizumab	Roche/ Genentech	Humanized	2000	Organ transplant anti-rejection therapy
4	Monoclonal Antibody of Mouse Anti-human CD3 Antigen of T Lymphocyte Injection	Wuhan Institute of Biological Products	Murine	2002	Organ transplant anti-rejection therapy
5	Anti Human Interleukin-8 Monoclonal Antibody Cream	Dongguan Winnerway YES Biotech & Pharmaceutical Co., Ltd	Murine	2003	Psoriasis
6	Trastuzumab	Roche/ Genentech	Humanized	2003	Breast Cancer
7	Basiliximab	Novartis	Chimeric	2004	Organ transplant anti-rejection therapy
8	Cetuximab	merck/ImClone LLC	Chimeric	2005	Colorectal cancer
9	Recombinant Human Tumor Necrosis Factor Receptor II: IgG Fusion Protein	Shanghai CP Guojian Pharmaceutical Co., Ltd.	Humanized	2005	Rheumatoid arthritis
10	Iodine [ <sup>131</sup> I] Tumor Necrosis Therapy Monoclonal Antibody Injection	Shanghai Meien Biotechnology Co., Ltd.	Chimeric	2006	Lung Cancer
11	Iodine[ <sup>131</sup> I] Metuximab Injection	the Fourth Military Medical University/ Chengdu Huasun Group Inc., Ltd.	Murine	2006	Lung Cancer
12	Infliximab/Remicade	Johnson & Johnson	Chimeric	2007	Rheumatoid arthritis, ankylosing spondylitis and Crohn's disease
13	Nimotuzumab	Beijing Biotech Pharmaceutical Company	Humanized	2008	Colorectal cancer
14	Bevacizumab	Roche	Humanized	2010	Colorectal metastatic cancer treatment
15	Adalimumab	Abbott	Humanized	2010	Rheumatoid arthritis
16	Etanercept	Amgen	Full humanized	2010	Chronic rheumatoid arthritis, ankylosing spondylitis, psoriatic
17	Recombinant Humanized Anti-CD25 Monoclonal Antibody Injection	Shanghai CP Guojian Pharmaceutical Co., Ltd.	Humanized	2011	Organ transplant anti-rejection therapy

Source: SFDA; ResearchInChina

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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