



Global and China Monoclonal Antibody Industry Report, 2019-2025

Apr. 2019

STUDY GOAL AND OBJECTIVES

This report provides the industry executives with strategically significant competitor information, analysis, insight and projection on the competitive pattern and key companies in the industry, crucial to the development and implementation of effective business, marketing and R&D programs.

REPORT OBJECTIVES

- ◆ To establish a comprehensive, factual, annually updated and cost-effective information base on market size, competition patterns, market segments, goals and strategies of the leading players in the market, reviews and forecasts.
- ◆ To assist potential market entrants in evaluating prospective acquisition and joint venture candidates.
- ◆ To complement the organizations' internal competitor information gathering efforts with strategic analysis, data interpretation and insight.
- ◆ To suggest for concerned investors in line with the current development of this industry as well as the development tendency.
- ◆ To help company to succeed in a competitive market, and

METHODOLOGY

Both primary and secondary research methodologies were used in preparing this study. Initially, a comprehensive and exhaustive search of the literature on this industry was conducted. These sources included related books and journals, trade literature, marketing literature, other product/promotional literature, annual reports, security analyst reports, and other publications. Subsequently, telephone interviews or email correspondence was conducted with marketing executives etc. Other sources included related magazines, academics, and consulting companies.

INFORMATION SOURCES

The primary information sources include Company Reports, and National Bureau of Statistics of China etc.

Abstract

Global monoclonal antibody market can be presented as follows:

1. Monoclonal antibody drug market booms and is highly concentrated with the approvals for such drugs.

Monoclonal antibody drugs have been maturing from a research target to an improved technology, from clinical research to commercialization over the past three decades. In recent years, the number of monoclonal antibody drugs approved for launch proliferated, with 78 approved and available on the market as of May 2018.

In 2017, 7 of 10 best-selling drugs worldwide were monoclonal antibody drugs, the fastest growing segment in global bio-pharmaceutical market. In Merck's case, the sales of its Keytruda which was launched in 2014, hit RMB7.171 billion in 2018 alone.

Global monoclonal antibody market has been expanding over the recent years, with its size posting USD115.2 billion in 2018, a year-on-year increase of 11%. As of April 2019, there have been 182 monoclonal antibody drugs undergoing Phase III clinical trials worldwide. It is expected that many a monoclonal antibody drug will be approved and rolled out into the market in the forthcoming years, favoring a ballooning market size to USD240.2 billion in 2025.

The world's monoclonal antibody market is now almost carved up by Roche, Johnson & Johnson, Merck, Novartis, AbbVie and Amgen. In 2018, the global top eight monoclonal antibody drugs by sales, collectively USD64,052 million, were HuMiRA, Herceptin, Avastin, Keytruda, Rituxan, Remicade, Stelara and ENBREL?, with a combined 55.6% share in global market.

2. The Chinese monoclonal antibody market has a rosy prospect but players compete with each other fiercely.

As of April 2019, the National Medical Products Administration (NMPA) of China has approved the roll-out of 33 antibody drugs (including fusion protein), including 21 imported and 12 homemade products, far lower than the volume approved by the US Food and Drug Administration (FDA). China has quickened its pace of approving monoclonal antibody drugs led by Opdivo and Keytruda, and projects to list them into its medical insurance drugs catalogue, giving impetus to the expansion of the market in the country.

China's monoclonal antibody market developed by leaps and bounds between 2013 and 2017 at a CAGR of 15.6%, and would be worth RMB14.2 billion in 2018, 20.3% higher than in the previous year. The monoclonal antibody market size in China will grow up to RMB120.7 billion in 2025 as more new such drugs and biosimilar drugs are approved and launched.

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In China, most monoclonal antibody drugs are at the clinical research stage, the majority of which are biosimilar products. Among those on the market, Sintilimab from Innovent Biologics and Toripalimab from Shanghai Junshi Biosciences are two new monoclonal antibody drugs, and HLX01 developed by Shanghai Henlius Biotech is China's first biosimilar. Other monoclonal antibody developers include Biotech Pharma, Chengdu Taihe Health Technology Group, Zhejiang Hisun Pharmaceutical, Genor Biopharma, Beijing Shuanglu Pharmaceutical, Zhejiang Huahai Pharmaceutical, Livzon Pharmaceutical Group, Mabpharm, Hualan Biological Engineering and Anhui Anke Biotechnology (Group) Co., Ltd..

Companies like Innovent Biologics, Shanghai Junshi Biosciences and Shanghai Henlius Biotech that stay ahead of others in drug approval for launch, will have an edge over their peers in the market. But several players' application for production and Phase III clinical trials by a number of companies which will then release their products under approval, means that competition between local firms and their foreign counterparts, between reference listed drugs (RLD) and biosimilars, will remain tough in the Chinese monoclonal antibody market.

3. As star monoclonal antibody drug patents expire, generic drugs will shock the market.

In the next five years, as the duration of star monoclonal antibody drug patents draws to an end, biosimilar market will be the battlefield of numerous pharmaceutical companies. Generic drugs for four monoclonal antibody drugs have been approved and become available on the market in European Union and the United States, signaling their squeeze of RLD in the market.

Expiration of Major Monoclonal Antibody Drug Patents Worldwide

Name	RLD Manufacturer	Expiration of American Patents	Expiration of European Patents
Enbrel (etanercept)	Amgen	2028	2015
Remicade (infliximab)	Janssen	2018	2015
Humira (adalimumab)	AbbVie	2022	2018
Herceptin (trastuzumab)	Roche	2019	2014
Lucentis (Ranibizumab)	Roche	2020	2022
Mabthera (Rituximab)	Roche	2019	2013
Avastin (Bevacizumab)	Roche	2019	2022

Source: ResearchInChina

4. Monoclonal antibodies with PD-1 and PD-L1 as targets spring up.

The editorial board of the New England Journal of Medicine indicates that the PD-1 monoclonal antibody is the best anticancer performer over the past thirty years. Following the approval and release of Opdiva and Keytruda, two PD-1 targeted monoclonal antibodies in 2014, PD-1/PD-L1 monoclonal antibody drugs like Tecentriq, Bavencio, Imfinzi and Libtayo have also been brought to market.

Sales of Opdivo and Keytruda have been on the rise since their launch, especially the later with sales of USD7,171 million in 2018, nearly doubling the figure in the previous year. Global PD-1/PD-L1 monoclonal antibody market size reached as much as USD13.9 billion in 2018, and will expectedly surge to a staggering USD57.4 billion in 2025.

The report highlights the following:

- Global monoclonal antibody industry (status quo, market size, market structure, competitive landscape and development prospects);
- China's monoclonal antibody industry (status quo, market size, market segments, competitive pattern and development outlook);
- Six foreign and nineteen Chinese monoclonal antibody companies (profile, operation and monoclonal antibody business).

1. Overview of Monoclonal Antibody Industry

- 1.1 Definition
- 1.2 Classification
- 1.3 Technological Development

2. Overview of Global Monoclonal Antibody Industry

- 2.1 Status Quo
- 2.2 Market Size
- 2.3 Market Structure
- 2.4 Competition Pattern
- 2.5 Development Prospect and Prediction
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