



Global and China Monoclonal Antibody Industry Report, 2013

Jan. 2013

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, Ministry of Health of the People's Republic of China, and National Bureau of Statistics of China etc.

Abstract

In recent years, the monoclonal antibody market around the globe has witnessed substantial growth, and the CAGR of market scale during 1997-2011 has reached 44% approximately. It is predicted that the global monoclonal antibody market scale will reach USD78 billion in 2012. Meanwhile, monoclonal antibody is also a key major source of blockbuster drugs. In 2011, the sales of six monoclonal antibody agents as Infliximab (Johnson & Johnson), Etanercept (Amgen), Bevacizumab (Roche), Rituximab (Roche), Adalimumab (Abbvie) and Trastuzumab (Roche) reached above USD5 billion around the globe, approximating 60% of global monoclonal antibody market.

Due to the features as high technical threshold, large capital demand and high rate of return, the international pharmaceutical giants (including Roche, Johnson & Johnson, Abbvie, Amgen, Novartis, etc.) are still accelerating the research and industrialization of monoclonal antibody agents through M&A or cooperation on the basis of existing monoclonal antibody products. For example, in April 2012, Amgen and AstraZeneca announced that they would jointly develop and sell the 5 monoclonal antibody agents of Amgen under research, namely, AMG827, AMG139, AMG181, AMG557 and AMG157.

Although the monoclonal antibody has witnessed rapid development, and the market scale is expected to share 8%-10% of world's total in 2012, the market in China is still mainly occupied by imported products. As

of the end of 2012, the number of imported monoclonal antibody products approved by SFDA amounted to 11, while that of domestic-made products only reached 8; the number of imported monoclonal antibody agents approved for clinical tests in China amounted to 27, while the figure of domestic products only hit 20, mainly imitating the overseas original drugs.

At present, the imported products as Rituximab, Trastuzumab, Cetuximab, Infliximab and Bevacizumab have contributed 70%-75% of monoclonal antibody market in China; the rest market is shared by the home-made drugs as Yisaipu? (Recombinant Human TNF Receptor-Ig Fusion Protein) and Xenopax? (Recombinant Humanized Anti-CD25 Monoclonal Antibody) of CPGJ, and Nimotuzomab of Biotech Pharma. Besides, several imported monoclonal antibody agents have accessed some local medical insurance systems. For example, Remicade? (Infliximab), which is used to treat rheumatoid, has accessed 11 local medical insurances, Simulect? (Bevacizumab, used in anti-transplant rejection) has accessed 10 local medical insurances, and Rituxan? (Rituximab, used to treat tumors) has accessed 9 local medical insurances. Meanwhile, since it may take 3-5 years for the domestic-made monoclonal antibody agents to achieve large scale and industrialized marketing, the imported markets will still embrace expectable development in future.

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In view of the optimistic market prospect, advancement of monoclonal antibody technologies, support of favorable policies and the upcoming patent expiration of several key monoclonal antibody agents, multiple local enterprises as Hisun Pharmaceutical, Fosun Pharmaceutical, Walvax Biotechnology and SL Pharmaceutical are now marching into the monoclonal antibody market by huge capitals successively.

As of December 2012, the first monoclonal antibody generic drug (generic drug of enbrel) – Anbainuo? of Hisun Pharmaceutical was under phase III clinical supplementary test, and is expected to be approved by the end of 2013. The commercialized capacity will be 3.2 million pieces per year; furthermore, Enbrel has been tested in Brazil, etc., and is expected to achieve export.

In July 2012, the environmental impact assessment concerning phase I of new medicine pilot test base project (monoclonal antibody agents) of Fosun Pharmaceutical was publicized. According to the notice, the pilot scale of the project will be 130kg/a (equal to 1.3 million pcs/a of Rituximab), and the construction content involves raw material storage, pilot workshop, quality inspection, administration building and supporting public auxiliary facilities.

In April 2012, Walvax Biotechnology announced to jointly sign Cooperation Framework Agreement with Shanghai Fengmao

Biotechnology, Shanghai Winlord Industries & Trading, and natural persons Wang Xiaofei and Kong Haiyan, planning to invest in Shanghai Fengmao in future four years, and research and industrialize Rituximab, Bevacizumab, Adalimumab, Panitumumab, Denosumab and long-acting EPO; in August, the company invested RMB246 million to establish the fully-owned subsidiary Shanghai Walvax, so as to promote the industrialization of the above six blockbuster bio-similar products. Nevertheless, according to the public information, the monoclonal antibody generic drugs of Walvax Biotechnology cannot be marketed until 2017 (Rituximab and Panitumumab as planned), and the commodity volume is expected to be 12kg/a, sharing 10% of planned capacity.

Global and China Monoclonal Antibody Industry Report, 2013 of ResearchInChina mainly involves the following contents:

- Development status, market scale, competitive pattern and development forecast, etc. of monoclonal antibody industry around the globe;
- Development status, market scale, competitive pattern and development forecast, etc. of monoclonal antibody industry in China;
- Operation, monoclonal antibody business, development in China, R&D status, etc. of 6 monoclonal antibody enterprises around the globe and 10 enterprises in China.

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