

China Recombinant Protein Drug Industry Report, 2014-2017

Nov. 2014

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.

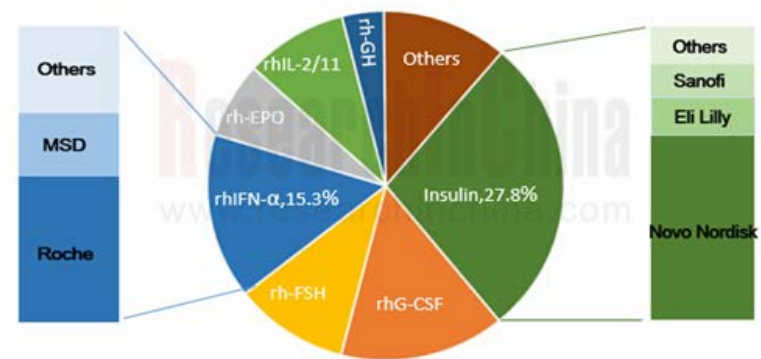
Abstract

The Chinese recombinant protein drug market has been expanding rapidly owing to the improvement of demand rigidity, consumption ability and the like. During 2005-2013, sales of recombinant protein drugs available in Chinese sample hospitals grew at a CAGR of 19.1%, and it is projected that China will see its actual demand for recombinant protein drugs exceed RMB40 billion in 2014.

The start of recombinant protein drugs in China is not late and common drugs are diversified in variety, for example, recombinant human erythropoietin (rhEPO), recombinant human granulocyte colony-stimulating factor (rhG-CSF) and recombinant human interferon (rhIFN) have gained market approval in the 1990s. Moreover, in 2013, domestic rhG-CSF, rhEPO and recombinant human growth hormone (rhGH) with price advantage took a respective share of 82.1%, 88.5% and 90.2% in Chinese sample hospitals, and recombinant human interleukin-2/11(rhIL-2/11) was fully localized.

However, as compared with products from leading bio-pharmaceutical enterprises in the United States and Europe, domestic recombinant protein drugs are still characterized by low-end technologies and largely remain in common short-acting areas. And foreign brands still prevail in the markets of recombinant insulin, rhIFN, recombinant coagulation factor and recombinant human follicle-stimulating hormone (rhFSH).

Recombinant Protein Drug Market Competition of Sample Hospitals in China (by Product or Enterprise), 2013



Source: China Recombinant protein drug Industry Report, 2014-2017 by ResearchInChina

1. Recombinant Insulin Market. In 2013, foreign brands such as Novo Nordisk's insulin aspart and insulin detemir, Sanofi's insulin glargine, Eli Lilly's insulin lispro accounted for 91.4% of recombinant insulin market of Chinese sample hospitals, while domestic insulin e.g. insulin glargine and insulin lispro of Gan & Lee Pharmaceuticals, recombinant insulin of Tonghua Dongbao Pharmaceutical and animal insulin of Wanbang Biopharmaceuticals was at a distinct disadvantage, whereas insulin analog products of Gan & Lee are still in the process of development, with huge potential for growth in the future.

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2. rhIFN- α Market. Roche's PEG-IFN α -2a, MSD's PEG-IFN α -2a and IFN- α -2a, and other imported products still dominate Chinese interferon market, sweeping as much as 70.7% of recombinant interferon market of sample hospitals in 2013; while more than a dozen local companies like Shanghai Huaxin High Biotechnology Inc., Beijing Tri-Prime Genetic Engineering Co., Ltd. and Anhui Anke Biotechnology (Group) Co., Ltd. mainly produce ordinary short-acting products, which lack strong competitiveness compared with PEG-Intron products (long-acting interferon)with better anti-hepatitisvirus effect.

Moreover, there is no domestic recombinant protein drug in such markets as rhIFN- β , rhFSH, recombinant coagulation factor VIIa and factorVIIIyet.

Based on support from favorable policies, R&D ability enhancement as well as being optimistic about market prospects, a large number of biotech companies are vigorously developing long-acting, high-end protein drugs.

In August 2014, PEG-rhGHof GeneScience Pharmaceuticals Co., Ltd. (GenSci, a subsidy of Changchun High & New Technology Industry (Group) Inc.) obtained the GMP certificate and could formally go on sale; however, as PEG-rhGH belongs to national new First-in-Class drugs, a phase IV clinical trial is a must, and mass production is expected to begin in 2016. In June 2014, Anke Biotechnology's PEG-rhIFN α and Dongbao Pharmaceutical'sultrolente insulin (insulin glargine)were both approved for clinical application. So far, PEG-GCSF of Jiangsu Hengrui Medicine Co., Ltd., PEG-rhIFN α of Xiamen Amoytop Biotech Co., Ltd. (a subsidiary of Dongbao Pharmaceutical) and rhFSH of GenSci have all declared for production and are expected to be approved and available on the market in 2015.

China Recombinant Protein Drug Industry Report, 2014-2017 highlights the followings:

- Market size, competition pattern, market segments, prospects, etc. of recombinant protein drugs worldwide;
- Market situation, competition pattern, R&D, forecasts for2014-2017, etc. of recombinant protein drugs in China;
- Development status, competition pattern, prospects, etc. of product segments e.g. recombinant insulin, rhG-CSF, rhEPO, rhGH, rhFSH in China;
- Operation, recombinant protein drug business, forecast, etc. of 10 keyrecombinant protein drug enterprises in China (including Anhui Anke Biotechnology (Group) Co., Ltd., 3SBio Inc., Livzon Pharmaceutical Group Inc., Tonghua Dongbao Pharmaceutical Co., Ltd., etc.).

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