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China Genetic Engineering Drug Industry Report, 2011-2012

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Abstracts

China gets a late start in developing genetic engineering drug industry, but has achieved leapfrog advance. At present, China has at least one hundred enterprises involved in genetic engineering drugs. In recent years, the compound growth rate of genetic engineering drug market in China is as high as 49%, with an average gross margin of more than 80%. However, the technology strength and efficacy of locally produced genetic engineering drugs are relatively weak. In particular, the pegylated recombinant human granulocyte colony stimulating factor (PEG-rhG-CSF) for injection of CSPC Pharmaceutical Group Limited that approved for marketing in March 2012 is the only homemade long-acting protein product. Still, due to the impetus of huge market capacity as well as a package of preferential policies, many domestic enterprises, including GeneScience Pharmaceuticals, Amoytop and Anhui Anke Biotechnology, are accelerating the industrialized research of long-acting protein drugs.

Monoclonal antibody is one of the most promising genetic engineering drugs. As of May 2012, SFDA approved the marketing of a total of 18 monoclonal antibody drugs. Among these drugs, nearly 60% are foreign brands including Roche, Merck and Novartis with the combined sales accounting for three fourths of the Chinese monoclonal antibody drug market. However, with the marketing of monoclonal antibody drugs made by companies such as Shanghai CP Guojian Pharmaceutical and Biotech Pharmaceutical, the market share of homemade monoclonal antibody industry is on the rise gradually.

In addition, recombinant human erythropoietin, recombinant human interferon, recombinant human growth hormone, recombinant human granulocyte-colony stimulating factor and recombinant human insulin are among the important genetic engineering drugs. As of late 2011, China had roughly 20 recombinant EPO manufacturers that approved for marketing of related products. In particular, as former

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EPO preparation exporters to China, enterprises including America-based Amgen and Germany-based Boehringer Mannheim GmbH have withdrawn from the Chinese market owning to low price competition. Presently, the Chinese EPO market is dominated by domestic manufacturers including 3SBio Inc. and DIAO Group. In 2011, the sales of 3SBio Inc. accounted for 42.7% in China's EPO market. As such, impacted by channel, price competition and other factors, recombinant human growth hormone and recombinant human granulocyte-colony stimulating factor markets are also dominated by domestic enterprises.

In the recombinant human interferon market, the high-performance long-acting interferon of Schering-Plough and Roche still maintained huge consumption in Chinese market in spite of the high prices. In recent years, the market share of imported long-acting interferon has remained at 60% or so in China.

Moreover, due to improving economic level and raising awareness of people, foreign-branded recombinant human insulin in Chinese market are predominant, occupying 90% market share in the corresponding period.

Although China lags behind in terms of the overall level of genetic engineering drugs, the industry has accumulated rich R&D and industrialization experience as well as capital reserves. Thus, with a host of genetic engineering drug patents to become due, Chinese enterprises, such as Walvax, are committed to the industrialization research of monoclonal antibody, long-acting recombinant protein drugs and other generic drugs with high technical barriers. On April 26th, 2012, Walvax announced to invest in Shanghai Fengmao in next four years to develop and produce genetic engineering generic drugs including rituximab, bevacizumab, adalimumab, panitumumab, denosumab and long-acting EPO.

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