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Research Report on Chinese Chemosynthetic Polypeptide Drug Industry, 2012

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Abstracts

Chemosynthetic polypeptide drugs are drugs combining the certain amino acids in chemical methods, which are characterized by favorable curable effects, few side-effects, high specificities and other advantages.

In the pharmaceutical industry, chemosynthetic polypeptides are the focus of attentions. On one hand, the indications of polypeptide drugs are in wide range and the curative effects are obvious, mainly for the application of tumor, metabolism, cardiovascular diseases, infectious diseases, etc. On the other hand, the development-success ratio of polypeptide drugs is high compared to that of traditional drugs and the approval ratio is also obviously higher than that of micromolecule chemical drugs. According to historical data, the approval ratio of polypeptide drugs in clinical research is 23 % to 26 %. As the rapid development of biochemical technologies and generic engineering field, polypeptide drugs are likely to replace the existing medicines.

By the end of 2011, there were 68 polypeptide drugs approved to the market (at least to sell in one country)globally, among which there were 51 treatment drugs mainly used in 14 cure fields, i.e., tumors, immunoregulation, cardiovascular diseases, metabolism, etc. In 2011, the total sales was about USD 20.8 billion. At present, there are over 140 polypeptide drugs globally amidst the clinical trial and also 500 to 600 drugs are at the stage of research before clinical work. In the perspective of history, there were 1.2 new polypeptide drug candidates entering clinical research period annually in the 70s of 20th century. The number of new polypeptide drug candidates was separately 4.6 in the 80s and 9.7 in the 90s. During 2000 and 2008, it was 16.8, with a steady increasing trend.

China's polypeptide drugs start late. A batch of multinational corporations did not introduce polypeptide drugs to China's market until the 1990s. It develops into relatively

mature technologies and supporting industries nowadays. According to incomplete statistics, pharmaceutical enterprises specializing in the production of biochemical and biological drugs reaches over 400, among which about 80% produce polypeptide drug preparations or active pharmaceutical ingredients in varying types. The number of manufacturers is gradually on the rise. With the constant improvement of the R&D ability of China's polypeptide drugs, China's polypeptide drugs are fast developing.

In 2011, the market scale of China's polypeptide drugs achieved CNY 28.9 billion. In view of advantages with the low impurity content, costs and so on of chemosynthetic method, compared to gene recombination method and animal and plant extraction method, it rapidly develops. In 2011, the market scale of China's chemosynthetic polypeptide drugs was CNY 8.92 billion, accounting for 30.87% of the total polypeptide drug market.

The annual consumption of China's polypeptide drugs also quickly increases. It was 75.95 million in 2007 and reached 260 million in 2011. The average annual growth rate during the four years was as high as 36%, far higher than the growth rate of market scale, mainly owing to the rapid increasing consumption of the low-price oxytocin. Among them, the production of China's domestic enterprises accounts for the majority, while the prices of imported or foreign branded products are generally over 3 to 5 times that of domestic medicine, the main sales are contributed by foreign-funded enterprises therefore.

In terms of the segmentation varieties, China's chemosynthetic polypeptide drug market is mainly composed of thymalfasin, thymopentin, somatostatin, octreotide and thyrocalcitonin, which is much different from product composition in developed polypeptide drug market abroad. In recent years, although the proportion of the five products in total market drastically declines, from nearly 85% in 2007 to 76% in 2011, in the coming period in the future, the five products will still occupy the major market, which is not only determined by the medicine use habit of China's residents and doctors but also the technological level of China's polypeptide drug manufacturers.

Generally, China's domestic enterprises are still in the period of imitating the polypeptide drugs sold in developed countries. At present, the technological difficulties of the imitation of China's chemosynthetic polypeptide drugs lies in how to produce polypeptide APIs in large scale and at low cost in line with the demand of GMP.

However, it can be seen that China's chemosynthetic polypeptide drug market quickly

develops out of nothing. In 2006, the market scale was only CNY 2.63 billion and it surmounted CNY 8.92 billion by 2011. Compared with the compound growth rates of China's market and global market during 2007 and 2011, the former was far higher than the later, separately 25% and 11%.

In the light of the sound trend of China's chemosynthetic polypeptide drugs, with the consideration of the development of China's economy and the increase of medical levels, it is predicted that the market scale of China's chemosynthetic polypeptide drugs will rapidly continue to expand in the future years, reaching CNY 15.7 billion by 2016.

More following information can be acquired through this report:

Supply and Demand of China's Chemosynthetic polypeptide drugs

Policy Environment of China's Chemosynthetic polypeptide drugs

China's Major Manufacturers of Chemosynthetic polypeptide drugs

Development Trend of Chemosynthetic polypeptide drugs

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