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Global and China Monoclonal Antibody Industry Report, 2014-2019

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Abstracts

Despite world-wide economic downturn and great changes in exchange rate, benefiting from robust market demand, global monoclonal antibody market size exceeded USD 80 billion in 2013, still one of biotech drugs with the fastest CAGR in recent years.

Global blockbuster monoclonal antibody agents are still concentrated in Roche (Genentech), Amgen, AbbVie (Abbott), Johnson & Johnson, Novartis, etc. In 2013, the top 10 best-selling monoclonal antibody agents (Humira, Remicade, Enbrel, Rituxa, Avastin, Herceptin, Lucents, Synagis, Prolia/Xgeva and Erbitux, in order) mostly came from these companies mentioned above. Global sales of these ten monoclonal antibody agents totaled about USD 58.1 billion in 2013, and are predicted to amount to USD 64.1 billion in 2014.

These companies construct mature monoclonal antibody R&D platform, have unparalleled technical advantages in a series of processes including the selection of target gene, genetic sequencing, construction of monoclonal antibody structure and industrialized production, and are well-capitalized (R&D costs of these companies accounted for 15%-20% of revenue during the same period.). It is expected that they will keep a leading position in global monoclonal antibody market over the next five to ten years.

In Sept. 2014, Opdivo (nivolumab) of Bristol-Myers Squibb was accepted for priority review by FDA and EMA. The indication of the drug is unresectable or metastatic melanoma. In the same month, KEYTRUDA (pembrolizumab) under Merck became the first FDA-approved Anti-PD-1 therapy, which can be used for advanced melanoma.

In Apr. 2014, Janssen under Johnson & Johnson announced the FDA had approved

SYLVANT (siltuximab) for the treatment of patients with multicentric Castleman's disease (MCD) who are human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative. Lilly's CYRAMZA (ramucirumab) became first FDA-approved treatment for with advanced gastric cancer or gastroesophageal junction (GEJ) adenocarcinoma with disease progression on or after prior chemotherapy.

The Chinese monoclonal antibody market developed rapidly in recent years, with market size recording a CAGR of 38.9% during 2010-2013. There are nine domestic monoclonal antibody agents introduced to the market, such as Shanghai CP Guojian Pharmaceutical's Nimotuzuma and Biotech Pharm's recombinant humanized anti-CD25 monoclonal antibody. However, the market is dominated by imported agents like Rituximab, Trastuzumab, Infliximab and Bevacizumab, which account for more than 70%.

However, in Aug. 2014, Hisun Pharm received notice from SFDA on applying for production field inspection for Recombinant Human Tumor Necrosis Factor Receptor Type II - Antibody Fusion Protein, which is expected to be introduced to the market by the end of 2014. Then supply capacity of domestic monoclonal antibody agents will be further enhanced.

With advancement of monoclonal antibody technology, incoming expiry date for patents of some blockbuster monoclonal antibody agents and bright future for monoclonal antibody, Livzon Pharmaceutical Group, Walvax Biotechnology, Hualan Biological Engineering, Shanghai Fosun Pharmaceutical and other companies invested heavily to enter monoclonal antibody market, and multiple products have entered stage of pre-preclinical or clinical research.

In Sept. 2014, Hualan Biological Engineering submitted clinical applications for its three monoclonal antibody generic drugs, namely, trastuzumab, bevacizumab and rituximab; In Aug. 2014, Walvax Biotechnology's recombinant anti-tumor necrosis factor-? fully human monoclonal antibody injection obtained clinical trial permission issued by Korean Food and Drug Administration (KFDA); In Apr. 2014, Shanghai Fosun Pharmaceutical formally received clinical trial permission approved and issued by CFDA for recombinant human-mouse chimeric anti-CD20 monoclonal antibody injection (rituximab monoclonal antibody genetic drug).

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