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TBI online: www.tbiweb.org

Email: editor@tbiweb.org
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Letter from Editor



Dear friends and colleagues,

Since it was first approved by FDA in 1986, therapeutic monoclonal antibodies have been increasingly used in treatment of various diseases from cancer to allergy, from autoimmune to cardiovascular diseases. Today, over one thousand clinical trials are being conducted in an effort to find new and better antibodies and new indications. In fact, monoclonal antibodies are now counting for more than 30% of sales of biologic drugs and the market for antibody therapeutics is estimated to reach \$60B by 2014. Early this year, Roche decided to obtain 100% ownership of Genentech, the leader in therapeutic

antibody research and development, for \$46.8 billion clearly reflects pharmaceutical company's expectation for the bright future of therapeutic antibodies.

In this issue of TBI, we have collected six articles from the experts who are in the field of developing monoclonal antibodies for many years. The authors represent the industry leaders in China as well as in the US. The topics cover from early discovery to manufacture. Technologies for development of therapeutic antibodies are discussed in all articles. Extensive discussions are made related to the nascent industry in China and its potential growth. It is clear that there are a number of key drivers for the continuous growth of worldwide antibody market. Research and development activity related to monoclonal antibodies has intensified and the number of candidate drugs gaining regulatory approval is likely to rise exponentially. Although currently only 0.3% of total pharmaceutical revenues in China are generated by antibody drugs, monoclonal antibody therapies are undoubtedly on the rise and look set to play a greater role in the future of China's healthcare, especially in cancer therapy and autoimmune disorders.

The major bottleneck for antibody commercialization in China is the ability of large scale manufacturing. The hope is that it will be overcome in the near future due to the willingness of infrastructure investments by the local and central governments and returning of talents who are trained in large international biopharmaceutical companies.

At the same time debates over "bio-similar" vs. "bio-better" extended from Europe to America to Asia. Although bio-similar drugs such as EPO and Embrel have had some commercial successes in China, bio-better offers a more sensible path to biopharmaceutical development in China due to the fact that the costs of manufacture and clinical development of a bio-similar antibody are not significantly different from that of "best in class" antibody against the same clinical validated target. Unlike generic small molecule drugs, the market price for bio-similar cannot be significantly lowered due to the high manufacture cost. Nonetheless, the commercial success in a dynamic market that is increasingly oriented towards proven cost-effectiveness and superiority will likely support a higher growth rate in the therapeutic monoclonal antibody market in China.

If the future biopharmaceutical depends largely on monoclonal antibodies, then opportunities have already showed up in China.

Enjoy reading.

Guo-liang Yu
Editor