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the business of Bio & Health Sciences
ASIA EDITION

Biosimilars to push growth in China, Korea, India

October 5, 2012 | News | By BioSpectrum Bureau

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Singapore:Ã?Â The annual revenue for biopharmaceuticals has been consistently growing since 2001, accounting for 15.6 percent of the total pharmaceutical market in 2011. The global biopharmaceutical market was valued at $138 billion in 2011 and is expected to grow to over $320 billion by 2020. By 2014, biosimilars are expected to enter the US market, and GBI Research estimates that they have significant potential for growth in the biopharmaceutical sector, reaching $9 billion by 2020.

According to GBI Research, the next decade will bring about a paradigm shift in biomanufacturing technologies, with improvements in equipment efficiency and the introduction of novel therapies. In pharmerging countries such as India, China and South Korea, the emergence of biosimilars is being seen as a key macroeconomic factor for generating revenues by attracting foreign direct investment (FDI) in starting manufacturing units.

Efficient manufacturing processes and equipment will reduce production costs, provide economic benefits and decrease healthcare expenditure. The US has the most advanced R&D in biopharmaceutical manufacturing, and most biopharmaceuticals are licensed first in the US. The approval of biopharmaceuticals has contributed significantly to the US economy and has saved many from life-threatening diseases.

Single-use bioprocessing and microbial technologies to dominate

Pharmaceutical companies, in the process of standardizing production technology, are installing single-use bioprocessing gears at manufacturing locations. Biopharmaceutical manufacturers are increasingly shifting their focus to disposable

bioprocessing equipment, which is mostly used in upstream manufacturing. The adoption of this equipment is in the initial stages, and GBI Research expects robust growth potential in the foreseeable future. This equipment is also finding application in preclinical and clinical trials.

Microbial manufacturing technology is relatively more acceptable and well proven. It has been under continuous development, and has led to the discovery of new subsidiary technologies. Recombinant proteins produced by mammalian cell culture processes are gaining significant traction by the pharmaceutical players, and biopharmaceuticals from these proteins have been successful in generating revenues of more than $1 billion. GBI Research believes these two technologies are the hallmark of biopharmaceutical manufacturing and are set to further advance the manufacturing process.

Biosimilars in Asia

Emerging economies, such as India and China, have developed regulatory approval guidelines which are relatively less stringent than their western counterparts. Lenient regulations and tax incentives during the initial industrial phase attracted industry players to operate in the region. For example, major supporters of the biopharmaceutical industry in India, such as Biocon and Dr. Reddy's Laboratories; and China-based companies, such as Hualan Biological Engineering and Shanghai Kehua Bio-Engineering, are planning large-scale product distribution strategies in western countries. Biosimilars of some of the biologics that are currently under exclusivity in western countries, such as Enbrel and Rituxan, are sold in developing countries.

The South Korean government has announced capital and institutional support to boost biopharmaceutical manufacturing, and has set an ambitious target of acquiring a 22 percent global biosimilars market share by 2020. Samsung, which operates in the electronics industry, has ventured into the biosimilars industry, and plans to invest over $2 billion before 2020. It has entered into a partnership with Quintiles, and the joint venture will be functional by 2013. It will initially manufacture biopharmaceuticals on a contract basis, and plans to launch biosimilar versions of Humira, Enbrel and Remicade after their patents expire in 2016.

Similarly, an Indian company called Cipla invested $65m in the biotech company MabPharm to build biologics manufacturing facilities. The Chinese company AutekBio has stayed one step ahead of its competitors by securing the FDA and European Medical Agency (EMA) certifications needed to produce biopharmaceuticals.

Nine companies account for 79 percent of global biopharmaceutical production.Ã?Â The new biological entity market is estimated to grow at a rate of seven percent until 2015. Globally, 79 percent of biopharmaceutical production is under the management of nine companies, and more than 60 percent of this share is produced from manufacturing plants located in the US. However, as demand is projected to escalate in Asian economies, companies are expanding their manufacturing capacities, or strategically investing in these economies, to manufacture biopharmaceuticals.