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ASIA EDITION

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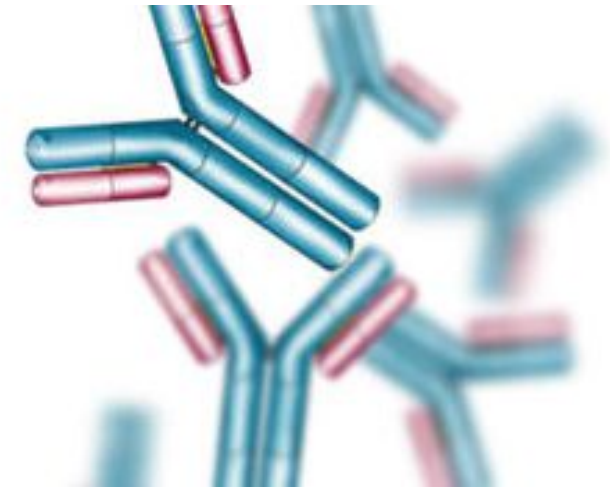

The antibody market has emerged as a hot segment at a time when pharmaceutical companies are facing a drying pipeline of products. Over 300 companies in the US are working on antibodies research and the number is set to increase in the coming years. According to analysts Frost and Sullivan, the research market of antibodies in the US alone was $672 million in 2011 and is expected to touch $775 million by 2016. The demand for antibody-based technologies and need for protein research is further expected to fuel the market.

Asia too is waking up to the call of antibodies market. While the drug pipeline of pharmaceutical companies drying up, the antibodies market in the region has received a fillip with many companies concentrating on R&D. Asian pharmaceutical companies are boosting their antibody profiles by enhancing their research capabilities and building alliances.

However, there are still very few companies in Asia capable of manufacturing antibodies on a commercial scale. Antibody manufacturing facilities require substantial capital investment and competencies and while the Asian firms have the technology, meeting international regulatory standards remains a challenge for them.

The way forward for now seems to be cooperation with some countries in the region, such as Singapore, having the expertise in R&D, while others like South Korea offering international standard manufacturing facilities. BioSpectrum explores the Asia market through the growth trends and developments in companies dealing with antibodies in the region.

Research gets a fillip

Scientists in Asia are focusing on innovation in antibodies that has put them at par with the global scientific fraternity. Recently, Australian scientists' overcame one of the most pressing problems faced by the pharmaceutical industry, which was of creating antibodies that are stable enough to meet stringent requirements necessary for production in large quantities and for long-term storage.

Researchers at the Antibody Engineering Laboratory of Sydney's Garvan Institute of Medical Research discovered that zero-to-50 percent of the antibody-based drugs that pharma companies develop have to be put on hold because of poor quality or non-compliance with the regulatory level. Scientists at the institute then developed specific mutations that universally increase the stability of antibody molecules.

Further boosting research in this field, the Australian Institute for Bioengineering and Nanotechnology (AIBN) entered into collaboration with Sydney-based Biosceptre International to develop a process for the production of monoclonal antibodies to treat cancer. AIBN's National Biologics Facility will characterize candidate therapeutic monoclonal antibodies that bind to Biosceptre's novel cancer target nf-P2X7.

"Australia has a successful track record in the development of human monoclonal antibodies," says Mr Mark Heffernan, CEO, Nexvet Biopharma. "There have been a number of platform technologies that have emerged from Australia and have been acquired by multinational companies. There are candidates progressing through clinical development. Then, there are some large contract manufacturing organizations are recognizing the potential of the market in Australia."

Evogenix was acquired by Arana and later by Cephalon, while global science-based company DSM is establishing manufacturing facilities in Brisbane.

In a separate stream, giving hope to dengue vaccine, research scientists in Singapore have discovered a human antibody that can neutralize and kill the virus. The team has found ways to reproduce this antibody in large quantities, opening the door for dengue treatment. By studying a group of cell lines from people who had recovered from dengue infection over a period of two years, the team identified a recombinant antibody that could attach itself to a specific part of the dengue virus and inhibit it from attacking other cells. The antibody eventually destroys the virus and does so faster than any other existing anti-dengue compounds.

Alliances is the way forward

Antibody expertise of one partner combined with commercial capacity of another is considered as a viable strategy to build the market in Asia. Keeping with this, a number of alliance deals have come to the fore in this market in the recent past. China-based WuXi PharmaTech entered into an alliance with Open Monoclonal Technology (OMT), an innovator in novel transgenic animals, for development of human therapeutic antibodies. The OmniRat technology generates fully human antibodies with great specificity, affinity and manufacturability. It eliminates time-consuming humanization of traditional mouse-derived antibodies and the need for optimization of lead candidates using phage display technology.

"OMT's collaboration with WuXi is initially focused on creating human antibodies against a series of clinically validated targets that WuXi can develop into preclinical stages using their integrated R&D infrastructure and subsequently license to third parties in China and around the world," says an OMT spokesperson who did not want to identified. "Such licensees may further continue to access WuXi's R&D services to clinical stage."

Commenting on the trend, the spokesperson adds that collaborations are critical for research institutions and industry to benefit from each other's strengths. "OMT is making its OmniRat platform available to academia worldwide as discoveries made by them can subsequently be licensed by industry and taken to the market place," he adds.

The spokesperson mentions that there are a number of trends in the market, such as adding toxic payloads to naked antibodies and making antibodies polyvalent (for example bispecific). "After Amgen's acquisition of Abgenix and BMS's acquisition of Medarex, there are only few providers of transgenic animal platforms for generation of human antibodies. We are expecting increased commoditization of human antibodies," he says, adding that OMT plans to lead the trend.

Investors and fund managers are also considering antibodies to be a lucrative domain and are showing interest in enriching research in the area. For instance, UniQuest, the University of Queensland's main commercialization company, has facilitated a research and antibody production agreement with support from investment company Medigen.

Japan's Chugai Pharmaceutical is investing $163 million (S$200 million) over the next five years in Singapore to generate new antibody candidates with its recycling and sweeping antibody technologies. Recycling antibodies can bind to the antigen multiple times by recycling the antibody whereas conventional antibody can bind to the antigen only once. Sweeping antibodies can actively eliminate the target antigen from the plasma in addition to binding to the antigen. The company is looking for significant improvements in therapeutic effects on numerous diseases that were previously considered impossible with conventional antibodies.

Even multinational companies are taking interest in acquiring antibody profiles to enrich their drying drug pipeline. This has given rise to an emerging trend of acquiring the rights of developed antibodies. Sanofi purchased licensing rights from India's Glenmark Pharmaceuticals for the development and commercialization of the latter's GBR 500, a novel monoclonal antibody for the treatment of Crohn's Disease and other inflammatory conditions. GBR 500 is an antagonist of the VLA-2 (alpha2-beta1) integrin. It is a first-in-class therapeutic monoclonal antibody and has established proof of concept in animal models across a range of anti-inflammatory conditions.

Discussing the trends in the Asia antibodies market, Dr Michael Buschle, chief scientific officer, Glenmark Pharmaceuticals, says governments too are stepping up efforts to boost the market. "Certain Asian countries like South Korea and Malaysia have received strong incentives (in the form of special economic zones and funding) from the government for setting up biotechnology infrastructure. Few biotech companies from Asia have been able to forge collaborations with the big pharma and can serve as a model for others," he says, adding that "though most Asian companies will aim to leverage on their low cost of production, only those that can address the quality and experience expectations will be able to emerge as formidable player."