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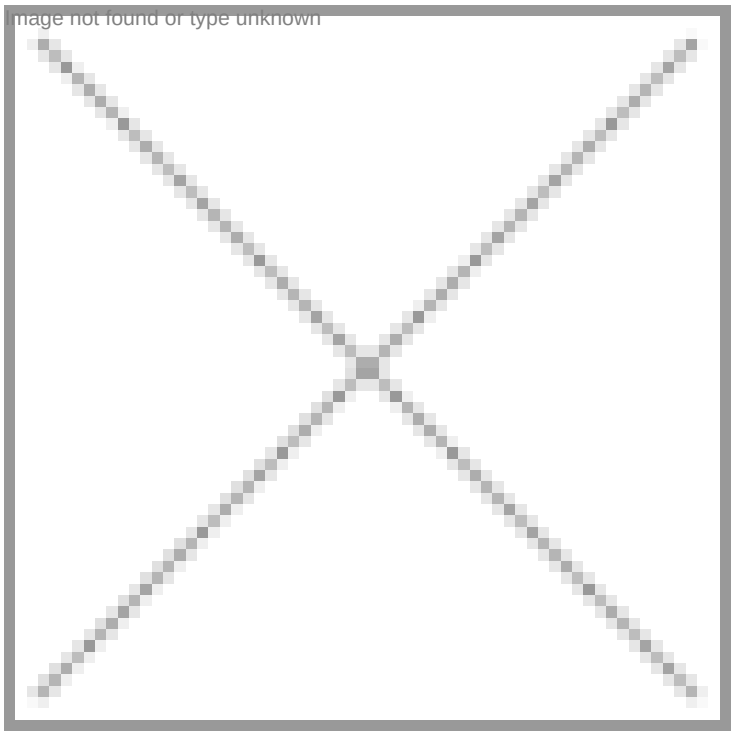

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The successful launch of Genentech's Rituxan in 1997 has not only opened up the market for monoclonal antibodies (mAbs), but also inspired many players (both big pharmas and small biotech companies) to make this profitable, low risk investment.

Since 2001, the mAb-based therapies have been posting the fastest growth within the protein therapeutics market. The mAbs market now classified as one of the most lucrative sectors of the pharmaceutical industry, registered a 37 percent growth during 2001-02 touching $5.4 billion. The market continued to witness an upward trend with an exceptional 48.1 percent growth between 2003-2004 and was estimated at $10.3 billion in 2004. The antibodies market, in 2005, was valued at about $14 billion, accounting for over 24 percent of the total protein therapeutics market. This share increased substantially since 2001, when it barely surpassed 13 percent.

According to the industry estimates, the current mAbs market is about $20 billion and will witness a two-fold increase in the next four-five years. This growth will continue in the coming years, boosted by a number of new mAbs on the market, new indications for successful medications, and their ability to treat conditions and diseases. It has the potential to increase in value over the years and reach $30 billion in 2010, driven by technological evolution.

It is forecasted that mAbs will act as the key growth segment of the prescription pharmaceutical market. According to a

Datamonitor report, the mAb revenues are projected to grow at a compound annual growth rate of 14.2 percent over the period 2006-12, versus 2.2 percent for the overall market over the period 2006-12.

Companies stake a claim

Genentech, Biogen Idec, MedImmune, Johnson & Johnson and Abbott hold a major share in the global mAb market. Datamonitor report says the number of companies with direct sales of monoclonal antibodies is expected to increase from 17 in 2004 to 36 by 2010, as new products and companies flood the market. It also forecasts that by 2012 a number of additional players will have significantly enhanced their presence in the mAb segment, with four companies-Biogen Idec, Amgen, Novartis and UCB Pharma each generating mAb sales in excess of $1 billion.

Over 150 companies are currently working on more than 400 antibody-based drugs that are in development for the treatment of cancer (solid tumors, non-Hodgkin's lymphoma), immune and inflammatory diseases, transplant rejection, rheumatoid arthritis, Crohn's disease, psoriasis, lupus, multiple sclerosis, asthma, age-related macular degeneration, HIV and Alzheimer's disease.

When asked how many companies are working on monoclonal antibodies, Dr David R Buckler, director, Alliance Research and Discovery Research, Dyax Corporation, US, said, "Many companies that are involved in drug discovery are working on monoclonal antibodies. Even the big pharmas that have traditionally been the small molecule companies seemed to be either acquiring or developing own internal capabilities to encompass biologics as well. Monoclonals are probably one of the biggest and interesting subcategory of biologics".

APAC region follows the mAb trend

Leveraging on the strengths and opportunities, about 40 companies in the Asia Pacific region are focusing on product development from mAbs. Companies in Australia, Japan, Korea, India and China, doing research and development, are entering into deals with major pharma companies to catch up the pace of development and for the early entry into the market. In some cases it may be other way also. One such example is the merger between Peptech and Evogenix from Australia. This has created one of the leading companies in antibody development in the Asia Pacific region and certainly the largest antibody/ protein engineering facility in the southern hemisphere. The new entity is named Arana Therapeutics.

The industry, in the last couple of years, saw as many as 24 deals (both technology and product) related to mAbs. In 2007, the region had some five-six deals. Japan's Astellas has forged a deal to buy Santa Monica, CA-based Agensys for $387 million plus up to $150 million more in milestones. The deal gives Astellas new antibody technology for combating cancer. Agensys has a phase Ib trial underway for one antibody plus several more preclinical candidates. Japanese drug maker Daiichi Sankyo received exclusive rights from the US biotechnology company Amgen to develop and commercialize an antibody to treat osteoporosis and other bone diseases in Japan. Amgen has also entered an exclusive licensing agreement to develop and commercialize Kyowa Hakko Kogyo's humanized monoclonal antibody KW-0761 worldwide, except in Japan, Korea, China and Taiwan, where Kyowa Hakko will retain development and commercialization rights.

On technology front, Protagen AG, a leading provider of products, services and software solutions for protein research announced its partnership with the Center for Applied Proteomics (ZAP), Dortmund, Schunde Kangdi Antibody Biotech, Foshan, China and the Beijing Proteome Research Center (Beijing PRC) to develop antibodies against liver proteins.

"The Asia Pacific region offers many advantages for the development of antibodies. The antibody development is driven by large corporations, leveraging available revenues to make foray in the antibody space. The lower development costs in the region on the clinical side allow for cheaper access to the same billion dollar markets", said Dr John Chiplin, CEO, Arana Therapeutics, Australia.

Move to humanized antibody

Beginning with murine anitbody in 1986 (Johnson& Johnson's product Muromonabâ€“CD3), the companies are focusing more towards humanized and human antibody. The approvals, so far, were moreso of chimeric and humanized. However, human antibody products will dominate the next wave of approvals. As of 2007, there were 22, the US FDA has approved therapeutic mAbs, comprising four different types, three murine, five chimeric, 11 humanized and three human.

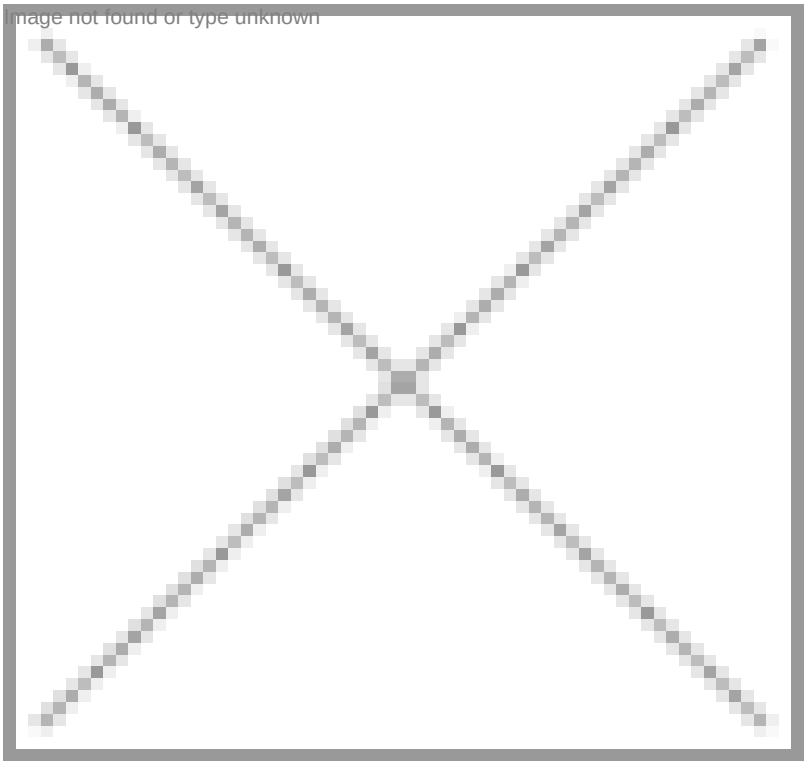
The development focus of the industry is moving away from murine and chimeric antibodies, to humanized and, in particular, fully human technologies. The market is expected to continue to evolve as antibody engineering capabilities advance further, including more efficient manufacturing and alternative delivery methods, broadening the commercial viability of antibodies treatments in a wider range of diseases. A wave of fully human products is expected to launch from 2007 onwards,

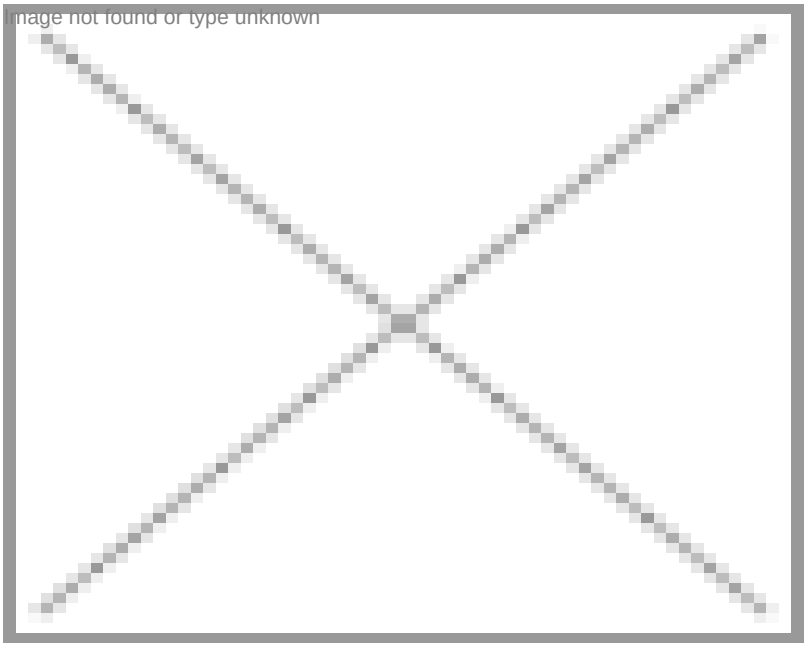
accounting for 12 of the 20 launches between 2007 and 2010, says a report from BioSeeker.

Sharing his views on the number of mAbs that will hit the market in next one or two years, Dr Michael Steward, senior scientist, Biopharm CEDD, Domantis, Cambridge, US, said "It is very difficult to say. The attrition rate for monoclonals is not as high as small molecules drugs. I expect to see probably doubling of monoclonals in the market by the middle of next decade. I would expect to see an annual approval rate of may be half-a-dozen a year".

The industry has the potential to double the number of approved mAbs, and also double the size of global mAbs market, as antibodies currently face no prospect of generic competition. To achieve this, the industry needs to continue to develop with technology integration and market expansion.

The market success will depend on strategies targeting shorter development times, higher success rates, innovative molecular engineering, robust intellectual property protection and the development of cost-effective manufacturing.





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