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Global Monoclonal Antibodies Pipeline Analysis

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Abstracts

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The market for monoclonal antibodies (mAB) has become the fastest growing segment of the pharmaceutical industry. In 2012, there were more than 30 monoclonal antibody therapies approved by the FDA which generated annual sales of more than US$ 40 Billion. As the therapeutic mABs already play a significant part in effective medical treatment, it is most likely that their importance would increase by manyfolds in the future.

There has been a continuous rise in the market for therapeutic monoclonal in recent years. In 2012, there were more than 25 monoclonals in US and the EU. Currently, there are about 10 monoclonals which have already achieved category of "blockbuster", that is they are widely used medications that have been able to generate profits of more than US$ 1 Billion (each) to companies that market them. It has been estimated that in 2012, the global sales of antibody-based therapeutic products was around US$ 55 Billion.

“Global Monoclonal Antibodies Pipeline Analysis” by PNS Pharma gives comprehensive insight on the various Monoclonal Antibodies based drugs being developed for the treatment of multiple diseases. Research report covers all Monoclonal Antibodies based being developed in various development phases. This report enables pharmaceutical companies, collaborators and other associated stake holders to identify and analyze the available investment opportunity in the Monoclonal Antibodies market based upon development process.

Following parameters for each orphan designated drug profile in development phase are covered in “Global Monoclonal Antibodies Pipeline Analysis” research report:

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Drug Profile Overview

Alternate Names for Drug

Active Indication

Phase of Development

Mechanism of Action

Brand Name

Patent Information

Orphan Designation by Indication, Country & Organisation

Country for Clinical Trial

Owner / Originator/ Licensee/Collaborator

Administrative Route

Drug Class

ATC Codes

Global Monoclonal Antibodies Pipeline by Clinical Phase:

Research: 117

Preclinical: 426

Clinical: 11

Phase-0: 1

Phase-I: 183

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Phase-I/II: 35

Phase-II: 159

Phase-II/III: 7

Phase-III: 64

Preregistration: 4

Registered: 2

Marketed: 56

Unknown: 7

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Each Drug Profile has Tables Representing Following Information:

Alternate Names

Originator & Owner

Collaborator

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Technology Provider

Licensee

Highest Development Phase

Indications

Class

Mechanism of Action

ATC code

Designated Brand Name & Orphan Designation

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About

The market for monoclonal antibodies (mAB) has become the fastest growing segment of the pharmaceutical industry. In 2011, there were xx monoclonal antibody therapies approved by the FDA which generated annual sales of USD xx billion. As the therapeutic Mabs already play a significant part in effective medical treatment, it is most likely that their importance would increase by manyfolds in the future.

There has been a continuous rise in the market for therapeutic monoclonal in recent years. In 2011, there were approximately xx monoclonals in US and the EU. Currently, there are about xx monoclonals which have already achieved category of "blockbuster", that is they are widely used medications that have been able to generate profits of more than one billion dollars (each) to companies that market them. It has been estimated that in 2012, the global sales of antibody-based therapeutic products was more than USD xx billion.

The share of monoclonal anitibodies in the entire biotech drug market is close to a significant 40%. It was observed that in 2012, out of the ten best-selling drugs, 6 were monoclonal antibody drugs, each with annual sales value exceeding USD 5 billion. These 6 monoclonal antibody agents, including Infliximab (Johnson & Johnson), Etanercept (Amgen), Bevacizumab (Roche), Rituximab (Roche), Adalimumab (Abbvie) and Trastuzumab (Roche), represented around 60% of the global monoclonal antibody market. The sales of these antibodies are expected to reach more than USD 160 billion in the US in the next 3-6 years.

Currently a two-fold average revenue per product premium is charged for monoclonal antibodies (mAbs) over small molecules. The factors supporting this premium include a higher demand due to targeting therapy areas with a high unmet need and lower competitive intensity due to accessing novel target space. The revenue growth is expected to be enhanced more due to the fact that many key mAb products are also the subject of horizontal indication broadening strategies. The most notable example of this strategy is Genentech and Roche's Avastin (bevacizumab). Given that it targets angiogenesis, it can also be used across a wide range of tumor types.

The major factors driving the market would be increasing strategic alliances and collaborations, advancements in the field of ADCs with respect to potency of drugs attached and improved linker technologies. Another factor instrumental in shaping the market would be the increased interest in bio-specific antibodies.

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Factors Driving the Market

Improving Survival Rates

In the world of biotechnology, monoclonal antibodies have opened the doors to a brave new world of revolutionary treatments. These antibodies have the unique capability to block cancer growth signals by inhibiting their ability to attract new blood vessels, or by injecting them with toxins more potent than chemotherapy. These versatile laboratory-made molecules have thus brought about an improved survival rate across the globe among the cancer patients. This factor is driving the growth of this market.

Patent Expiration

As many popular branded drugs are expected to lose U.S. market protection between 2013 and 2016, there is a desperate search on by the pharma and biotech companies to restock their pipelines.

Premium Pricing Of Monoclonal Antibodies

The antibodies represent the most complex class of molecules for medical use. They have specific binding properties, which are typically larger and more complicated to copy by biosimilars. Additionally, the process of development, production and marketing of a biosimilar version currently costs about 50 times the amount needed to launch a generic copy of conventional chemical drugs. This leads to a premium pricing for monoclonal antibodies in the market.

Future Scenario

A major trend which is expected to gain popularity in the future is deal making in the monoclonal antibodies market. The larger players of the industry are more likely to partner with the smaller companies and third parties and invest significant amounts in restocking their R&D pipelines.

The field of cancer is growing mainly because of the globally aging population, increasing rates of obesity and rising smoking rates across all regions. This opens the door of opportunities for the drug makers globally because the mAbs market is already well-established and is currently in its growth stage, thus having significant areas of unmet medical need.

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The record for monoclonal antibodies to treat cancer has been encouraging in the past few years. Additionally, with the industry undergoing the “patent cliff”, the first of the monoclonal antibody patents have already expired. It is upto the drug makers now to develop efficient and accurate biosimilars of mAbs to treat cancers.

A significant amount of research is being carried out currently to improve the level of potency of monoclonal antibodies. Consequently, a relatively new approach has been indentified in which the precision of targeting molecules would be combined with the proved killing power of radiation or cytotoxic chemotherapy which is referred to as payload to precise molecular carriers, mostly monoclonal antibodies. However, still a lot of work needs to be done in this arena.

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