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US Biosimilars Market Opportunity & Clinical Pipeline Analysis

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Abstracts

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Pharmaceutical companies benefited from the revolution in biotechnology that hit US market in 1980’s. Some of the blockbuster biologics have been introduced in market helping pharmaceutical companies to occupy major market shares. Their presence could be felt in every disease segment as they were improved with time. Over the years, biologics lost patent giving way to biosimilars. US is late entrant and its market is largely untouched by biosimilars resulting in lots of commercialization opportunities. Now, US has become center of attraction for generating significant revenues by introducing biosimilars in different disease categories. Future prospects of US biosimilars markets have yet to be deciphered as this market is at nascent stages offering unique opportunities and challenges.

Biosimilars in US has been approved after a long-time while they have been introduced in other places over a decade ago. Late entry in US market has prevented the patients from getting benefit of biosimilars. Also, spending on healthcare could have been mitigated but absence of proper regulatory framework prevented commercialization of biosimilars in US. Number of indication under biosimilar coverage are also less, single at present, which is going to have modest effect on US market. Number of indications will increase in coming years till then US biosimilar market is expected to grow at modest rates. Slow market growth is of great concern as it is also related to cost cutting by regulators in health care spending. US biosimilars market is at nascent stage and it would take few years to become suitable niche for biosimilars.

Biologics have dominated the US market for several decades due to absence of worthy competitor in different disease segment. In coming years, this situation is expected to

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change as biosimilars are expected to be commercialized. Zarxio, first US biosimilar, has created lot of enthusiasm among masses but some physicians, investigators and payers have reservation against biosimilars. This scenario may cause hindrance in uptake of biosimilars in coming years. To increase acceptance rates, biosimilar developers have to produce head-to-data confirming pharmacological efficacy. Biosimilars are also expected to have higher cost-effectiveness promoting patients to switch from biologics. In this way, biosimilar developers would be able to generate more revenues by developing positive attitude towards biosimilars.

Newly developed biosimilars in US market are expected to face hard time as regulations are not in place. Both patient and payers are expected to suffer from this issue that has to be resolved as soon as possible. Implication of new rules is expected to take some time as lots of issues have to be solved. Naming of biosimilars and assigning of appropriate billing code is one of the fore most necessities. This situation is likely to deteriorate when monoclonal antibodies will be introduced in US market. Substitution and reimbursement will become easy if clear demarcation is made between which molecule belongs to which category. Regulators are likely to resolve these issues in coming years as they have just entered in biosimilars segment.

“US Biosimilars Market Opportunity & Clinical Pipeline Analysis” Report Highlight:

US Biosimilars Market Introduction

US Biosimilars Regulatory Scenario

Unique Features of US Biosimilars Market

Impact of Biosimilars in US Market

Impact of Reimbursement Policies on US Biosimilars Market

Zarxio: First Approved Biosimilar in US

US Biosimilar Clinical Pipeline By Company, Indication & Phase

US Biosimilar Clinical Pipeline: 104 Biosimilars

Marketed Biosimilars: 1 Biosimilar

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