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Europe Orphan Drug Pipeline Analysis 2014

https://marketpublishers.com/r/E2FA3902AC5EN.html
Date: January 2014
Pages: 1430
Price: US$ 2,400.00 (Single User License)
ID: E2FA3902AC5EN

Abstracts

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Rare diseases are classified as those that affect fewer than 200,000 in the United States and less than 5 in 10,000 in the EU. The term “orphan” was associated with these drugs in order to reflect the lack of interest by pharma companies. In the European Union, orphan drugs are known as orphan medicinal products. Many treatments which are commercially available in today’s world lack the ability to address most of the rare disease indications. This throws open significant potential and opportunities in the European Union and other regions of the world which are currently untapped.

The rare diseases normally include certain cancers, metabolic conditions, diseases of the nervous system and musculoskeletal disorders, which are extremely life-threatening and impact lesser than 5 people in every 10,000 people. However, as a group, these diseases together could possibly affect close to 30 million people directly or indirectly in Europe. This shows the significant of the need to develop an increasing number of orphan medicinal products in the European region.

“Europe Orphan Drug Pipeline Analysis 2014” by PNS Pharma gives comprehensive insight on the various orphan designated drugs being developed in Europe. Research report covers all orphan designated drugs being developed in various clinical phases. This report enables pharmaceutical companies, collaborators and other associated stake holders to identify and analyze the available investment opportunity in the Europe orphan designated drug market based upon development process.

Following parameters for each drug profile in development phase are covered in “Europe Orphan Drug Pipeline Analysis 2014” research report:

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Drug Profile Overview

Active Indication

Phase of Development

Country for Clinical Trial

Owner / Originator/ Licensee/Collaborator

Administrative Route

Drug Class

Patent Information

Molecular Formula

Brand Names

Development Agreements

ATC Codes

Number of Orphan Designated Drugs in Pipeline by Clinical Phase:

Preclinical: 35

Clinical: 2

Phase-I: 27

Phase-I/II: 49

Phase-II: 92

Phase-II/III: 16

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Phase-III: 86

Preregistration: 24

Registered: 21

Marketed: 75

Unknown: 1

No Development Reported: 5

Suspended: 6

Discontinued: 80

Application Withdrawn: 4

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EACH DRUG PROFILE HAS TABLES REPRESENTING FOLLOWING INFORMATION:

Alternate Names

Originator & Owner

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Collaborator

Technology Provider

Licensee

Highest Development Phase

Indications

Class

Mechanism of Action

ATC code

Designated Brand Name & Orphan Designation

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About

Rare diseases are also known as Orphan diseases. These diseases are generally categorized as chronic, degenerative, and life-threatening. As per the official definition, rare diseases are classified as those that affect fewer than 200,000 in the United States and less than 5 in 10,000 in the EU. The term “orphan” was associated with these drugs in order to reflect the lack of interest by pharma companies. In the European Union, orphan drugs are known as orphan medicinal products. Many treatments which are commercially available in today’s world lack the ability to address most of the rare disease indications. This throws open significant potential and opportunities in the European Union and other regions of the world which are currently untapped.

As the volume of population impacted by rare diseases is very small, the pharma giants have historically not been attracted to a major extent to invest in the development of drugs required for such rare diseases. Historically, the development of 70-75% of orphan drugs was mostly in the realm of smaller biotechnology and specialty pharmaceutical companies, and the remaining 25-30% of the orphan drugs were developed by the pharma giants. However, in the past 2-3 years, the share of pharma giants in the orphan drug approvals has increased to close to 40-45%. Thus, the share of these big pharma companies increased from 53% to 70% in 2009 in the rare diseases market.

The rare diseases normally include certain cancers, metabolic conditions, diseases of the nervous system and musculoskeletal disorders, which are extremely life-threatening and impact lesser than 5 people in every 10,000 people. However, as a group, these diseases together could possibly affect close to 30 million people directly or indirectly in Europe. This shows the significant of the need to develop an increasing number of orphan medicinal products in the European region.

Additionally, the investment in R&D by the European companies for developing orphan medicinal products has increased by more than 200%, while the total number of employees in these companies has recorded an increase of more than 150% since 2000. With the long durations of lead times in the biopharmaceuticals industry for R&D projects, it is most likely that the EU Regulation for Orphan medicinal products would have a significant impact in the coming years.

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