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Global Orphan Drug Clinical Pipeline Insight 2022

https://marketpublishers.com/r/G3A0814C9EFEN.html
Date: December 2016
Pages: 2200
Price: US$ 3,000.00 (Single User License)
ID: G3A0814C9EFEN

Abstracts

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“Global Orphan Drug Clinical Pipeline Insight 2022” report gives comprehensive insight on various clinical and non-clinical aspects associated with ongoing clinical trials of 808 orphan designated drugs across the globe. The in-depth clinical insight presented in the report helps the reader to analyze and identify the various stakeholders involved in the clinical development and commercialization of orphan designated drugs in the global market. Currently there are more than 300 orphan designated drugs commercially available in the global market and around 800 drugs in clinical development phase.

As of 2016, almost 30 million people in the U.S. and 350 million people worldwide suffer from rare ailments known as “Orphan Diseases.” The name comes from the treatment meted out for such diseases, wherein the pharma industry was reluctant to develop drugs for such illnesses due to their economic unviability.

Elaborating the concept, a rare disease or orphan diseases are the one’s which affects only a small population. 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. Consequently, in earlier times such truncated prevailed diseases were least attractive to the researchers and the investors. Previously, the market for orphan drugs was not as lucrative as it is today.

Nevertheless, the Scenario has changed after the Orphan Drug Act (ODA), 1983 was passed in United States and later various countries enacted similar laws. The number of requests for orphan drug designation received by FDA’s Office of Orphan Products Development (OOPD) has grown dramatically in recent years and is prompting FDA to adjust its timeframes for reviewing orphan drug designations in order to meet the demand.

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The Orphan drug Market has seen a tremendous growth in last 2 decades. There has been a paradigm shift in the pharma or biopharmaceutical market with focus on research and development for unmet medical / clinical needs, investing resources in developing drugs to treat rare clinical conditions thus targeting small pool of patients. More than 7000 diseases have been given the designation of being rare. Subsequently, the global market is ever growing for the orphan drugs due to many factors including tax credits, grants, waived FDA fees, reduced timelines for clinical development and a higher probability of regulatory approval. Other aspects such as the patent expirations, generic completions and drying pipelines are also enhancing the market growth.

Orphan drugs are not merely lifesavers for patients suffering from these debilitating diseases, but also a huge growth opportunity for the pharma industry. With ROIs nearly twice that of non-orphan drugs, R&D activity for newer orphan drugs is expected to witness an exponential increase in the near future. Most big pharma players are capitalizing on rare disease treatments by enhancing their pipelines or by acquiring promising molecules of smaller companies. While the orphan drug market is mostly restricted to the U.S. and Europe now, pharma companies are likely to start tapping into the Asian market which has a high population of untreated rare diseases. It seems growth of the global orphan drug market is inevitable.

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