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The World Market for Orphan Drugs

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Abstracts

In recent years, there has been a substantial increase in the number of drugs available to treat rare ("orphan") diseases. This comprehensive report, The World Market for Orphan Drugs, looks at this trend and provides estimates for the market opportunity in the U.S., Europe, Japan and globally. With over 400 pages of market analysis and over 120 figures and tables, the report provides in-depth coverage of key competitors and important trends and challenges for makers of orphan drug treatments.

Osteoporosis, arthritis, Alzheimer’s, and Parkinson’s are major factors affecting quality of life. Mortality from cancer, diabetes, liver and kidney diseases has been slow to change, offering significant areas for research breakthroughs. Cancer, poorly served by traditional chemotherapies, is a major opportunity for biotech firms because the investment compared to return can be favorable: the field has high priority with regulatory authorities who are willing to give it fast track status on the basis of smaller (and therefore cheaper) clinical trials (a few extra months of survival could be enough to win FDA approval); the clinical community is highly concentrated; and the market size is often larger than the approved indication because of a high off-label use (for other cancers). Infectious diseases, the third most common cause of death in many geographic regions, highlight the pressing need for new therapies with novel mechanisms of action to avoid growing issues affecting this industry including a top area of concern—drug resistance.

This report provides estimates for the world market for orphan drugs, as well as the E.U. and Japan markets. Given the size of the U.S. opportunity, the report offers in-depth market data for the U.S. market. Several segments are discussed, including:

Oncology

Hematology

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Musculoskeletal

Neurology

Endocrine

Metabolic

Others

These segments are the most common areas of development and success for orphan drug developers/marketers which required providing detailed information about these orphan drug market segments.

In the U.S., a drug may be designated an orphan drug if the disease or condition for which it is indicated, affects less than 200,000 Americans. Orphan medicinal products in the E.U. member states are intended for the diagnosis, prevention or treatment of life-threatening or very serious conditions that affect not more than 5 in 10,000 persons. In Japan an orphan drug may be designated for a patient population of less than 50,000 and provide for an unmet medical need. Other countries have similar designations. These three regional markets for drugs are examined in separate sections of the report.

Analysis of The “Pure” Orphan Drug Market

Some publicized estimates of orphan drug markets include brand revenue that is not truly related to the orphan status of the drug. In this unique research effort, Kalorama Information separates strictly orphan revenue from total brand revenue where necessary to provide a true picture of the pure orphan drug market opportunity. The world orphan drug market is difficult to determine due to the variances in orphan drug status and requirements by country. Products may be available as an orphan drug on one country and be a traditional marketing approval for another country. In addition, some products gain orphan status, are granted approval and then removed from the orphan drug database at the request of the developer. There are a number of factors involved, including reimbursement by country, regulation by country, disease status by country and general development by country.

For this market research report, market numbers discussed in this report are focused on

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the global market in brief with in-depth market coverage of the U.S. market. Additionally, there is select coverage for the European Union and Japanese market. All sales are displayed at the manufacturers' level in U.S. dollars.

This report includes orphan drugs. In cases where sales are generated by indications for both orphan indications and non-orphan indications, we have attempted to extract just the orphan portion of sales. The base year is 2012, with forecasts provided for each year through 2017. The market was generated using estimates of individual product sales and compared with market data from a combination of other methods including disease prevalence trends, population trends, pricing trends, government regulations and reimbursements. Both primary and secondary sources were consulted in developing market estimates.

Demographics, Costs, Regulation and Other Trends Examined

The list of trends and factors affecting the orphan drug market remain lengthy. The orphan drug market is affected by both trends that affect the pharmaceutical industry as a whole and trends that specifically affect the orphan drug market:

Orphan drug pricing

Aging of the population

Increasing life expectancy

Trends in birth rates

Cost effectiveness

Regulatory environments

Orphan drug incentives

Population demographics

Product availability by country/region

Due to the wide variety of products to receive orphan designations, there are numerous

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developers with products in this area. Some of the developers that have received an orphan designation have followed through to receive a full product approval but others may not gain additional approvals.

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