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Global HIV Infection Drug Market & Pipeline Insight

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Abstracts

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The rate of HIV infection and the number of deaths due to AIDS has been on a declining note at a positive rate across the globe. It has been estimated that the death rate reduced from 2.3 million in 2005 to 1.5 in 2013, with the rates for children being even much lower. A major cause for such drastic changes in the infection rates has been the improved access to antiretroviral drugs and therapy in recent years. The access to these drugs and therapy has improved significantly, particularly in many developing countries where these drugs and treatments were previously not available at all. At present these solutions have been made accessible and affordable also.

However, a major trend observed in this market has been that although the HIV infection rates are falling, the number of new patients being affected by the virus is increasing. With all the conscious efforts undertaken by all the related organizations and stakeholders, it is expected that by 2015, significant investments would be recorded in this field with the WHO setting an aim to treat close to 15 million HIV patients.

In terms of the market, with the rising popularity of this disease and the growing efforts to combat its spread, it is most likely that an increasing number of companies would enter this market, which would, in the long run, reduce the overall cost of drugs owing to increased competition among the players. Additionally, economies of scale would also be a major factor driving down the cost of drugs targeted for the HIV virus infected people. This in turn would make the drugs and treatment options more affordable.

It is expected that in the next 5-8 years, the pharmaceutical companies would focus more on the development of a successful efficient vaccine to control the spread of this disease. The allocation of resources should necessarily reflect ongoing, strategic prioritization of candidates in the pipeline. With the progress of trials and accumulation

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of information on the safety and efficacy of new products, there is an urgent demand for strategizing the product pipelines and the prioritization of the decisions. There needs to be complete scrutiny of every single technological area of HIV prevention R&D so as to reflect the best methods of channelizing the funds which are limited in nature. The funds need to be specifically directed towards only those products and approaches which have a high probability of succeeding, instead of those which are less promising.

“Global HIV Infection Drug Market & Pipeline Insight” Report Highlight:

Global HIV Infection Drug Market Overview & Incidence Scenario

FDA & EMA Regulation for Development of HIV Drug

Global HIV Infection Drug Clinical Pipeline by Phase, Company & Country

Global HIV Clinical Pipeline: 315 Drugs in Development Phases

Majority HIV Drug in Preclinical Phase: 144 Drugs

Marketed HIV Drugs: 37

Suspended & Discounted HIV Drug in Clinical Pipeline: 539 Drugs

Patent Analysis: Patent Number & Technology

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About

This guidance is intended to assist sponsors in the clinical development of drugs for the treatment of human immunodeficiency virus (HIV) infection. Specifically, this guidance addresses the Food and Drug Administration's (FDA's) current thinking regarding the role of HIV resistance testing during antiretroviral drug development and marketing and serves as a focus for continued discussion among the Division of Antiviral Products (DAVP), pharmaceutical sponsors, the academic community, and the public. The goal of this guidance is to stimulate the generation of more complete resistance data and analyses for antiretroviral drug products.

This guidance uses a broad definition of the term drugs including, but not limited to, small chemical entities, biologics, monoclonal antibodies, synthetic oligonucleotides, and siRNA, and focuses on resistance to antiretroviral agents as manifested by mutations in the HIV viral genome that result in reduced phenotypic susceptibility to a given drug product. Although mechanisms of cellular resistance to antiretrovirals exist, a discussion of these mechanisms is beyond the scope of this guidance. In addition, loss of susceptibility to drugs is highlighted, rather than hypersusceptibility. However, we acknowledge the potential for results to show increased susceptibility of the virus to one or more antiretroviral drugs and we encourage sponsors to report such observations to the FDA.

Although this guidance focuses on characterization of resistance and cross-resistance during drug development, we recommend application of these principles to currently marketed antiretroviral agents; therefore, we recommend ongoing resistance testing in the postmarketing setting.

This guidance does not imply one type of resistance testing is more useful than another type of resistance testing in the clinical management of HIV infection. This guidance addresses how serial assessments of both genotype and phenotype can be useful in antiretroviral drug development. For characterizing the utility of an antiretroviral drug, both phenotypic and genotypic resistance testing have strengths and limitations as discussed in this guidance.

For information on trial design and endpoints in phase 3 antiretroviral drug development, see the related guidance for industry Antiretroviral Drugs Using Plasma HIV RNA Measurements — Clinical Considerations for Accelerated and Traditional Approval.

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Becaue the field of HIV resistance is evolving, we intend to revise this guidance as new information accumulates. FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not required.

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