R&D Trends: HIV - An active pipeline faces fierce competition in the HIV market

Description:

Introduction

Although there are a number of novel approaches in early-stage development for HIV, fierce competition is thinning out the late-stage pipeline. Novel treatment approaches, biomedical HIV prevention and genetic profiling could diversify an HIV market currently dominated by a one-pill once-daily regimen.

Features and benefits

- Overview of the HIV late-and early-stage pipeline and potential drug targets.
- Examination of innovative treatment approaches, such as vaccines, monoclonal antibodies and gene therapy
- Identification of the target product profile for novel HIV treatments
- Discussion of the future of HIV treatment and trends towards personalized HAART

Highlights

- It is believed that the foreseeable future of HIV treatment will be defined by earlier treatment initiation, further progress in the field of pre-exposure prophylaxis and a HIV market driven by convenience and patients’ individual preferences
- Monoclonal antibodies and gene treatments are among the most innovative approaches in the HIV pipeline. Progenics’ Pro-140 recently entered Phase Ib clinical trials, making it the furthest advanced monoclonal antibody against HIV. In contrast, novel gene therapies deliver first promising results, but are still in very early stages of development
- The majority of pipeline drugs can be classified according to the historical HIV drug classes, but several innovative treatment approaches promise to extend future HIV treatment options

Your key questions answered

- Understand current trends in HIV drug development and HIV prevention and learn about key factors set to shape the field in the future
- Understand challenges, unmet needs and future opportunities by learning about the views of HIV key opinion leaders
- Review the late- and early-stage HIV pipeline and explore innovative approaches in HIV treatment

Contents:

Executive Summary
- Strategic scoping and focus
- Datamonitor key findings
- Related reports

OVERVIEW
- Catalyst
- Summary

CLINICAL PIPELINE OVERVIEW
- Key findings
- Pipeline overview
  - Only seven compounds are currently in Phase III/registration
  - Drugmakers are seeking to co-formulate their lead HIV pipeline candidates into cross-class fixed-dose combinations
- Entry inhibitors dominate the early- and mid-stage pipeline
- Several pipeline agents are developed as non-oral formulations
- Therapeutic vaccines – an alternative to HAART?
- HIV lifecycle and mechanism of action of HIV drug classes
  - The HIV lifecycle offers diverse targets for antiretroviral drugs
  - Mechanism of action of currently available anti-HIV drugs
Late-stage development compounds recently discontinued
In 2010, two Phase III drugs fell victim to the increasing competition in the HIV market space

TARGET PRODUCT PROFILE
Key findings
Atripla (tenofovir disoproxil fumarate/emtricitabine/efavirenz; Gilead Sciences/Bristol-Myers Squibb)
Target product profile versus current level of attainment

CLINICAL TRIAL DESIGN IN HIV
Key findings
Trial design for treatment-naive and treatment-experienced patients
Non-inferiority trials are the standard design for HIV drug development
Choice of control arms
Background regimens
Duration of studies
Clinical trial endpoints
Future developments in clinical trial design

INNOVATIVE EARLY-STAGE APPROACHES
Key findings
Monoclonal antibodies and gene treatments as novel HIV therapeutics
Progenics's Pro-140 is the lead candidate among anti-HIV monoclonal antibodies
Gene therapy for the treatment of HIV is still in its infancy but excites with early successes
2010 was a milestone year for biomedical HIV prevention
Truvada as oral pre-exposure prophylaxis in men having sex with men
HIV microbicides: new developments boost hopes for topical pre-exposure prophylaxis
Vaccines for the prevention of HIV

THE FUTURE OF TREATMENT IN HIV
Key findings
Earlier initiation of HIV treatment
Disagreement in US and EU HIV treatment guidelines about treatment initiation thresholds continues
Pre-exposure prophylaxis
Greater use of genetic profiling

BIBLIOGRAPHY
Journal papers
Websites
Datamonitor reports

APPENDIX
Contributing experts
Conferences attended
Report methodology

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