R&D Trends: Hepatitis C

Description: Introduction

Pegylated interferon in combination with ribavirin is the current standard of care for hepatitis C. While effective in patients infected with genotypes 2 and 3, this regimen has limited efficacy against genotype 1. In light of this, companies are focusing developmental efforts on patients infected with genotype 1 and those that have failed a prior course of pegylated interferon/ribavirin therapy.

Features and benefits

- Overview of the clinical pipeline for hepatitis C along with an assessment of the key R&D trends.
- Analysis of current clinical trial design and various strategies pursued for hepatitis C drug development
- Discussion of the future of clinical trial design and how it will evolve once new products and classes reach the market.
- Review of feedback from key opinion leaders on the future of hepatitis C therapy

Highlights

- The approval of Vertex’s and Tibotec/Johnson & Johnson’s telaprevir and Merck and Co.’s boceprevir will have a significant impact on the current treatment paradigm. Should both drugs successfully reach the market in 2011, triple combination therapy is set to become the new standard of care for patients infected with hepatitis C genotype 1.
- Add-on therapy to current standard of care, interferon-sparing regimens using combinations of small molecule antivirals alone, and interferon-replacement using newer interferon products are the main strategies being investigated for hepatitis C treatment.
- While several companies are pursuing the development of interferon sparing regimens, trial data to date indicates that interferon helps maintain viral suppression and slows down resistance development. Datamonitor believes that interferon-sparing regimens will not be widely adopted in the short- to mid-term future, at least.

Your key questions answered

- Gain an insight into key trends in the hepatitis C pipeline and drugs currently in development.
- Assess the changes in clinical trial design as products advance in clinical development.
- Understand the impact of new product approvals on current treatment algorithms.

Contents:

Executive Summary

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

OVERVIEW

- Catalyst
- Summary

CLINICAL PIPELINE OVERVIEW

- Hepatitis C pipeline overview
  - Small molecule antivirals
  - Therapeutic vaccines
  - Others
- Late-stage development compounds recently discontinued
  - Albuferon (albinterferon alpha-2b; Novartis/Human Genome Sciences)

TARGET PRODUCT PROFILE

- Overview
  - PEGylated interferon combined with ribavirin is the current gold standard in HCV therapy
  - Two PEGylated interferons are currently available
  - Ribavirin enhances the effects of interferons but is associated with anemia
Target product profile versus current level of attainment

CLINICAL TRIAL DESIGN IN HEPATITIS C

Clinical trial design for hepatitis C falls into three distinct categories

Add-on therapy currently seems the most promising strategy

Several interferon-sparing strategies are under investigation, but suffer from high resistance development

Newer interferon products with reduced dosing frequency and greater tolerability may eventually replace existing interferon therapies

HCV trial participants are stratified according to genotype and response to therapy

Clinical trials for novel agents mainly focus on genotype 1 patients

The treatment-failure population is also attractive given the high unmet need

Late-stage trials involve comparison with current standard of care

Response-guided therapy is increasingly utilized to help reduce the duration of treatment

Clinical endpoints

Sustained virological response is the most frequently used endpoint

Early virological response and rapid virological response are strong predictors of sustained virological response

Future developments in clinical trial design

Comparator therapy set to change as small molecule antivirals reach the market

THE FUTURE OF TREATMENT IN HEPATITIS C

Triple combination therapy will become the new standard of care

Duration of therapy for treatment-naïve patients infected with genotype 1 could be cut significantly

Interferon-sparing regimens are unlikely to gain acceptance in the short- to mid-term future

The role of response-guided treatment will become more crucial in a triple-drug regimen

Lead-in strategy adds complexity to treatment but helps identify patients likely to respond

IL28B may be used to predict treatment outcomes

BIBLIOGRAPHY

Journal papers
Websites
Datamonitor reports

APPENDIX

Contributing experts
Conferences attended
Report methodology

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