Sofosbuvir and Sofosbuvir/Ledipasvir (Hepatitis C Virus) Forecast and Market Analysis to 2022

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Sales for Sofosbuvir and Sofosbuvir/Ledipasvir in the HCV Market

GlobalData expects the launch of the multi-pill sofosbuvir regimens in the US in 2013 and in the EU and Japan in 2014. The sofosbuvir/ledipasvir fixed-dose combination is expected to launch in the US, EU, and Japan in 2015. We estimate that 2022 sales of Sofosbuvir and Sofosbuvir/Ledipasvir will reach $5.2 billion across these markets.

Key factors affecting the uptake of Sofosbuvir and Sofosbuvir/Ledipasvir will include:

- The once-daily formulation and pan-genotypic activity of sofosbuvir is a major advantage. The expected absence of interferon and ribavirin will enable the sofosbuvir/ledipasvir regimen to be administered as a single pill taken once a day. The low pill burden will likely enable sofosbuvir/ledipasvir to retain its patient share.

- Sofosbuvir’s short duration of therapy and inclusion in an interferon-free regimen for HCV GT2/3 are expected to result in it becoming the standard of care for HCV in 2013 and 2014.

- There are several drugs in development that are expected to challenge sofosbuvir for patient share, but AbbVie’s all-oral, combination therapy (ritonavir-boosted ABT-450, ABT-267, and ABT-333) and BMS’ fixed-dose, interferon-free regimen (daclatasvir/asunaprevir/BMS-791325) are expected to generate the stiffest competition.

- The premium price of sofosbuvir/ledipasvir could hinder its ability to take more market share from its competitors.
What Do the Physicians Think?

“The most important thing for new drugs would be that they are less toxic. Companies really should aim for treatments which are interferon-free, because it is really a problem to treat patients for 24–48 weeks with interferon.”

OUS Key Opinion Leader, February 2013

“The patients don’t have any idea this [HCV] is a disease that can really destroy the liver silently, and if they don’t have to be checked by us, they have no clue they are infected with Hep C. I think the main limiting factor [for treatment] is patient awareness.”

OUS Key Opinion Leader, March 2013

“Complexity of HCV treatment, in general, is a problem. One of the things that makes the current regimens with protease inhibitors tough is that there are various time points and people have to wait to see PCR results, and so on, because the concern about resistance. Complexity of a therapy is a factor as well as its toxicity...It’s been a logistical challenge.”

US Key Opinion Leader, February 2013

“It’s a race against time [to identify people infected with HCV], and I would say we are profoundly losing it, because the people who have been infected for a long time are typically the people that are hardest to identify. They’re anybody. They’re somebody who had a blood transfusion back in the 70s or somebody who has experimented with drugs. The only way to find them is population screening.”

OUS Key Opinion Leader, February 2013

“Public health initiatives are going to be critical important. It’s one of these weird circumstances where the Institutes of Medicine, the CDC, the departmental services and the pharmaceutical industry all have the same objective to identify the patients, treat them, and cure them. It doesn’t happen very often in American medicine, in general, where commercial interest aligned nearly precisely with the public health interest.”

US Key Opinion Leader, January 2013
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2 Introduction

2.1 Catalyst

There are two simultaneous R&D ventures occurring in HCV drug development: interferon-sparing therapies and interferon-free regimens. Development of both categories has been proceeding at breakneck speed, and the HCV treatment algorithm is expected to be fundamentally altered by the arrival of each wave of next-generation HCV regimens.

- The data presented at the 2012 International Liver Conference have provided fresh insight into where pipeline agents are likely to reside in the HCV treatment algorithm.
- Concerns over the tolerability of current HCV therapies have resulted in many patients deciding to forego treatment in order to await the launch of next-generation HCV therapies.
- Awareness of HCV is expected to increase throughout the forecast period as a result of public and private initiatives to educate people about the disease.
- The movement toward preventative treatment of HCV is expected to occur in many countries in order to decrease the overall healthcare costs associated with the disease. Governments are, therefore, expected to expand HCV screening recommendations and programs and increase patient access to therapy during the forecast period.
- The simplicity of Gilead’s fixed-dose, single-pill HCV genotype 1 regimen, sofosbuvir/ledipasvir, compared with the complicated nature of current HCV therapies, is expected to profoundly change how HCV is treated.

2.2 Related Reports

- GlobalData (2013) PharmaFocus: Vaccine Adjuvants in Infectious Disease. GDHC001PFR
- GlobalData (2013). Pegasys (HCV) – Forecast and Market Analysis to 2022. GDHC1142DFR
- GlobalData (2013). PegIntron (HCV) – Forecast and Market Analysis to 2022. GDHC1143DFR
- GlobalData (2013). Copegus and Rebetol (HCV) – Forecast and Market Analysis to 2022. GDHC1144DFR
- GlobalData (2013). Incivek (HCV) – Forecast and Market Analysis to 2022. GDHC1145DFR
- GlobalData (2013). Victrelis (HCV) – Forecast and Market Analysis to 2022. GDHC1146DFR
- GlobalData (2013). Vaniprevir (HCV) – Forecast and Market Analysis to 2022. GDHC1147DFR
- GlobalData (2013). Faldaprevir and BI 207127 (HCV) – Forecast and Market Analysis to 2022. GDHC1148DFR
- GlobalData (2013). Simeprevir (HCV) – Forecast and Market Analysis to 2022. GDHC1149DFR
- GlobalData (2013). HCV – Current and Future Players. GDHC1012FPR
2.3 Upcoming Related Reports

- GlobalData (2013) PharmaFocus: Market Access Strategies in Gram Negative Bacteria. GDHC004PFR
- GlobalData (2013) PharmaFocus: Research and Development Strategies in HIV. GDHC003PFR
- GlobalData (2013) PharmaFocus: Public-Private Partnerships in Infectious Disease. GDHC005PFR
9.8 About GlobalData

GlobalData is a leading global provider of business intelligence in the healthcare industry. GlobalData provides its clients with up-to-date information and analysis on the latest developments in drug research, disease analysis, and clinical research and development. Our integrated business intelligence solutions include a range of interactive online databases, analytical tools, reports and forecasts. Our analysis is supported by a 24/7 client support and analyst team.

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