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Physician Views: What opportunity for Gilead Sciences' hepatitis C therapy sofosbuvir before interferon-sparing regiments reach the market?

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Abstracts

One of the key features of the hepatitis C treatment landscape over the past year to 18 months has been a trend for physicians to warehouse patients in anticipation for the launch of all-oral therapies that do not require treatment with interferon or ribavirin, thus significantly reducing side-effect burden.

A Physician Views poll run by FirstWord in December 2012 (among 74 US-based gastroenterologists) indicated that on average around 30 percent of diagnosed HCV patients were being warehoused.

Understandably, this trend is likely to increase as the approval of oral, interferon-free treatments moves closer (anticipated in 2015). Indeed, a more recent survey of the US hepatitis C landscape carried out by analysts at Wells Fargo in May suggested that on average 36 percent of diagnosed patients remain untreated.

Momentum towards an oral, interferon-free treatment landscape should receive a notable boost this week when an FDA advisory committee discusses Gilead Sciences' sofosbuvir and Johnson & Johnson’s simeprevir. Analysts expect positive recommendation to be followed by approval in late 2013/early 2014.

As a potential first-in-class NS5B polymerase inhibitor, sofosbuvir is broadly expected to act as a key backbone therapy for oral, interferon-free treatment regimens that emerge from 2015 onwards (including Gilead’s proposed once-daily, one-tablet combination of sofosbuvir and ledipasvir). But what of its commercial opportunity in the meantime, assuming the drug is launched in early 2014?

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Sofosbuvir – when used in combination with ribavirin – will offer the first all-oral treatment (and one which does not require interferon) to patients with genotype 2 and 3 HCV, who account for approximately 25 percent of US patients. Thus among this patient subset, a viable new treatment option could become available within months.

In genotype 1 patients – which account for the vast majority of the US hepatitis C population – the outlook is more complicated. Treatment with sofosbuvir will still require co-administration with ribavirin and interferon, however, the duration of therapy will be significantly reduced versus current standard of care with a protease inhibitor, ribavirin and interferon (12 weeks versus 48 weeks), which could encourage uptake among both warehouse and newly diagnosed patients.

Significantly, although the commercial opportunity for simeprevir is expected to be fairly limited in 2014 – until Johnson & Johnson launches its own oral, interferon-free combinations – data from the COSMOS study have demonstrated that when used in combination with sofosbuvir this treatment regimen demonstrates compelling efficacy in genotype 1 null responder patients.

This week's Physician Views poll will ask US and EU5-based gastroenterologists and infectious disease specialists how they expect to use sofosbuvir based on its likely initial label, and prior to the entry of oral, interferon-free regimens that can be used across a broad spectrum of patient genotypes. Results should help to gauge how much of the warehousing effect will be left intact when subsequent oral, interferon-free drugs are launched in 2015. Specifically this week's poll will ask...

> What percentage of warehoused genotype 2/3 patients they plan to treat with sofosbuvir + ribavirin assuming Gilead's drug is approved late 2013/early 2014 prior to the approval of subsequent oral therapies?
>
> What percentage of newly-diagnosed genotype 2/3 patients they plan to treat with sofosbuvir + ribavirin assuming Gilead's drug is approved late 2013/early 2014 prior to the approval of subsequent oral therapies?
>
> What percentage of warehoused genotype 1 patients they plan to treat with sofosbuvir + pegylated interferon + ribavirin prior to the approval of subsequent oral, interferon-sparing therapies?
>
> What percentage of newly diagnosed genotype 1 patients they plan to treat with simeprevir + pegylated interferon + ribavirin prior to the approval of subsequent

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oral, interferon-sparing therapies?

Based on available data from the COSMOS study, what percentage of null responder genotype 1 patients they anticipate treating with an off-label combination of sofosbuvir + simeprevir (with or without ribavirin) prior to the approval of subsequent therapies?

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