

Physician Views: And then there were two – will AbbVie's 3-DA regimen prove a compelling competitor to Gilead's Harvoni?

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Abstracts

Later this month, the FDA is expected to approve AbbVie's oral '3-DA' product - comprising Viekirax (ombitasvir/ paritaprevir/ ritonavir) plus Exviera (dasabuvir) - for the treatment of genotype 1 hepatitis C patients. European approval is expected to occur in early 2015 following a positive recommendation from a European Medicines Agency committee last month.

Payers in the US are hoping that AbbVie will deliver festive cheer by announcing a notable 'sticker price' discount versus Gilead Sciences' Harvoni brand, which costs \$94,500 for a 12-week supply. Analysts are increasingly certain, however, that such a scenario is unlikely to play out – although rebating will play a key role in driving uptake.

Strategically, however, AbbVie is more likely to promote the 3-DA regimen as being more suitable in cirrhotic patients, based on an assumption that the scale of the hepatitis C market will support multi-billion dollar revenues at a lower penetration rate.

However, while the cirrhotic population may provide an entry point for the 3-DA regimen, perception of AbbVie's superiority may diminish over the next few years as Gilead publishes further data for Harvoni in these patients, argue analysts at Deutsche Bank. A strong early performance for 3-DA may therefore be critical in establishing AbbVie in the hepatitis C market.

The label approved for 3-DA could be crucial in driving uptake. For example, there remains uncertainty as to whether AbbVie will receive approval for a 12-week duration of therapy in treatment-experienced patients with cirrhosis, an indication for which Harvoni use is only approved over a 24-week period. Debate is focused on whether the

FDA takes the view that a minimum 95 percent sustained virological response (SVR) rate is required to grant approval; in Phase III studies, 3-DA demonstrated a 92 percent SVR over 12 weeks.

Another uncertainty is focused on whether the FDA feels it is necessary that 3-DA is dosed in combination with ribavirin in genotype 1a treatment-experienced and cirrhotic patients, and whether physicians also use ribavirin in treatment-naïve genotype 1a patients (given the 7 percent delta in SVR rate demonstrated with and without ribavirin in Phase III studies).

Away from the label for AbbVie's 3-DA, other key issues that will shape usage focus on Gilead's competing therapy Harvoni. Specifically, how frequently physicians will use the drug in genotype 1 treatment-naïve patients over an eight-week (rather than 12 week) duration, thereby potentially limiting AbbVie's ability to compete on price, and just how significant a role Harvoni's convenience and compliance profile will play in limiting uptake of 3-DA. AbbVie's drug will require six tablets a day (four in the morning, two in the evening), while Harvoni requires one tablet a day.

To better ascertain how these factors may shape uptake of AbbVie's product, FirstWord is polling US and EU5-based gastroenterologists/hepatologists and infectious disease specialists with the following questions...

At peak, what percentage of total genotype 1 treatment-naïve patients who receive therapy with Gilead's Harvoni do you expect to treat for an eight-week (rather than 12 week) duration?

At peak, what percentage of genotype 1 treatment-experienced cirrhotic patients would you expect to treat with AbbVie's 3-DA regimen if its label necessitates a 24-week duration of therapy (also assuming ribavirin co-administration in genotype 1a patients)? – Phase III data demonstrated a SVR of 96 percent.

As a follow-up...what percentage of genotype 1 treatment-experienced cirrhotic patients would you expect to treat with AbbVie's 3-DA regimen, if its label necessitates a 12-week duration of therapy in this indication (also assuming ribavirin co-administration in genotype 1a patients)? – Phase III data demonstrated a SVR of 92 percent.

Do you have any concerns using ribavirin in combination with either AbbVie's 3-DA regimen or Gilead's Harvoni in treatment-experienced cirrhotic patients if this allows the duration of therapy to be reduced?

Just how important a role do you think the convenience/compliance advantage associated with Gilead's Harvoni (one tablet a day) will play in limiting the competitiveness of AbbVie's 3-DA regimen?

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