

Physician Views: Can the launch of ViiV Healthcare's dolutegravir disrupt Gilead's dominance in the HIV market?

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Abstracts

Based on current timelines, the FDA is poised to approve the HIV therapy dolutegravir later this month (it has a PDUFA date of August 17).

A once-daily integrase inhibitor, dolutegravir has been developed by ViiV Healthcare, a joint venture between GlaxoSmithKline, Pfizer and Shionogi. The drug was granted priority review by the FDA in February having been submitted for regulatory approval in December 2012.

Dolutegravir is poised to become the second available integrase inhibitor, following in the footsteps of Merck & Co.'s Isentress (raltegravir), which was approved in October 2007 and generated global sales of \$1.5 billion in 2012.

A key advantage for dolutegravir versus Isentress is its once-daily dosing profile. This is widely expected to support uptake, following Phase III study results (from the SPRING-2 trial), which demonstrated non-inferiority for dolutegravir versus Isentress.

Potential usage of dolutegravir as a first-line therapy option has also been boosted by Phase III data (from the SINGLE study) demonstrating superiority to Gilead Sciences' gold-standard three-drug combination Atripla (when dosed in combination with abacavir and lamivudine) - see ViewPoints: Analysts hike peak forecasts for GlaxoSmithKline, Pfizer and Shionogi HIV drug.

These results triggered analysts to increase their forecasts for dolutegravir, and according to data from Bloomberg, the ViiV drug is expected to generate global sales of \$1.1 billion by 2018. Significantly, in head-to-head trials with Atripla, Gilead's newer

products Stribild and Complera had only demonstrated non-inferiority. In addition to strong efficacy, analysts have noted the potential for a better resistance profile with dolutegravir (no notable resistance in treatment naive patients versus 2-3 percent for Stribild) and fewer drug-drug interactions (due to it being a non-boosted regimen). Extension study data will provide greater clarity on these issues.

However, although dolutegravir is now positioned as a keenly anticipated market entrant there remain some question marks regarding its commercial outlook. Some analysts have noted, for example, that combination use with Epzicom (abacavir) could prove to be a barrier to uptake (given the safety profile of GlaxoSmithKline's older drug), while dolutegravir may fail to demonstrate sustained superiority versus Atripla over a longer duration of therapy (superiority versus Atripla in the SINGLE study may have also been boosted by higher drop-out rates among patients taking Gilead's drug, a number of analysts have noted).

Others have also argued that despite its status as a seemingly best-in-class integrase inhibitor, there is a chance that physicians could use dolutegravir primarily in Isentress failure patients (similarly as to how newer generation antibiotics are increasingly 'held back' to treat patients who have developed resistance to older drugs). According to consensus forecasts, Isentress sales will reach \$1.6 billion in 2013, but stabilise at this level for the next few years.

To help gauge a more accurate view on how dolutegravir may shape the HIV market, this week's Physician Views poll will ask US-based infectious disease specialists:

How aware/informed they are about dolutegravir ahead of its pending PDUFA date

How they expect the availability of dolutegravir to impact their usage of Gilead's Stribild

What percentage of dolutegravir usage they anticipate to occur in Isentress failure patients

Whether combination use with Epzicom will have any negative impact on their prescribing of the drug

What percentage of total patients they expect to be prescribing dolutegravir to in two year's time

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