Topics: Drug Safety

Gilead warns of fatal reaction to Sovaldi, Harvoni and heart drug

9 patients taking hep C drugs with amiodarone develop bradycardia, 1 dies and 3 need pacemakers

March 23, 2015 | By Eric Palmer

Gilead Sciences' ($GILD) superselling hepatitis C drugs have hit a speed bump after 9 patients taking either Harvoni or Sovaldi, as well as a common drug for heart arrhythmias, had serious reactions. One of the 9 had a heart attack and died. Three others had to receive pacemakers.

The FDA said on Friday it approved an update to the label warning of serious symptomatic bradycardia when the drugs are coadministered with amiodarone. In a letter to providers, Gilead said that 6 cases of symptomatic bradycardia happened within 24 hours of starting one of the drugs and the other three in two to 12 days. The drugmaker's share price was unfazed by the news.

Three of the 9 patients were receiving Gilead's combo drug Harvoni, a combination of Sovaldi (sofosbuvir) and ledipasvir. Five were getting Sovaldi along with Bristol-Myers Squibb's ($BMY) daclatasvir, a hepatitis C treatment which has been approved in Europe but which the FDA has responded to with a complete response letter asking for more data about how it interacts with other antiviral agents in treating hepatitis C. In the last case, the patient was taking Sovaldi along with Johnson & Johnson's ($JNJ) hep C treatment Olysio, a combination that the FDA approved in November. All were also getting amiodarone.

Gilead said in its letter that, "The mechanism of the potential interaction between amiodarone and Harvoni, or Sovaldi in combination with another DAA (direct antiviral agent) is unknown." It said it is recommended that patients who need amiodarone and Sovaldi and amiodarone be monitored in an inpatient setting for the first 48 hours, followed by daily outpatient or self-monitoring of their heart rate for at least the first two weeks of treatment. It said that because amiodarone has a "long half-life," patients who have just gone off of amiodarone ahead of starting Harvoni or Sovaldi along with a DAA should also be monitored.

Gilead's Sovaldi, the first all-oral interferon-free hepatitis C treatment to hit the market had unprecedented sales in its first year on the market, $10.28 billion. The combo treatment Harvoni, which was approved by the FDA in October for hepatitis C virus genotype 1, has also been spectacular out of the gate, racking up $2.13 billion in sales in the few months in 2014 that it was on the market. The drugmaker has taken huge criticism for how it set the retail prices for the 12-week treatments, $85,000 for Sovaldi and $94,500 for Harvoni. Gilead has defended the costs, saying that because both treatments have cure rates above 90%, payers will save in the long run by avoiding having to pay for hospital stays and high-cost liver transplants.

Prices of the drugs are starting to ease, however. When AbbVie ($ABBV) got its competing treatment, Viekira Pak, approved by the FDA late last year, pharmacy benefits manager Express Scripts ($ESRX) cut an exclusive for that drug, setting off a price war that has led to deep discounts. Gilead has indicated that this year, its hep C gross-to-net adjustments--the difference between upfront pricing and sales after rebates--will run 46%. More than double the 22% applied last year.

Other drugs have received such warnings and it is always difficult to know how they might affect sales. The FDA in November added a description of a death to the label of Biogen's ($BIIB) hot multiple sclerosis pill Tecfidera after a patient developed a rare brain infection and died last year. The drug's sales in the fourth quarter will still up nearly three times to $916 million compared with the fourth quarter of 2013.

- here's the FDA release
- here's the Gilead letter

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