

Gilead Sciences, Inc. (**GILD** - [Analyst Report](#)) announced encouraging top-line data from four international phase III studies – ASTRAL-1, ASTRAL-2, ASTRAL-3 and ASTRAL-4 – evaluating a once-daily, fixed-dose combination of its blockbuster hepatitis C virus (HCV) infection drug, Sovaldi with velpatasvir (an investigational pangenotypic NS5A inhibitor). The fixed-dose combination is being developed for the treatment of genotype 1-6 chronic HCV infection.

While ASTRAL-1, ASTRAL-2 and ASTRAL-3 studies evaluated the use of Sovaldi with velpatasvir in genotype 1-6 HCV infection patients including those with compensated cirrhosis or who have failed prior treatments, the ASTRAL-4 study assessed the use of the candidate with or without ribavirin in patients with decompensated cirrhosis (Child-Pugh class B).

Approximately 98% of the patients treated with the Sovaldi–velpatasvir combination in the ASTRAL-1, ASTRAL-2 and ASTRAL-3 studies achieved the primary efficacy endpoint of sustained virological response at week 12 (SVR12). In the ASTRAL-4 study, patients with Child-Pugh class B cirrhosis receiving the Sovaldi–velpatasvir combination with ribavirin achieved higher SVR12 rates than patients receiving Sovaldi and velpatasvir.

Overall, the ASTRAL study data showed that the first fixed-dose combination of Sovaldi and velpatasvir for 12 weeks has the potential to provide high cure rates for patients with all HCV genotypes, thus eliminating the need for HCV genotype testing.

The FDA has granted the fixed-dose combination a Breakthrough Therapy status. Breakthrough Therapy status is granted to candidates that have the potential to offer major advances in treatment over existing options.

Our Take

Gilead's revenues received a major boost with the launch of hepatitis C virus (HCV) drugs Sovaldi (Dec 2013) and Harvoni (Oct 2014). Although Sovaldi and Harvoni sales have been impressive, Sovaldi sales are already weakening owing to availability of newer HCV therapies. Other approved HCV therapies include Johnson & Johnson's (**JNJ** - [Analyst Report](#)) Olysio and AbbVie's (**ABBV** - [Analyst Report](#)) Viekira Pak. Pricing measures in the form of rebates and discounts could lead to a slowdown in Harvoni sales. With uncertainty surrounding the future of its blockbuster HCV drugs, Gilead must be looking to augment its portfolio. In this scenario, approval of new HCV therapies including the Sovaldi/velpatasvir combination would boost revenues.

Gilead carries a Zacks Rank #1 (Strong Buy). Regeneron Pharmaceuticals, Inc. (**REGN** - [Analyst Report](#)) is another favorably ranked stock in the health care sector carrying the same Zacks Rank as Gilead.