BioSpectrum the business of Bio & Health Sciences

US FDA nod for Olysio/Sovaldi HCV combo

07 November 2014 | News | By BioSpectrum Bureau

US FDA nod for Olysio/Sovaldi HCV combo

The US Food and Drug Administration (US FDA) has approved Johnson & Johnson (J&J)and Medivir's Olysio (simeprevir) in combination with Gilead Sciences' Sovaldi (sofosbuvir) as an oral, interferon- and ribavirin-free treatment option for genotype 1 chronic hepatitis C infection in adults. J&J and Medivir further mentioned that the recommended treatment duration of the combination is 12 weeks for patients without cirrhosis or 24 weeks for patients with cirrhosis.

The approval was based on the data from two cohorts of the COSMOS study, which showed that 95 percent of patients with METAVIR scores of F0-F3 receiving 12 weeks of treatment of the drug Olysio in combination with Sovaldi achieved sustained virologic response or cure, the absence of HCV detected in the blood 12 weeks after the end of treatment.

"We are pleased that an interferon-free, ribavirin-free Olysio-based combination is now approved in the US. The availability of multiple treatment options is important to help offer an opportunity for cure and we believe Olysio will play a meaningful role in this respect," commented Mr Gaston Picchio, hepatitis disease area leader at J&J's Janssen R&D unit.