Sovaldi/Olysio Combo Cures 94% of Those With Liver Disease

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In a recent trial, combination therapy with Gilead Sciences' Sovaldi (sofosbuvir) and Janssen's Olysio (simeprevir) cured 94 percent of people who had genotype 1 of hepatitis C virus (HCV) and advanced liver disease, MedPage Today reports. Eagerly anticipated results from the Phase II COSMOS trial were presented at the 49th annual meeting of the European Association for the Study of the Liver (EASL) in London.

Eighty-seven study participants with F3 or F4 METAVIR fibrosis scores were divided into four groups: One took the NS5B nucleotide polymerase inhibitor Sovaldi plus the NS3/4A protease inhibitor Olysio for 12 weeks, and the other took the combination for 24 weeks; two other groups added ribavirin to the regimen and were treated for either 12 or 24 weeks.

Neither treatment length nor ribavirin use affected the success rate. In the 24-week groups, 93 percent (28/30) of those who took ribavirin achieved a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure), compared with 100 percent (16/16) who did not take ribavirin. In the 12-week groups, 93 percent (25/27) of those who took ribavirin were cured, compared with 93 percent (13/14) of those who did not take ribavirin.

Notably, those who had the Q80K polymorphism had the same outcomes as those who did not. Past research has found that the polymorphism lowers cure rates among those treated with protease inhibitors. Sovaldi apparently canceled out this effect.

While the U.S. Food and Drug Administration has not approved Sovaldi and Olysio for use together, many physicians are apparently prescribing them together off-label, using past research as a guide. Earlier in the year, the American Association for the Study of Liver Diseases recommended 24 weeks of Sovaldi, Olysio and ribavirin for people with genotype 1 of hep C who are interferon intolerant.

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