Janssen/Achillion's Triple-Drug Hep C Regimen Cures All Those With Genotype 1

The joint venture between the two companies will push the three-drug Olysio/odalasvir/AL-335 into further development.

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Both six and eight weeks of the triple-drug hepatitis C virus (HCV) regimen JNJ-4178, which contains Olysio (simeprevir) plus the experimental odalasvir and AL-335, cured all those with genotype 1 of the virus and no cirrhosis in an ongoing Phase II trial. Achillion and Janssen, which are developing the triple-drug regimen in partnership, will push it further into development.

Researchers from the Phase II 604 Study gave odalasvir and AL-335, with or without Olysio, for various durations to people with genotype 1 or 3 of hep C and no cirrhosis. All participants were being treated for hep C for the first time.

Findings were presented at the 52nd International Liver Congress in Amsterdam.

The researchers categorized as cured those genotype 1 participants who achieved a sustained virologic response 24 weeks after completing therapy, known as SVR24. For the genotype 3 participants, researchers relied on SVR12, which in recent years has become the more standard threshold for categorizing individuals as cured.

Twenty people with genotype 1 received 400 milligrams of AL-335, 50 mg of odalasvir and 100 mg of Olysio with instructions to take them once daily for eight weeks; all were cured.

The remainder of the study participants received 800 mg of AL-335, 50 mg of odalasvir; those who also received Olysio took 75 mg of that drug, with instructions to take AL-335 and Olysio daily and odalasvir every other day.

Two groups of 20 people with genotype 1 received the entire triple-drug JNJ-4178 regimen, one group for eight weeks and the other for six weeks; all 40 people were cured.

A respective 25 and eight people with genotype 1 received just AL-335 and odalasvir for eight and 12 weeks; a respective 84 percent (21 of 25) and 88 percent (7 of 8) were cured. Achillion and

Janssen will not continue pursuing this two-drug regimen.

A respective five and 13 people with genotype 3 received JNJ-4178 for eight and 12 weeks; a respective 0 percent (0 of 5) and 77 percent (10 of 13) were cured. One of those treated for 12 weeks did not return for the follow-up visit required to determine whether this person was cured.

The regimens studied were generally safe and well tolerated.

Janssen has already started a multi-center, randomized open-label Phase IIb OMEGA-1 study of once-daily JNJ-4178, including 25 mg of odalasvir, 800 mg of AL-335 and 75 mg of Olysio given for six or eight weeks. The trial has completed enrollment of 365 people without cirrhosis, including both those who have and have not been treated for hep C before. The participants have genotypes 1, 2, 4, 5 or 6. Results from the trial are expected in the second half of the year.

Meanwhile, 604 Study will continue and will assess JNJ-4178 among those with compensated cirrhosis.

To read a press release about the study, click here.

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