Bristol-Myers Squibb Combo Boasts High Cure Rates for Hepatitis C

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An all-oral, interferon- and ribavirin-free hepatitis C combination treatment including daclatasvir, asunaprevir and BMS-791325 achieved a sustained virologic response (SVR, considered a cure) in 88 to 94 percent of treatment-naive people with genotype 1 of hepatitis C virus (HCV). Bristol-Myers Squibb (BMS) presented the preliminary results from this open-label, two-part Phase II study of people with both genotype 1a and 1b of the virus at the International Liver Congress, the 48th annual meeting of the European Association for the Study of the Liver (EASL) in Amsterdam.

Daclatasvir, an NS5A replication complex inhibitor, is in Phase III of development. Asunaprevir, an NS3 protease inhibitor, is also in Phase III of development, in combination with daclatasvir. BMS-791325 ('325), meanwhile, is still in Phase II of development as an adjunct to daclatasvir-based drug regimens.

The study divided participants into four groups: All received daclatasvir, asunaprevir and '325, with half of the total receiving a double dose of BMS-791325; participants were further divided by one half, one of which stayed on treatment for 12 weeks and the other for 24 weeks.

Fourteen out of 16 (88 percent) of those in the study group receiving the smaller dose of '325 for 24 weeks achieved an SVR 24 weeks after completing therapy. The group receiving the smaller dose of '325 for 12 weeks achieved the exact same figures, although for an SVR 36 weeks after completing therapy. Fifteen out of 16 (94 percent) of the group receiving the double dose of '325 for 24 weeks achieved an SVR four weeks after completing therapy. Sixteen out of 18 (89 percent) or those receiving the double dose of '325 for 12 weeks achieved an SVR 12 weeks after completing therapy.

The most common adverse events were headache (27.3 percent), asthenia/loss of strength (16.7 percent), diarrhea (16.7 percent) and nausea (13.6 percent).

BMS plans to begin a Phase III study of the three drugs as a single combination pill by the latter part of the year.

To read the BMS release, click here.

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http://beta.docker.hepmag.com/article/BMS-daclatasvir-23822-630813054