nal Article

J - 4178 (AL - 335, Odalasvir, and Simeprevir) for 6 or 8 Weeks in patitis C Virus - infected Patients without Cirrhosis: OMEGA - 1

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Abstract

The combination of 3 direct - acting antiviral agents (AL - 335, odalasvir and simeprevirJNJ - 4178 regimen) for 6 or 8 weeks demonstrated good efficacy and safety in a Phase IIa study in chronic hepatitis C virus (HCV) genotype (GT) - 1 - infected patients without cirrhosis and has now been evaluated in a larger Phase IIb study, OMEGA - 1. This multicenter, randomized, open - label study (NCT02765490) enrolled treatment - naïve and interferon (±ribavirin) treatment - experienced patients with HCV GT1, 2, 4, 5, or 6 infection. Patients with HCV GT3 infection and/or liver cirrhosis were excluded. Patients received AL - 335 800 mg, odalasvir 25 mg, and simeprevir 75 mg once daily for 6 or 8 weeks. The primary endpoint was sustained virologic response 12 weeks after the end of treatment (SVR12). In total, 365 patients (GT1a, 29.3%; GT1b, 42.5%; GT2, 12.3%; GT4, 14.2%; GT5, 1.4%; GT6, 0%) were randomized to receive 6 (N = 183) or 8 weeks (N = 182) of treatment. SVR12 rates after 6 (98.9%) or 8 weeks of treatment (97.8%) were non - inferior to a historical control (98%). Viral relapse occurred in 5 (1.4%) patients (4 with HCV GT2c; 1 with GT1a). With the exception of 4 patients in the 8 - week group, including 3 patients with missing data at the SVR24 timepoint, all patients who achieved SVR12 also achieved SVR24. One GT1a - infected patient experienced late viral relapse after achieving SVR18. Most adverse events (AEs) were mild

with no treatment‐related serious AEs. All randomized patients completed treatment.

Conclusion

In HCV‐infected patients, 6 and 8 weeks of treatment with JNJ‐4178 resulted in SVR12 rates of 98.9% and 97.8%, respectively, and was well tolerated.

Supporting Information

Accepted Articles

Accepted, unedited articles published online and citable. The final edited and typeset version of record will appear in the future.