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Viral Hepatitis

Grazoprevir, Ruzasvir, and Uprifosbuvir for HCV After NS5A Treatment Failure

David Wyles, Heiner Wedemeyer, Ziv Ben-Ari, Edward J. Gane, Jesper Bach Hansen, Ira M. Jacobson, Alex L. Laursen, Annie Luetkemeyer, Ronald Nahass, Stephen Pianko, Stefan Zeuzem, Patricia Jumes, Hsueh-Cheng Huang, Joan Butterton, Michael Robertson, Janice Wahl, Eliav Barr, Hee-Koung Joeng, Elizabeth Martin, Lawrence Serfaty, for the C-CREST Part C and C-SURGE Investigators

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Abstract

People with hepatitis C virus (HCV) infection who have failed treatment with an all-oral regimen represent a challenging treatment population. The present studies evaluated the safety and efficacy of grazoprevir, ruzasvir, and uprifosbuvir, with or without ribavirin, in participants who had failed an NS5A inhibitor-containing regimen. C-SURGE (PN-3682-021) and C-CREST Part C (PN-3682-011 and -012) were open-label, multicenter studies. Participants who had previously relapsed following an NS5A inhibitor–containing all-oral regimen were retreated with grazoprevir 100 mg, ruzasvir 60 mg, and uprifosbuvir 450 mg alone for 24 weeks or with ribavirin for 16 weeks. The primary efficacy endpoint was undetectable HCV RNA (<15 IU/mL) 12 weeks after treatment completion (SVR12). In C-SURGE, SVR12 was achieved by 49/49 (100%) and 43/44 (98%) genotype (GT)1 participants in the 24-week no ribavirin arm and the 16-week plus ribavirin arm (lost to follow-up, n = 1), respectively. In C-CREST Part C, SVR12 was achieved by 23/24 (96%) participants treated for 16 weeks with ribavirin (GT1, 2/2 [100%]; GT2, 13/14 [93%]; GT3, 8/8 [100%]). One participant with GT2 infection discontinued study medication after a single dose of grazoprevir, ruzasvir, and uprifosbuvir plus ribavirin due to serious adverse events of vomiting and tachycardia. The presence of baseline resistance-associated substitutions had no impact on SVR12. No participant who completed treatment in either study experienced virologic failure. ***Conclusion*****:** Grazoprevir, ruzasvir,

and uprifosbuvir, with or without ribavirin, for 16 or 24 weeks was safe and highly effective in participants with HCV infection who had previously failed NS5A inhibitor–containing therapy.

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