Appendix 1: Phase III published trials of sofosbuvir in combination with ribavirin or peginterferon-ribavirin for the treatment of hepatitis C virus (HCV) infection

Trial	Study design	Mean age (years)	Genotype (s)	N	Study population	Proportion of cirrhotic patients	Treatment regimens	Treatment durations	SVR12
NEUTRINO <sup>1</sup>	Single-group, open-label	52	1,4,5,6	327	Treatment naive	17%	SOF+ IFN + RBV	12 weeks	90%
FISSION <sup>1</sup>	Randomized, open-label, active-control	48	2	499	Treatment nave	20%	SOF+RBV IFN + RBV	12 weeks 24 weeks	97% 78%
			3				SOF+RBV IFN + RBV	12 weeks 24 weeks	56% 63%
POSITRON <sup>2</sup>	Blinded, placebo- controlled	52	2,3	278	Interferon intolerant or ineligible; Naive or experienced to treatment	16%	SOF+RBV Placebo	12 weeks 12 weeks	78% 0%
FUSION <sup>2</sup>	Blinded, active- control	54	2,3	201	Treatment experienced	30%	SOF + RBV SOF + RBV	12 weeks 16 weeks	50% 73%
VALENCE <sup>3</sup>	Initially blinded, randomized, then protocol amended and	50	2,3	419	Naïve or experienced to treatment	21%	SOF + RBV	12 weeks (genotype 2) 24 weeks	93% 85%
	open label							(genotype 3)	

Note: SOF, sofosbuvir; IFN, peginterferon; RBV, ribavirin; SVR, sustained virologic response.

## References

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- 3. Zeuzem S, Dusheiko GM, Salupere R, et al. Sofosbuvir and ribavirin in HCV genotypes 2 and 3. N engl J Med 2014;370(21):1993-2001.