TABLE 79: SUMMARY OF RANDOMIZED CONTROLLED TRIALS FROM TR0007 — TREATMENT-EXPERIENCED GENOTYPE 1 PATIENTS

AUTHOR, YEAR, STUDY NAME, DESIGN	N	POPULATION[a]	ACTIVE COMPARATOR[b]	PLACEBO/ CONTROL GROUP[b]	COUNTRY	OUTCOMES, FOLLOW-UP
Studies included in the NMA						
Bacon et al. 2011, RESPOND2 DB, RCT Phase 3	403	Prior non-response or relapse, genotype 1 CHC Age ≥ 18 years	Peg2b-R × 4 wks, then • Boceprevir 800 mg q8h + Peg2b-R × 32 wks, then Peg2b-R + placebo up to 12 wks (RGT), or • Boceprevir 800 mg q8h + Peg2b-R × 44 wks	Peg2b-R × 4 wks, then Peg2b-R + placebo × 44 wks	N. America, Europe	SVR24, relapse, treatment completion, harms 72 wks
Forns et al. 2014, PROMISE DB, RCT Phase 3	393	Relapsed, genotype 1 CHC Age ≥ 18 years	Simeprevir 150 mg daily + Peg2a-R × 12 wks, then Peg2a-R × 12 to 36 wks (RGT)	Peg2a-R + placebo × 12 wks, then Peg2a-R × 36 wks	N. America, Europe, Asia-Pacific	SVR12, relapse, harms (12 wks) 72 wks planned (60-wk data available)
Zeuzem et al. 2011, REALIZE DB, RCT Phase 3	662	No or partial response to previous therapy, genotype 1 CHC 18 to 70 years	• Telaprevir 750 mg q8h + Peg2a-R × 12 wks, then Peg2a-R × 36 wks[c] • Peg2a-R × 4 wks, then telaprevir 750 mg q8h + Peg2a-R × 12 wks, then Peg2a-R × 32 wk	Peg2a-R + placebo × 16 wks, then Peg2a-R × 32 wks	Europe, S. America, N. America	SVR12/24, relapse, treatment completion, harms 72 wks
Zeuzem et al. 2014, ASPIRE DB, RCT Phase 2b	462	Null or partial response, or relapse, after Peg-R; genotype 1 CHC 18 to 70 years	7 treatment groups[c] Simeprevir 100 mg or 150 mg daily for 12, 24, or 48 wks in combination with Peg2a-R × 48 wks	Peg2a-R + placebo × 48 wks	Europe, N. America, Australia, New Zealand	SVR12/24, relapse, treatment completion, harms 72 wks

CHC = chronic hepatitis C; DB = double-blind; N. = North; Peg2a/b-R = peginterferon 2a or 2b plus ribavirin; q8h = every 8 hours; RCT = randomized controlled trial; RGT = response-guided therapy; SVR12/24 = sustained viral response 12 or 24 weeks after the end of treatment; wk = week.

[a] Enrolled patients who did not achieve an SVR with peginterferon with ribavirin therapy for a minimum of 12 weeks in RESPOND2 and ASPIRE; 24 weeks in PROMISE; or 80% of intended dose in REALIZE.

[b] Patients received the following standard dose of peginterferon plus ribavirin: peg2a 180 mcg per week + ribavirin 1,000 mg if body mass < 75 kg, or 1,200 mg if body mass ≥ 75 kg, divided into two doses per day; peg2b 1.5 mcg/kg per week with weight-based ribavirin (800 mg to 1,400 mg), except for RESPOND2 (ribavirin 600 mg to 1,400 mg).

[c] Patients received placebo when not on direct-acting antivirals during the first 16, 24, or 48 weeks of treatment in the REALIZE and ASPIRE trials, respectively.