APPENDIX 6: DETAILED STUDY CHARACTERISTICS

TABLE 77: SUMMARY OF RANDOMIZED CONTROLLED TRIALS FROM TR0007 — TREATMENT-NAIVE GENOTYPE 1 PATIENTS

AUTHOR, YEAR, STUDY NAME, DESIGN	N	POPULATION	ACTIVE COMPARATOR[a]	PLACEBO/ CONTROL GROUP[a]	COUNTRY	OUTCOMES, STUDY FOLLOW-UP
Studies Included in the NMA						
Buti et al. 2014, OPTIMIZE RCT, OL, NI Phase 3	740	Treatment-naive Genotype 1 CHC Age 18 to 70 years	• Telaprevir 750 mg q8h + Peg2a-R × 12 wks • Telaprevir 1,125 mg q12h with Peg2a-R × 12 wks Then 12 to 36 wks Peg2a-R (RGT)	—	Europe, N. America	SVR12/24, relapse, harms Up to 72 wks
Fried et al. 2013, PILLAR (C205) RCT, DB Phase 2	386	Treatment-naive Genotype 1 CHC Non-cirrhotic Adult	• Simeprevir 150 mg daily + Peg2a-R × 12 wks, then placebo + Peg2a-R × 12 wks • Simeprevir 75 mg daily + Peg2a-R × 12 wks, then placebo + Peg2a-R × 12 wks • Simeprevir 150 mg daily + Peg2a-R × 24 wks • Simeprevir 75 mg daily + Peg2a-R × 24 wks then stop therapy or Peg2a-R × 24 wks (RGT)	Peg2a-R + placebo × 24 wks, then Peg2a-R × 24 wks	N. America, Europe, Asia-Pacific	SVR12/24, relapse, treatment completion, harms 72 wks
Jacobson et al. 2011, ADVANCE RCT, DB Phase 3	1,088	Treatment-naive Genotype 1 CHC Age 18 to 70 years	• Telaprevir 750 mg q8h + Peg2a-R × 12 wks • Telaprevir 750 mg q8h + Peg2a-R × 8 wks, then Peg2a-R + placebo × 4 wks Then Peg2a-R × 12 to 36 wks (RGT)	Peg2a-R + placebo × 12 wks then Peg2a-R × 36 wks	N. America, Europe, Argentina, Australia, Israel	SVR12/24, relapse, treatment completion, HRQoL, harms 72 wks

AUTHOR, YEAR, STUDY NAME, DESIGN	N	POPULATION	ACTIVE COMPARATOR[a]	PLACEBO/ CONTROL GROUP[a]	COUNTRY	OUTCOMES, STUDY FOLLOW-UP
Marcellin et al. 2011, C208 RCT, OL Phase 2	161	Treatment-naive Genotype 1 CHC Non-cirrhotic Age 18 to 65 years	• Telaprevir 750 mg q8h + Peg2a-R × 12 wks • Telaprevir 750 mg q8h + Peg2b-R × 12 wks • Telaprevir 1,125 mg q12h with Peg2a-R × 12 wks • Telaprevir 1,125 mg q12h with Peg2b-R × 12 wks Then 12 to 36 wks Peg2a/b-R (RGT)	—	Austria, Belgium, France, Germany, Italy, Spain, Netherlands	SVR24, relapse, treatment completion, harms Up to 72 wks
Poordad et al. 2011, SPRINT-2 RCT, DB Phase 3	1,097	Treatment-naive Genotype 1 CHC Age > 18 years	Peg2b-R × 4 wks, then • Boceprevir 800 mg q8h + Peg2b-R × 24 wks, then stop therapy or Peg2b-R + placebo × 20 wks (RGT) • Boceprevir 800 mg q8h + Peg2b-R × 44 wks	Peg2b-R × 4 wks, then Peg2b-R + placebo × 44 wks	N. America, Europe, Latin America	SVR24, relapse, treatment completion, harms 72 wks
Studies Not Included in the NMA						
Sherman et al. 2011, ILLUMINATE RCT, OL, NI Phase 3	540	Treatment-naive Genotype 1 CHC Age 18 to 70 years	All patients received telaprevir 750 mg q8h + Peg2a-R × 12 wks, then Peg2a-R × 8 wks Patients with eRVR randomized to either • Peg2a-R × 4 wks • Peg2a-R × 28 wks Patients with no eRVR received Peg2a-R × 28 wks		Belgium, Netherlands, US	SVR12/24, relapse, treatment completion, harms 72 wks

CHC = chronic hepatitis C; DB = double-blind; eRVR = extended rapid virologic response; HRQoL = health-related quality of life; NI = non-inferiority study; NMA = network meta-analysis; OL = open-label; Peg2a/b-R = peginterferon 2a or 2b plus ribavirin; q8h = every 8 hours; q12h = every 12 hours; RCT = randomized controlled trial; RGT = response-guided therapy; SVR12/24 = sustained virologic response 12 or 24 wks after the end of treatment; wk = week.

Note: Please refer to Treatment Regimen Nomenclature table for description of dosages.
[a] Patients received the standard dose of peg-R (peginterferon 2a 180 mcg per week + ribavirin 1,000 mg if < 75 kg, or 1,200 mg if ≥ 75 kg, divided into two doses per day; peginterferon 2b 1.5 mcg/kg per week with weight-based ribavirin [800 mg to 1,400 mg]) except for Poordad et al. (ribavirin 600 mg to 1,400 mg/day).