

TABLE 189: SERIOUS ADVERSE EVENTS

AUTHOR, YEAR, STUDY NAME	GENOTYPE	TREATMENT	n	N	%
Afdhal et al., 2014 ION-1	1	(6) SOF12 + LDV12	1	214	0%
		(7) SOF24 + LDV24	18	217	8%
		(10) SOF12 + LDV12 + RBV12	7	217	3%
		(11) SOF24 + LDV24 + RBV24	7	217	3%
Buti et al., 2014 OPTIMIZE	1	(32) T12 PR24-48 RGT q8	48	371	13%
		(33) T12 PR24-48 RGT q12	42	369	11%
Feld et al., 2014 SAPPHIRE-I	1	(15) PAR/RIT12 + OMB12 + DAS12 + RBV12	10	473	2%
Ferenci et al., 2014 PEARL-III	1b	(14) PAR/RIT12 + OMB12 + DAS12	4	209	2%
Ferenci et al., 2014 PEARL-IV	1a	(15) PAR/RIT12 + OMB12 + DAS12 + RBV12	3	100	3%
Fried et al., 2013 PILLAR	1	(1) PR48	10	77	13%
		(42) SIM12 PR24-48 RGT	4	77	5%
Gane et al., 2013 ELECTRON	2+3	(3) SOF12 + RBV12	1	10	10%
		(40) SOF12 + PR12	0	11	0%
Gane et al., 2013 ELECTRON	1	(3) SOF12 + RBV12	1	25	4%
Gane et al., 2014 ELECTRON	1	(10) SOF12 + LDV12 + RBV12	2	25	8%
Hassanein et al., 2015	4	(52) DCV12 + ASU12 + BEC12 (75 mg b.i.d.)	0	11	0%
		(53) DCV12 + ASU12 + BEC12 (150 mg b.i.d.)	0	10	0%

AUTHOR, YEAR, STUDY NAME	GENOTYPE	TREATMENT	n	N	%
Jacobson et al., 2014 QUEST-1	1	(1) PR48	8	130	6%
		(42) SIM12 PR24-48 RGT	10	264	4%
Jacobson et al., 2011 ADVANCE	1	(1) PR48	24	361	7%
		(32) T12 PR24-48 RGT q8	33	363	9%
Kohli et al., 2015	1	(6) SOF12 + LDV12	0	20	0%
Kowdley et al., 2014 ION-3	1	(6) SOF12 + LDV12	5	216	2%
		(8) SOF8 + LDV8	4	215	2%
		(9) SOF8 + LDV8 + RBV8	1	216	0%
Kowdley et al., 2013 ATOMIC	1	(40) SOF12 + PR12	2	52	4%
Kumada et al., 2014	1b	(17) DCV24 + ASU24	9	135	7%
Lalezari et al. et al., 2015	1	(15) PAR/RIT12 + OMB12 + DAS12 + RBV12	2	38	5%
Lawitz et al., 2013 NEUTRINO	1+4+5+6	(40) SOF12 + PR12	4	327	1%
Lawitz et al., 2013 FISSION	2+3	(3) SOF12 + RBV12	7	256	3%
		(70) PR24	3	243	1%
Lawitz et al., 2014 LONESTAR	1	(6) SOF12 + LDV12	1	19	5%
		(8) SOF8 + LDV8	0	20	0%
		(9) SOF8 + LDV8 + RBV8	1	21	5%
Lawitz et al., 2013-1 PROTON	1	(1) PR48	1	26	4%
		(41) SOF12 PR24-48 RGT	3	47	6%
Lawitz et al., 2013-2 PROTON	2+3	(40) SOF12 + PR12	0	25	0%
Lawitz et al., 2015-1 C-WORTHY	1	(57) GRZ12 + ELB12 (50 mg q.d.)	2	29	7%
		(59) GRZ18 + ELB18 (50 mg q.d.)	0	31	0%
		(63) GRZ12 + ELB12 (50 mg q.d.) + RBV12	0	31	0%
		(65) GRZ18 + ELB18(50 mg q.d.) + RBV18	1	32	3%
Manns et al., 2014 HALLMARK-DUAL	1b	(17) DCV24 + ASU24	12	205	6%
Manns et al., 2014 QUEST-2	1	(1) PR48	10	134	7%
		(42) SIM12 PR24-48 RGT	16	257	6%
Marcellin et al., 2011	1	(32) T12 PR24-48 RGT q8	6	82	7%
		(33) T12 PR24-48 RGT q12	5	79	6%
Molina et al., 2015-1+3+4 PHOTON-2	1+3+4	(4) SOF24 + RBV24	10	200	5%
Molina et al., 2015-2 PHOTON-2	2	(3) SOF12 + RBV12	0	19	0%
Osinusi et al., 2013 SPARE-1	1	(4) SOF24 + RBV24	0	10	0%

AUTHOR, YEAR, STUDY NAME	GENOTYPE	TREATMENT	n	N	%
Osinusi et al., 2013 SPARE-2	1	(4) SOF24 + RBV24	0	25	0%
		(71) SOF24 + RBV (low dose) 24	2	25	8%
Osinusi et al., 2015	1	(6) SOF12 + LDV12	1	50	2%
Poordad et al., 2011 SPRINT2	1	(1) PR48	31	363	9%
Poordad et al., 2011 SPRINT2	1	(46) B24 PR28-48 RGT	42	368	11%
Rodriguez-Torres et al., 2015	1+2+3+4	(40) SOF12 + PR12	0	23	0%
Sulkowski et al., 2015-1 C-WORTHY	1	(23) GRZ12 + ELB12 + RBV12	1	86	1%
		(57) GRZ12 + ELB12 (50 mg q.d.)	0	43	0%
		(61) GRZ8 + ELB8(50 mg q.d.) + RBV8	0	30	0%
Sulkowski et al., 2015-2 C-WORTHY	1	(57) GRZ12 + ELB12 (50 mg q.d.)	1	30	3%
		(63) GRZ12 + ELB12 (50 mg q.d.) + RBV12	1	29	3%
Sulkowski et al., 2014-1 ^a	2+3	(3) SOF12 + RBV12	5	68	7%
Sulkowski et al., 2014-2	1	(4) SOF24 + RBV24	8	114	7%
Sulkowski et al., 2014	1	(19) DCV12 + SOF12	1	41	2%
Sulkowski et al., 2013-1+2 ^{#b}	1	(1) PR48	2	22	9%
		(39) T12 PR48 q8	7	38	18%
Sulkowski et al., 2013	1	(1) PR48	7	34	21%
		(50) B44 PR48	11	64	17%
Zeuzem et al., 2015-1+2+3	1+4+6	(22) GRZ12 + ELB12	9	316	3%

ASU = asunaprevir; B = boceprevir; BEC = beclabuvir; b.i.d. = twice daily; CrI = credible interval; DAS = dasabuvir; DCV = daclatasvir; ELB = elbasvir; GRZ = grazoprevir; LDV = ledipasvir; OMB = ombitasvir; PAR = paritaprevir; PR = pegylated interferon plus ribavirin; q8 = every 8 hours; q12 = every 12 hours; q.d. = once daily; RBV = ribavirin; RD = risk difference; RGT = response-guided therapy; RIT = ritonavir; RR = relative risk; SIM = simeprevir; SOF = sofosbuvir; T = telaprevir; vs. = versus.

Note: Please refer to Treatment Regimen Nomenclature table for description of dosages.

^a Data for ineligible treatment for genotype 3, (3) SOF12 + RBV12, are included.

^b Data for ineligible participants who receive efavirenz-based antiretroviral and 1,125 mg of telaprevir every 8 hours are also included.