## TABLE 203: SERIOUS ADVERSE EVENTS

| AUTHOR, YEAR, STUDY NAME | GENOTYPE | TREATMENT | n | N | % |
|---|---|---|---|---|---|
| Afdhal et al., 2014 ION-2 | 1 | (6) SOF12 + LDV12 | 0 | 109 | 0% |
| | | (10) SOF12 + LDV12 + RBV12 | 0 | 111 | 0% |
| | | (7) SOF24 + LDV24 | 6 | 109 | 6% |
| | | (11) SOF24 + LDV24 + RBV24 | 3 | 111 | 3% |
| Andreone et al., 2014 PEARL-II | 1b | (14) PAR/RIT12 + OMB12 + DAS12 | 2 | 95 | 2% |
| Bacon et al., 2011 RESPOND2 | 1 | (1) PR48 | 4 | 80 | 5% |
| | | (74) B32 PR36-48 RGT | 16 | 162 | 10% |
| Bourlière et al., 2015 SIRIUS | 1 | (7) SOF24 + LDV24 | 8 | 77 | 10% |
| | | (10) SOF12 + LDV12 + RBV12 | 4 | 78 | 5% |
| Forns et al., 2014 PROMISE | 1 | (1) PR48 | 10 | 133 | 8% |
| | | (42) SIM12 PR24-48 RGT | 14 | 260 | 5% |
| Forns et al., 2015 C-SALVAGE | 1 | (23) GRZ12 + ELB12 + RBV12 | 4 | 79 | 5% |
| Gane et al., 2013-2 ELECTRON | 1 | (3) SOF12 + RBV12 | 0 | 10 | 0% |
| Gane et al., 2014-2 ELECTRON | 1 | (10) SOF12 + LDV12 + RBV12 | 0 | 9 | 0% |
| Gane et al., 2014-3 ELECTRON | 1 | (10) SOF12 + LDV12 + RBV12 | 0 | 9 | 0% |
| Jacobson et al., 2013 FUSION | 2+3 | (3) SOF12 + RBV12 | 5 | 103 | 5% |
| Jensen et al., 2015 HALLMARK-QUAD | 1+4 | (18) DCV24 + ASU24 + PR24 | 22 | 398 | 6% |
| Kumada et al., 2014 | 1b | (17) DCV24 + ASU24 | 4 | 87 | 5% |
| Lawitz et al., 2014 | 2+3 | (40) SOF12 + PR12 | 4 | 47 | 9% |
| Lawitz et al., 2014 LONESTAR | 1 | (6) SOF12 + LDV12 | 1 | 19 | 5% |
| | | (10) SOF12 + LDV12 + RBV12 | 1 | 21 | 5% |

| AUTHOR, YEAR, STUDY NAME | GENOTYPE | TREATMENT | n | N | % |
|---|---|---|---|---|---|
| Lawitz et al., 2014 COSMOS | 1 | (72) SOF12 + SIM12 + RBV12 | 0 | 27 | 0% |
| Lawitz et al., 2014 COSMOS | 1 | (5) SIM12 + SOF12 | 0 | 14 | 0% |
| Lawitz et al., 2015-2 C-WORTHY | 1 | (57) GRZ12 + ELB12 (50 mg q.d.) | 1 | 33 | 3% |
| | | (59) GRZ18 + ELB18 (50 mg q.d.) | 1 | 32 | 3% |
| | | (63) GRZ12 + ELB12 (50 mg q.d.) + RBV12 | 2 | 32 | 6% |
| | | (65) GRZ18 + ELB18 (50 mg q.d.) + RBV18 | 0 | 33 | 0% |
| Lok et al., 2014 DUAL A2 | 1b | (17) DCV24 + ASU24 | 2 | 20 | 10% |
| Lok et al., 2014 QUAD B2 | 1 | (18) DCV24 + ASU24 + PR24 | 0 | 21 | 0% |
| Manns et al., 2014 HALLMARK-DUAL | 1b | (17) DCV24 + ASU24 | 11 | 205 | 5% |
| Molina et al., 2015 PHOTON-2 | 2+3 | (4) SOF24 + RBV24 | 5 | 55 | 9% |
| Osinusi et al., 2014 SYNERGY | 1 | (6) SOF12 + LDV12 | 0 | 14 | 0% |
| Pol et al., 2015 | 1 | (40) SOF12 + PR12 | 1 | 80 | 1% |
| Reddy et al., 2015 ATTAIN | 1 | (39) T12 PR48  q8 | 33 | 384 | 9% |
| | | (68) SIM12 PR48 | 8 | 379 | 2% |
| Sulkowski et al., 2014-3 | 2+3 | (4) SOF24 + RBV24 | 1 | 41 | 2% |
| Wyles et al., 2015 | 1 | (10) SOF12 + LDV12 + RBV12 | 2 | 51 | 4% |
| Zeuzem et al., 2014 SAPPHIRE-II | 1 | (15) PAR/RIT12 + OMB12 + DAS12 + RBV12 | 6 | 297 | 2% |
| Zeuzem et al., 2011 REALIZE | 1 | (1) PR48 | 7 | 132 | 5% |
| | | (39) T12 PR48  q8 | 33 | 266 | 12% |
| Zeuzem et al., 2014 ASPIRE | 1 | (1) PR48 | 4 | 66 | 6% |
| | | (68) SIM12 PR48 | 7 | 66 | 11% |

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

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