**Table 59.** Number (%) of Subjects With an Important Adverse Event by Adverse Event Category of Special Interest and by Treatment Group
(CONCERTA EU SCS: All Treated Subjects Analysis Set)

| Adverse Event Categories of Special Interest | Placebo (N=309) n (%) | DB CONCERTA (N=596) n (%) | Total CONCERTA (N=1369) n (%) |
|---|---|---|---|
| **Total no. subjects with Adverse Events** | 87 (28.2) | 307 (51.5) | 815 (59.5) |
| Hypertension | 12 ( 3.9) | 32 ( 5.4) | 136 ( 9.9) |
| Tachycardia | 0 | 36 ( 6.0) | 81 ( 5.9) |
| Raynaud's phenomenon | 2 ( 0.6) | 3 ( 0.5) | 6 ( 0.4) |
| Psychosis/mania | 3 ( 1.0) | 17 ( 2.9) | 45 ( 3.3) |
| Anorexia | 23 ( 7.4) | 174 (29.2) | 394 (28.8) |
| Migraine | 6 ( 1.9) | 7 ( 1.2) | 25 ( 1.8) |
| Repetitive behaviours | 0 | 1 ( 0.2) | 1 ( 0.1) |
| QT prolongation | 1 ( 0.3) | 0 | 4 ( 0.3) |
| Arrhythmias | 11 ( 3.6) | 80 (13.4) | 240 (17.5) |
| Cerebrovascular disorders | 0 | 1 ( 0.2) | 1 ( 0.1) |
| Aggression | 17 ( 5.5) | 71 (11.9) | 202 (14.8) |
| Hostility | 0 | 3 ( 0.5) | 11 ( 0.8) |
| Depression | 32 (10.4) | 100 (16.8) | 270 (19.7) |
| Suicidality | 0 | 1 ( 0.2) | 3 ( 0.2) |
| Tics/tourette's syndrome/dystonias | 4 ( 1.3) | 25 ( 4.2) | 72 ( 5.3) |
| Carcinogenicity | 0 | 0 | 5 ( 0.4) |
| Withdrawal syndrome | 0 | 1 ( 0.2) | 1 ( 0.1) |