| Table 1: Incidence of Treatment-Emergent Adverse Events Reported in at Least 5% of Subjects in Either Treatment Group, by System Organ Class and Preferred Term | | |
| --- | --- | --- |
|  | Drug A (N=791) | Placebo (N=394) |
|  | Total | Total |
| Number of subjects with a treatment-emergent adverse event | 782 (98.9%) | 390 (99.0%) |
|  |  |  |
| System organ class/preferred term |  |  |
|  |  |  |
| Musculoskeletal and connective tissue disorders | 576 (72.8%) | 291 (73.9%) |
| Back pain | 233 (29.5%) | 129 (32.7%) |
| Arthralgia | 215 (27.2%) | 89 (22.6%) |
| Bone pain | 194 (24.5%) | 110 (27.9%) |
| Pain in extremity | 134 (16.9%) | 79 (20.1%) |
| Musculoskeletal pain | 117 (14.8%) | 51 (12.9%) |
| Muscular weakness | 80 (10.1%) | 35 (8.9%) |
| Muscle spasms | 68 (8.6%) | 37 (9.4%) |
| Groin pain | 43 (5.4%) | 22 (5.6%) |
|  |  |  |
| General disorders and administration site conditions | 549 (69.4%) | 262 (66.5%) |
| Fatigue | 346 (43.7%) | 169 (42.9%) |
| Oedema peripheral | 197 (24.9%) | 68 (17.3%) |
| Asthenia | 104 (13.1%) | 52 (13.2%) |
| Pyrexia | 71 (9.0%) | 35 (8.9%) |
|  |  |  |
| Gastrointestinal disorders | 531 (67.1%) | 264 (67.0%) |
| Nausea | 233 (29.5%) | 124 (31.5%) |
| Constipation | 206 (26.0%) | 120 (30.5%) |
| Vomiting | 168 (21.2%) | 97 (24.6%) |
| Diarrhoea | 139 (17.6%) | 53 (13.5%) |
| Abdominal pain | 95 (12.0%) | 44 (11.2%) |
| Dry mouth | 55 (7.0%) | 21 (5.3%) |
| Dyspepsia | 48 (6.1%) | 13 (3.3%) |
|  |  |  |
| Metabolism and nutrition disorders | 365 (46.1%) | 164 (41.6%) |
| Hypokalaemia | 135 (17.1%) | 33 (8.4%) |
| Anorexia | 131 (16.6%) | 72 (18.3%) |
| Decreased appetite | 75 (9.5%) | 34 (8.6%) |
| Hyperglycaemia | 48 (6.1%) | 19 (4.8%) |
|  |  |  |
| Nervous system disorders | 339 (42.9%) | 178 (45.2%) |
| Headache | 94 (11.9%) | 42 (10.7%) |
| Dizziness | 75 (9.5%) | 38 (9.6%) |
| Spinal cord compression | 28 (3.5%) | 20 (5.1%) |
|  |  |  |
| Infections and infestations | 328 (41.5%) | 134 (34.0%) |
| Urinary tract infection | 91 (11.5%) | 28 (7.1%) |
| Nasopharyngitis | 45 (5.7%) | 24 (6.1%) |
| Upper respiratory tract infection | 43 (5.4%) | 10 (2.5%) |
|  |  |  |
| Respiratory, thoracic and mediastinal disorders | 267 (33.8%) | 116 (29.4%) |
| Dyspnoea | 102 (12.9%) | 46 (11.7%) |
| Cough | 84 (10.6%) | 30 (7.6%) |
|  |  |  |
| Vascular disorders | 247 (31.2%) | 123 (31.2%) |
| Hot flush | 150 (19.0%) | 66 (16.8%) |
| Hypertension | 67 (8.5%) | 27 (6.9%) |
|  |  |  |
| Investigations | 242 (30.6%) | 105 (26.6%) |
| Weight decreased | 84 (10.6%) | 55 (14.0%) |
|  |  |  |
| Renal and urinary disorders | 240 (30.3%) | 111 (28.2%) |
| Haematuria | 65 (8.2%) | 31 (7.9%) |
| Pollakiuria | 57 (7.2%) | 20 (5.1%) |
| Nocturia | 49 (6.2%) | 16 (4.1%) |
|  |  |  |
| Blood and lymphatic system disorders | 210 (26.5%) | 116 (29.4%) |
| Anaemia | 178 (22.5%) | 104 (26.4%) |
|  |  |  |
| Psychiatric disorders | 194 (24.5%) | 104 (26.4%) |
| Insomnia | 82 (10.4%) | 50 (12.7%) |
| Anxiety | 45 (5.7%) | 21 (5.3%) |
| Depression | 37 (4.7%) | 20 (5.1%) |
|  |  |  |
| Injury, poisoning and procedural complications | 174 (22.0%) | 56 (14.2%) |
| Contusion | 53 (6.7%) | 21 (5.3%) |
|  |  |  |
| Reproductive system and breast disorders | 41 (5.2%) | 39 (9.9%) |
| Pelvic pain | 17 (2.1%) | 22 (5.6%) |