| Table : Incidence of Treatment-Emergent Adverse Events Reported in at Least 5% of Subjects in Either Treatment Group, by System Organ Class and Preferred Term  (Study XXXXX: Safety Analysis Set - China) | | |
| --- | --- | --- |
|  | Drug A (N=143) | Placebo (N=71) |
|  | Total | Total |
| Number of subjects with a treatment-emergent adverse event | 136(95.1%) | 66(93.0%) |
|  |  |  |
| System organ class/preferred term |  |  |
|  |  |  |
| Musculoskeletal and connective tissue disorders | 73(51.0%) | 37(52.1%) |
| Bone pain | 34(23.8%) | 15(21.1%) |
| Back pain | 19(13.3%) | 9(12.7%) |
| Arthralgia | 17(11.9%) | 5(7.0%) |
| Pain in extremity | 15(10.5%) | 10(14.1%) |
| Musculoskeletal pain | 6(4.2%) | 5(7.0%) |
|  |  |  |
| Metabolism and nutrition disorders | 56(39.2%) | 22(31.0%) |
| Hypokalaemia | 37(25.9%) | 8(11.3%) |
| Hyperglycaemia | 14(9.8%) | 4(5.6%) |
| Decreased appetite | 3(2.1%) | 9(12.7%) |
|  |  |  |
| Investigations | 55(38.5%) | 27(38.0%) |
| Weight decreased | 4(2.8%) | 3(4.2%) |
|  |  |  |
| Blood and lymphatic system disorders | 39(27.3%) | 16(22.5%) |
| Anaemia | 37(25.9%) | 16(22.5%) |
|  |  |  |
| General disorders and administration site conditions | 38(26.6%) | 20(28.2%) |
| Pyrexia | 12(8.4%) | 3(4.2%) |
| Fatigue | 11(7.7%) | 5(7.0%) |
| Oedema peripheral | 10(7.0%) | 8(11.3%) |
|  |  |  |
| Infections and infestations | 33(23.1%) | 12(16.9%) |
| Urinary tract infection | 13(9.1%) | 6(8.5%) |
| Upper respiratory tract infection | 8(5.6%) | 3(4.2%) |
|  |  |  |
| Gastrointestinal disorders | 32(22.4%) | 19(26.8%) |
| Constipation | 11(7.7%) | 4(5.6%) |
| Vomiting | 4(2.8%) | 6(8.5%) |
|  |  |  |
| Vascular disorders | 31(21.7%) | 10(14.1%) |
| Hypertension | 23(16.1%) | 9(12.7%) |
|  |  |  |
| Renal and urinary disorders | 27(18.9%) | 16(22.5%) |
| Haematuria | 8(5.6%) | 4(5.6%) |
|  |  |  |