### Supplementary Table 1. Overall AEs and SAEs by MedDRA System Organ Class by tofacitinib formulation

| MedDRA System Organ Class | Tofacitinib immediate-release | Tofacitinib extended-release |
|---------------------------|-------------------------------|-------------------------------|
|                           | Number of AEs | Number of cases with an AE (%) | Number of SAEs | Number of AEs | Number of cases with an AE (%) | Number of SAEs |
| General disorders and administration site conditions | 2949 | 1964 (54.3) | 215 | 59 | 40 (40.8) | 2 |
| Gastrointestinal disorders | 1922 | 1063 (29.4) | 584 | 37 | 20 (20.4) | 19 |
| Injury, poisoning, and procedural complications | 1372 | 1055 (29.2) | 48 | 58 | 44 (44.9) | 6 |
| Infections and infestations | 818 | 604 (16.7) | 251 | 16 | 13 (13.3) | 6 |
| Investigations | 776 | 536 (14.8) | 66 | 11 | 9 (9.2) | - |
| Nervous system disorders | 633 | 512 (14.2) | 65 | 6 | 6 (6.1) | 1 |
| Psychiatric disorders | 477 | 383 (10.6) | 16 | 8 | 5 (5.1) | 1 |
| Skin and subcutaneous tissue disorders | 485 | 353 (9.8) | 20 | 5 | 4 (4.1) | - |
| Musculoskeletal and connective tissue disorders | 478 | 337 (9.3) | 40 | 9 | 7 (7.1) | - |
| Respiratory, thoracic, and mediastinal disorders | 450 | 313 (8.7) | 61 | 8 | 6 (6.1) | 1 |
| Vascular disorders | 154 | 140 (3.9) | 105 | 3 | 3 (3.1) | 3 |
| Metabolism and nutrition disorders | 112 | 108 (3.0) | 11 | - | - | - |
| Renal and urinary disorders | 98 | 85 (2.4) | 26 | 1 | 1 (1.0) | - |
| Blood and lymphatic system disorders | 69 | 65 (1.8) | 16 | 2 | 2 (2.0) | 1 |
| Eye disorders | 78 | 63 (1.7) | 24 | 1 | 1 (1.0) | - |
| Immune system disorders | 64 | 62 (1.7) | 17 | - | - | - |
| Cardiac disorders | 65 | 49 (1.4) | 45 | 1 | 1 (1.0) | - |
| Neoplasms benign, malignant, and unspecified | 45 | 41 (1.1) | 39 | 1 | 1 (1.0) | 1 |

MedDRA System Organ Classes with <1% of AEs are not shown.

AE, adverse event; MedDRA, Medical Dictionary for Regulatory Activities; N, total number of cases/events; SAE, serious adverse event.