**Table 7. Incidence of Serious Related Treatment-Emergent Adverse Events**
**By System Organ Class and Preferred Term**
**Safety Population**
**(Based on the 09JAN2015 Data Transfer)**

| System Organ Class<br>Preferred Term | Total<br>(N = 129) |
|---|---|
| Number of Subjects With Any Serious Related TEAE | 27 (20.9%) |
| General disorders and administration site conditions | 6 (4.7%) |
| Pyrexia | 3 (2.3%) |
| Chills | 1 (0.8%) |
| Fatigue | 1 (0.8%) |
| General physical health deterioration | 1 (0.8%) |
| Infections and infestations | 6 (4.7%) |
| Infection | 2 (1.6%) |
| Pneumonia | 2 (1.6%) |
| Bronchitis bacterial | 1 (0.8%) |
| Sepsis | 1 (0.8%) |
| Septic shock | 1 (0.8%) |
| Upper respiratory tract infection | 1 (0.8%) |
| Investigations | 6 (4.7%) |
| Blood creatinine increased | 3 (2.3%) |
| Alanine aminotransferase increased | 1 (0.8%) |
| Aspartate aminotransferase increased | 1 (0.8%) |
| Gamma-glutamyltransferase increased | 1 (0.8%) |
| Liver function test abnormal | 1 (0.8%) |
| Platelet count decreased | 1 (0.8%) |
| Blood and lymphatic system disorders | 5 (3.9%) |
| Thrombocytopenia | 3 (2.3%) |
| Anaemia | 2 (1.6%) |
| Febrile neutropenia | 1 (0.8%) |
| Haemolytic anaemia | 1 (0.8%) |
| Pancytopenia | 1 (0.8%) |
| Respiratory, thoracic and mediastinal disorders | 4 (3.1%) |
| Alveolitis | 1 (0.8%) |

**Table 7. Incidence of Serious Related Treatment-Emergent Adverse Events**
**By System Organ Class and Preferred Term**
**Safety Population**
**(Based on the 09JAN2015 Data Transfer)**

| System Organ Class<br>Preferred Term | Total<br>(N = 129) |
|---|---|
| Hypoxia | 1 (0.8%) |
| Pulmonary embolism | 1 (0.8%) |
| Pulmonary mass | 1 (0.8%) |
| Vascular disorders | 3 (2.3%) |
| Deep vein thrombosis | 1 (0.8%) |
| Extremity necrosis | 1 (0.8%) |
| Vasculitis | 1 (0.8%) |
| Venous thrombosis limb | 1 (0.8%) |
| Metabolism and nutrition disorders | 2 (1.6%) |
| Decreased appetite | 1 (0.8%) |
| Hypercalcaemia | 1 (0.8%) |
| Eye disorders | 1 (0.8%) |
| Toxic cataract | 1 (0.8%) |
| Gastrointestinal disorders | 1 (0.8%) |
| Constipation | 1 (0.8%) |
| Hepatobiliary disorders | 1 (0.8%) |
| Hepatic failure | 1 (0.8%) |
| Skin and subcutaneous tissue disorders | 1 (0.8%) |
| Rash | 1 (0.8%) |