Table 3. Incidence of Adverse Events

By System Organ Class and Preferred Term
Safety Population
(Based on the 09JAN2015 Data Transfer)

System Organ Class Preferred Term	Total (N = 129)
Number of Subjects With Any Adverse Event	125 (96.9%)
General disorders and administration site conditions	105 (81.4%)
Fatigue	48 (37.2%)
Pyrexia	47 (36.4%)
Oedema peripheral	27 (20.9%)
Chills	21 (16.3%)
Infusion site pain	18 (14.0%)
Asthenia	12 (9.3%)
Pain	12 (9.3%)
Chest pain	5 (3.9%)
Oedema	5 (3.9%)
Malaise	4 (3.1%)
Mucosal inflammation	4 (3.1%)
Extravasation	3 (2.3%)
Face oedema	3 (2.3%)
General physical health deterioration	3 (2.3%)
Infusion site reaction	3 (2.3%)
Multi-organ failure	3 (2.3%)
Generalised oedema	2 (1.6%)
Injection site pain	2 (1.6%)
Axillary pain	1 (0.8%)
Chest discomfort	1 (0.8%)
Device occlusion	1 (0.8%)
Disease progression	1 (0.8%)
Euthanasia	1 (0.8%)
Feeling of body temperature change	1 (0.8%)
Infusion site coldness	1 (0.8%)
Infusion site extravasation	1 (0.8%)
Infusion site inflammation	1 (0.8%)
Infusion site thrombosis	1 (0.8%)

Table 3. Incidence of Adverse Events

By System Organ Class and Preferred Term
Safety Population
(Based on the 09JAN2015 Data Transfer)

System Organ Class Preferred Term	Total (N = 129)
Injection site induration	1 (0.8%)
Injection site inflammation	1 (0.8%)
Injection site phlebitis	1 (0.8%)
Injection site pruritus	1 (0.8%)
Injection site reaction	1 (0.8%)
Local swelling	1 (0.8%)
Thrombosis in device	1 (0.8%)
Gastrointestinal disorders	93 (72.1%)
Nausea	55 (42.6%)
Vomiting	37 (28.7%)
Constipation	30 (23.3%)
Diarrhoea	28 (21.7%)
Abdominal pain	14 (10.9%)
Abdominal pain upper	7 (5.4%)
Dyspepsia	5 (3.9%)
Stomatitis	5 (3.9%)
Dry mouth	4 (3.1%)
Gastrooesophageal reflux disease	4 (3.1%)
Abdominal distension	3 (2.3%)
Ascites	3 (2.3%)
Abdominal discomfort	2 (1.6%)
Dysphagia	2 (1.6%)
Haematemesis	2 (1.6%)
Melaena	2 (1.6%)
Paraesthesia oral	2 (1.6%)
Abdominal pain lower	1 (0.8%)
Anal fissure	1 (0.8%)
Anal pruritus	1 (0.8%)
Bowel movement irregularity	1 (0.8%)
Cheilitis	1 (0.8%)

Table 3. Incidence of Adverse Events

By System Organ Class and Preferred Term
Safety Population
(Based on the 09JAN2015 Data Transfer)

System Organ Class Preferred Term	Total (N = 129)
Defaecation urgency	1 (0.8%)
Epigastric discomfort	1 (0.8%)
Eructation	1 (0.8%)
Flatulence	1 (0.8%)
Gastric ulcer	1 (0.8%)
Gastritis	1 (0.8%)
Gastrointestinal haemorrhage	1 (0.8%)
Gastrointestinal obstruction	1 (0.8%)
Gingival ulceration	1 (0.8%)
Lip ulceration	1 (0.8%)
Odynophagia	1 (0.8%)
Oesophagitis	1 (0.8%)
Pancreatitis	1 (0.8%)
Proctalgia	1 (0.8%)
Salivary hypersecretion	1 (0.8%)
Tongue haematoma	1 (0.8%)
Toothache	1 (0.8%)
Infections and infestations	64 (49.6%)
Bronchitis	11 (8.5%)
Pneumonia	11 (8.5%)
Upper respiratory tract infection	10 (7.8%)
Nasopharyngitis	7 (5.4%)
Sinusitis	7 (5.4%)
Infection	6 (4.7%)
Device related infection	5 (3.9%)
Oral candidiasis	5 (3.9%)
Urinary tract infection	5 (3.9%)
Pharyngitis	4 (3.1%)
Staphylococcal infection	4 (3.1%)
Cellulitis	3 (2.3%)

Table 3. Incidence of Adverse Events

By System Organ Class and Preferred Term
Safety Population
(Based on the 09JAN2015 Data Transfer)

System Organ Class Preferred Term	Total (N = 129)
Herpes simplex	3 (2.3%)
Sepsis	3 (2.3%)
Septic shock	3 (2.3%)
Administration site infection	2 (1.6%)
Bronchopneumonia	2 (1.6%)
Candidiasis	2 (1.6%)
Cystitis	2 (1.6%)
Cytomegalovirus infection	2 (1.6%)
Herpes zoster	2 (1.6%)
Lung infection	2 (1.6%)
Oral herpes	2 (1.6%)
Tonsillitis	2 (1.6%)
Acute sinusitis	1 (0.8%)
Anal candidiasis	1 (0.8%)
Bacterial infection	1 (0.8%)
Body tinea	1 (0.8%)
Bronchitis bacterial	1 (0.8%)
Clostridial infection	1 (0.8%)
Ear infection	1 (0.8%)
Endocarditis	1 (0.8%)
Epstein-Barr virus infection	1 (0.8%)
Escherichia infection	1 (0.8%)
Eye infection	1 (0.8%)
Eye infection bacterial	1 (0.8%)
Fungaemia	1 (0.8%)
Fungal infection	1 (0.8%)
Gastroenteritis	1 (0.8%)
Gastroenteritis viral	1 (0.8%)
Gastrointestinal fungal infection	1 (0.8%)
Genital herpes	1 (0.8%)
Infusion site cellulitis	1 (0.8%)

Table 3. Incidence of Adverse Events

By System Organ Class and Preferred Term
Safety Population
(Based on the 09JAN2015 Data Transfer)

System Organ Class Preferred Term	Total (N = 129)
Opportunistic infection	1 (0.8%)
Oral fungal infection	1 (0.8%)
Otitis media	1 (0.8%)
Pharyngitis bacterial	1 (0.8%)
Pneumonia viral	1 (0.8%)
Respiratory syncytial virus infection	1 (0.8%)
Respiratory tract infection	1 (0.8%)
Rhinitis	1 (0.8%)
Skin candida	1 (0.8%)
Staphylococcal sepsis	1 (0.8%)
Staphylococcal skin infection	1 (0.8%)
Urinary tract infection bacterial	1 (0.8%)
Urinary tract infection staphylococcal	1 (0.8%)
Urosepsis	1 (0.8%)
Investigations	64 (49.6%)
Blood lactate dehydrogenase increased	20 (15.5%)
Electrocardiogram QT prolonged	15 (11.6%)
Aspartate aminotransferase increased	11 (8.5%)
Alanine aminotransferase increased	9 (7.0%)
Blood creatinine increased	9 (7.0%)
Platelet count decreased	9 (7.0%)
Weight decreased	8 (6.2%)
Blood alkaline phosphatase increased	7 (5.4%)
International normalised ratio increased	5 (3.9%)
Activated partial thromboplastin time prolonged	4 (3.1%)
Blood bilirubin increased	4 (3.1%)
Blood potassium decreased	4 (3.1%)
Gamma-glutamyltransferase increased	4 (3.1%)
White blood cell count decreased	4 (3.1%)
Blood urea increased	3 (2.3%)

Table 3. Incidence of Adverse Events

By System Organ Class and Preferred Term
Safety Population
(Based on the 09JAN2015 Data Transfer)

System Organ Class Preferred Term	Total (N = 129)
C-reactive protein increased	3 (2.3%)
Glomerular filtration rate decreased	3 (2.3%)
Blood albumin decreased	2 (1.6%)
Blood calcium increased	2 (1.6%)
Blood creatinine	2 (1.6%)
Blood glucose increased	2 (1.6%)
Blood magnesium decreased	2 (1.6%)
Blood phosphorus decreased	2 (1.6%)
Blood uric acid increased	2 (1.6%)
Body temperature increased	2 (1.6%)
Eastern Cooperative Oncology Group performance status worsened	2 (1.6%)
Haemoglobin decreased	2 (1.6%)
Mean cell volume increased	2 (1.6%)
Neutrophil count decreased	2 (1.6%)
Prothrombin time prolonged	2 (1.6%)
Blood bilirubin unconjugated increased	1 (0.8%)
Blood calcium decreased	1 (0.8%)
Blood chloride decreased	1 (0.8%)
Blood phosphorus increased	1 (0.8%)
Blood potassium increased	1 (0.8%)
Blood pressure increased	1 (0.8%)
Blood thyroid stimulating hormone decreased	1 (0.8%)
Cardiac murmur	1 (0.8%)
Electrocardiogram ST segment depression	1 (0.8%)
Gamma-glutamyltransferase	1 (0.8%)
Glucose urine present	1 (0.8%)
Haematocrit decreased	1 (0.8%)
Hepatic enzyme increased	1 (0.8%)
International normalised ratio decreased	1 (0.8%)
Liver function test abnormal	1 (0.8%)

Table 3. Incidence of Adverse Events

By System Organ Class and Preferred Term
Safety Population
(Based on the 09JAN2015 Data Transfer)

System Organ Class Preferred Term	Total (N = 129)
Monocyte count decreased	1 (0.8%)
Oxygen saturation decreased	1 (0.8%)
PCO2 decreased	1 (0.8%)
Protein total decreased	1 (0.8%)
Prothrombin time shortened	1 (0.8%)
Red blood cell count decreased	1 (0.8%)
Weight increased	1 (0.8%)
White blood cell count increased	1 (0.8%)
Blood and lymphatic system disorders	61 (47.3%)
Anaemia	41 (31.8%)
Thrombocytopenia	21 (16.3%)
Leukopenia	13 (10.1%)
Neutropenia	13 (10.1%)
Lymphopenia	11 (8.5%)
Febrile neutropenia	7 (5.4%)
Leukocytosis	3 (2.3%)
Haemolytic anaemia	2 (1.6%)
Lymphadenopathy	2 (1.6%)
Pancytopenia	2 (1.6%)
Splenomegaly	2 (1.6%)
Anaemia haemolytic autoimmune	1 (0.8%)
Basophilia	1 (0.8%)
Coagulopathy	1 (0.8%)
Eosinophilia	1 (0.8%)
Lymphocytosis	1 (0.8%)
Thrombocytosis	1 (0.8%)
Metabolism and nutrition disorders	61 (47.3%)
Decreased appetite	20 (15.5%)
Hypokalaemia	17 (13.2%)

Table 3. Incidence of Adverse Events

By System Organ Class and Preferred Term
Safety Population
(Based on the 09JAN2015 Data Transfer)

System Organ Class Preferred Term	Total (N = 129)
Hyperglycaemia	12 (9.3%)
Hypoalbuminaemia	10 (7.8%)
Hypomagnesaemia	9 (7.0%)
Hyperuricaemia	8 (6.2%)
Hypocalcaemia	6 (4.7%)
Dehydration	4 (3.1%)
Diabetes mellitus	4 (3.1%)
Hyperkalaemia	4 (3.1%)
Hyponatraemia	4 (3.1%)
Tumour lysis syndrome	4 (3.1%)
Hypercalcaemia	3 (2.3%)
Hyperlipidaemia	2 (1.6%)
Fluid retention	1 (0.8%)
Gout	1 (0.8%)
Hypermagnesaemia	1 (0.8%)
Hypoglycaemia	1 (0.8%)
Hypophosphataemia	1 (0.8%)
Hypoproteinaemia	1 (0.8%)
Respiratory, thoracic and mediastinal disorders	61 (47.3%)
Dyspnoea	29 (22.5%)
Cough	25 (19.4%)
Oropharyngeal pain	8 (6.2%)
Hiccups	5 (3.9%)
Nasal congestion	5 (3.9%)
Pulmonary embolism	4 (3.1%)
Hypoxia	3 (2.3%)
Rhinorrhoea	3 (2.3%)
Atelectasis	2 (1.6%)
Bronchitis chronic	2 (1.6%)
Pleural effusion	2 (1.6%)

Table 3. Incidence of Adverse Events

By System Organ Class and Preferred Term
Safety Population
(Based on the 09JAN2015 Data Transfer)

System Organ Class Preferred Term	Total (N = 129)
Acute respiratory distress syndrome	1 (0.8%)
Alveolitis	1 (0.8%)
Bronchospasm	1 (0.8%)
Chylothorax	1 (0.8%)
Dysphonia	1 (0.8%)
Haemoptysis	1 (0.8%)
Lung infiltration	1 (0.8%)
Nasal discomfort	1 (0.8%)
Nasal dryness	1 (0.8%)
Obstructive airways disorder	1 (0.8%)
Oropharyngeal discomfort	1 (0.8%)
Pharyngeal ulceration	1 (0.8%)
Productive cough	1 (0.8%)
Pulmonary haemorrhage	1 (0.8%)
Pulmonary mass	1 (0.8%)
Pulmonary oedema	1 (0.8%)
Rales	1 (0.8%)
Respiratory alkalosis	1 (0.8%)
Respiratory distress	1 (0.8%)
Respiratory failure	1 (0.8%)
Sinus polyp	1 (0.8%)
Tachypnoea	1 (0.8%)
Wheezing	1 (0.8%)
Skin and subcutaneous tissue disorders	57 (44.2%)
Rash	26 (20.2%)
Pruritus	21 (16.3%)
Night sweats	8 (6.2%)
Hyperhidrosis	7 (5.4%)
Erythema	4 (3.1%)
Rash papular	3 (2.3%)

Table 3. Incidence of Adverse Events

By System Organ Class and Preferred Term
Safety Population
(Based on the 09JAN2015 Data Transfer)

System Organ Class Preferred Term	Total (N = 129)
Alopecia	2 (1.6%)
Dry skin	2 (1.6%)
Eczema	2 (1.6%)
Pain of skin	2 (1.6%)
Rash pruritic	2 (1.6%)
Acne	1 (0.8%)
Actinic keratosis	1 (0.8%)
Decubitus ulcer	1 (0.8%)
Dermatitis contact	1 (0.8%)
Palmar erythema	1 (0.8%)
Palmar-plantar erythrodysaesthesia syndrome	1 (0.8%)
Pruritus generalised	1 (0.8%)
Rash macular	1 (0.8%)
Rash maculo-papular	1 (0.8%)
Skin burning sensation	1 (0.8%)
Skin exfoliation	1 (0.8%)
Skin necrosis	1 (0.8%)
Skin ulcer	1 (0.8%)
Subcutaneous nodule	1 (0.8%)
Urticaria	1 (0.8%)
Vascular disorders	49 (38.0%)
Hypotension	14 (10.9%)
Phlebitis	12 (9.3%)
Flushing	9 (7.0%)
Deep vein thrombosis	7 (5.4%)
Hypertension	7 (5.4%)
Vein pain	3 (2.3%)
Hot flush	2 (1.6%)
Thrombophlebitis	2 (1.6%)
Vasculitis	2 (1.6%)

Table 3. Incidence of Adverse Events

By System Organ Class and Preferred Term
Safety Population
(Based on the 09JAN2015 Data Transfer)

System Organ Class Preferred Term	Total (N = 129)
Aortic aneurysm	1 (0.8%)
Arteriosclerosis	1 (0.8%)
Essential hypertension	1 (0.8%)
Extremity necrosis	1 (0.8%)
Hypovolaemic shock	1 (0.8%)
Iliac artery thrombosis	1 (0.8%)
Phlebitis superficial	1 (0.8%)
Shock	1 (0.8%)
Thrombophlebitis superficial	1 (0.8%)
Thrombosed varicose vein	1 (0.8%)
Thrombosis	1 (0.8%)
Venous thrombosis limb	1 (0.8%)
Nervous system disorders	46 (35.7%)
Headache	19 (14.7%)
Dizziness	13 (10.1%)
Neuropathy peripheral	9 (7.0%)
Dysgeusia	5 (3.9%)
Peripheral sensory neuropathy	3 (2.3%)
Ageusia	2 (1.6%)
Hypoaesthesia	2 (1.6%)
Paraesthesia	2 (1.6%)
Syncope	2 (1.6%)
Tremor	2 (1.6%)
Amnesia	1 (0.8%)
Aphasia	1 (0.8%)
Cerebral ischaemia	1 (0.8%)
Convulsion	1 (0.8%)
Encephalopathy	1 (0.8%)
Extrapyramidal disorder	1 (0.8%)
Hypotonia	1 (0.8%)

Table 3. Incidence of Adverse Events

By System Organ Class and Preferred Term
Safety Population
(Based on the 09JAN2015 Data Transfer)

System Organ Class Preferred Term	Total (N = 129)
Lethargy	1 (0.8%)
Peripheral motor neuropathy	1 (0.8%)
Polyneuropathy	1 (0.8%)
Poor quality sleep	1 (0.8%)
Restless legs syndrome	1 (0.8%)
Somnolence	1 (0.8%)
Musculoskeletal and connective tissue disorders	44 (34.1%)
Pain in extremity	11 (8.5%)
Muscle spasms	9 (7.0%)
Arthralgia	6 (4.7%)
Back pain	6 (4.7%)
Myalgia	5 (3.9%)
Musculoskeletal pain	4 (3.1%)
Bone pain	3 (2.3%)
Muscular weakness	3 (2.3%)
Pathological fracture	3 (2.3%)
Groin pain	2 (1.6%)
Joint swelling	2 (1.6%)
Musculoskeletal chest pain	2 (1.6%)
Neck pain	2 (1.6%)
Spinal osteoarthritis	2 (1.6%)
Arthritis	1 (0.8%)
Crystal arthropathy	1 (0.8%)
Flank pain	1 (0.8%)
Periostitis	1 (0.8%)
Psychiatric disorders	29 (22.5%)
Insomnia	9 (7.0%)
Anxiety	8 (6.2%)
Depression	6 (4.7%)

Table 3. Incidence of Adverse Events

By System Organ Class and Preferred Term
Safety Population
(Based on the 09JAN2015 Data Transfer)

System Organ Class Preferred Term	Total (N = 129)
Confusional state	3 (2.3%)
Depressed mood	3 (2.3%)
Sleep disorder	3 (2.3%)
Restlessness	2 (1.6%)
Aggression	1 (0.8%)
Impaired self-care	1 (0.8%)
Listless	1 (0.8%)
Mood altered	1 (0.8%)
Injury, poisoning and procedural complications	17 (13.2%)
Infusion related reaction	5 (3.9%)
Fall	2 (1.6%)
Allergic transfusion reaction	1 (0.8%)
Arthropod sting	1 (0.8%)
Complications of transplanted liver	1 (0.8%)
Excoriation	1 (0.8%)
Lower limb fracture	1 (0.8%)
Multiple fractures	1 (0.8%)
Procedural pain	1 (0.8%)
Spinal fracture	1 (0.8%)
Tooth fracture	1 (0.8%)
Tracheostomy malfunction	1 (0.8%)
Eye disorders	15 (11.6%)
Vision blurred	4 (3.1%)
Dry eye	2 (1.6%)
Cataract	1 (0.8%)
Conjunctivitis	1 (0.8%)
Eye discharge	1 (0.8%)
Eye pain	1 (0.8%)
Eyelid oedema	1 (0.8%)

Table 3. Incidence of Adverse Events

By System Organ Class and Preferred Term
Safety Population
(Based on the 09JAN2015 Data Transfer)

System Organ Class Preferred Term	Total (N = 129)
Eyelid ptosis	1 (0.8%)
Glaucoma	1 (0.8%)
Keratoconjunctivitis sicca	1 (0.8%)
Lacrimation increased	1 (0.8%)
Periorbital oedema	1 (0.8%)
Retinal vein thrombosis	1 (0.8%)
Toxic cataract	1 (0.8%)
Visual impairment	1 (0.8%)
Vitreous haemorrhage	1 (0.8%)
Cardiac disorders	14 (10.9%)
Atrial fibrillation	3 (2.3%)
Tachycardia	3 (2.3%)
Cardiac failure	2 (1.6%)
Sinus tachycardia	2 (1.6%)
Bundle branch block right	1 (0.8%)
Cardiac failure congestive	1 (0.8%)
Cor pulmonale	1 (0.8%)
Coronary artery disease	1 (0.8%)
Sinus bradycardia	1 (0.8%)
Supraventricular tachycardia	1 (0.8%)
Ventricular extrasystoles	1 (0.8%)
Renal and urinary disorders	13 (10.1%)
Pollakiuria	3 (2.3%)
Renal impairment	3 (2.3%)
Dysuria	2 (1.6%)
Renal failure	2 (1.6%)
Azotaemia	1 (0.8%)
Micturition urgency	1 (0.8%)
Oliguria	1 (0.8%)

Table 3. Incidence of Adverse Events

By System Organ Class and Preferred Term
Safety Population
(Based on the 09JAN2015 Data Transfer)

System Organ Class Preferred Term	Total (N = 129)
Renal failure acute	1 (0.8%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	11 (8.5%)
Tumour pain	3 (2.3%)
Tumour associated fever	2 (1.6%)
Keratoacanthoma	1 (0.8%)
Lung neoplasm	1 (0.8%)
Lung squamous cell carcinoma stage unspecified	1 (0.8%)
Mycosis fungoides	1 (0.8%)
Neoplasm skin	1 (0.8%)
Skin cancer	1 (0.8%)
Tumour haemorrhage	1 (0.8%)
Hepatobiliary disorders	8 (6.2%)
Hyperbilirubinaemia	3 (2.3%)
Bile duct stenosis	1 (0.8%)
Cholangitis	1 (0.8%)
Cholecystitis	1 (0.8%)
Cholecystitis acute	1 (0.8%)
Cholelithiasis	1 (0.8%)
Hepatic cirrhosis	1 (0.8%)
Hepatic failure	1 (0.8%)
Hepatomegaly	1 (0.8%)
Hepatosplenomegaly	1 (0.8%)
Ear and labyrinth disorders	6 (4.7%)
Deafness unilateral	1 (0.8%)
Ear discomfort	1 (0.8%)
Hypoacusis	1 (0.8%)
Otorrhoea	1 (0.8%)

Table 3. Incidence of Adverse Events

By System Organ Class and Preferred Term
Safety Population
(Based on the 09JAN2015 Data Transfer)

System Organ Class Preferred Term	Total (N = 129)
Tympanic membrane disorder	1 (0.8%)
Vertigo	1 (0.8%)
Immune system disorders	4 (3.1%)
Hypersensitivity	3 (2.3%)
Anaphylactic reaction	1 (0.8%)
Reproductive system and breast disorders	3 (2.3%)
Breast pain	1 (0.8%)
Prostatomegaly	1 (0.8%)
Testicular pain	1 (0.8%)
Surgical and medical procedures	1 (0.8%)
Central venous catheterisation	1 (0.8%)