|  | **Cohort A**, N = 68 | | | **Cohort B**, N = 283 | | |
| --- | --- | --- | --- | --- | --- | --- |
| **Adverse Event** | **Grade Grade 1-2** | **Grade Grade 3** | **Grade Grade 4** | **Grade Grade 1-2** | **Grade Grade 3** | **Grade Grade 4** |
| **Blood and lymphatic system disorders** | 14 (20.6) | 17 (25.0) | 15 (22.1) | 58 (20.5) | 36 (12.7) | 35 (12.4) |
| Anaemia | 21 (30.9) | 5 (7.4) | — | 65 (23.0) | 21 (7.4) | — |
| Neutropenia | 7 (10.3) | 11 (16.2) | 8 (11.8) | 22 (7.8) | 17 (6.0) | 15 (5.3) |
| Thrombocytopenia | 14 (20.6) | 3 (4.4) | — | 34 (12.0) | 8 (2.8) | 2 (0.7) |
| Febrile neutropenia | — | 5 (7.4) | 9 (13.2) | 1 (0.4) | 15 (5.3) | 23 (8.1) |
| Leukopenia | 3 (4.4) | 2 (2.9) | 1 (1.5) | 6 (2.1) | 5 (1.8) | — |
| Lymphopenia | 2 (2.9) | — | — | 2 (0.7) | — | — |
| Platelet production decreased | — | — | — | 1 (0.4) | 1 (0.4) | — |
| Hand and foot syndrome secondary to sickle cell anaemia | — | — | — | 1 (0.4) | — | — |
| Increased tendency to bruise | 1 (1.5) | — | — | — | — | — |
| Iron deficiency anaemia | — | — | — | 1 (0.4) | — | — |
| Leukocytosis | — | — | — | 1 (0.4) | — | — |
| Lymph node pain | — | — | — | 1 (0.4) | — | — |
| Neutrophilia | — | — | — | 1 (0.4) | — | — |
| Normochromic normocytic anaemia | — | — | — | 1 (0.4) | — | — |
| **Cardiac disorders** | 3 (4.4) | — | — | 12 (4.2) | — | — |
| Tachycardia | 1 (1.5) | — | — | 4 (1.4) | — | — |
| Palpitations | 2 (2.9) | — | — | 2 (0.7) | — | — |
| Atrioventricular block second degree | — | — | — | 2 (0.7) | — | — |
| Angina pectoris | — | — | — | 1 (0.4) | — | — |
| Atrial fibrillation | — | — | — | 1 (0.4) | — | — |
| Sinus bradycardia | — | — | — | 1 (0.4) | — | — |
| Ventricular dysfunction | — | — | — | 1 (0.4) | — | — |
| **Congenital, familial and genetic disorders** | 1 (1.5) | — | 1 (1.5) | 1 (0.4) | — | — |
| Acral peeling skin syndrome | 1 (1.5) | — | — | — | — | — |
| Aplasia | — | — | 1 (1.5) | — | — | — |
| Epidermal naevus | — | — | — | 1 (0.4) | — | — |
| **Ear and labyrinth disorders** | 5 (7.4) | — | — | 12 (4.2) | — | — |
| Vertigo | — | — | — | 6 (2.1) | — | — |
| Tinnitus | 3 (4.4) | — | — | 2 (0.7) | — | — |
| Hypoacusis | 1 (1.5) | — | — | 3 (1.1) | — | — |
| Deafness | — | — | — | 2 (0.7) | — | — |
| Ear pain | 1 (1.5) | — | — | — | — | — |
| **Endocrine disorders** | — | — | — | 2 (0.7) | — | — |
| Goitre | — | — | — | 1 (0.4) | — | — |
| Hypothyroidism | — | — | — | 1 (0.4) | — | — |
| **Eye disorders** | 13 (19.1) | — | — | 33 (11.7) | — | — |
| Lacrimation increased | 4 (5.9) | — | — | 12 (4.2) | — | — |
| Dry eye | 1 (1.5) | — | — | 5 (1.8) | — | — |
| Vision blurred | 1 (1.5) | — | — | 3 (1.1) | — | — |
| Eye disorder | 2 (2.9) | — | — | 1 (0.4) | — | — |
| Eye pruritus | 1 (1.5) | — | — | 2 (0.7) | — | — |
| Visual acuity reduced | 1 (1.5) | — | — | 2 (0.7) | — | — |
| Diplopia | — | — | — | 2 (0.7) | — | — |
| Eyelid myoclonus | — | — | — | 2 (0.7) | — | — |
| Noninfective conjunctivitis | 1 (1.5) | — | — | 1 (0.4) | — | — |
| Visual impairment | 1 (1.5) | — | — | 1 (0.4) | — | — |
| Xerophthalmia | — | — | — | 2 (0.7) | — | — |
| Blepharitis | — | — | — | 1 (0.4) | — | — |
| Eye irritation | 1 (1.5) | — | — | — | — | — |
| Eye swelling | — | — | — | 1 (0.4) | — | — |
| Eyelid oedema | — | — | — | 1 (0.4) | — | — |
| Ocular discomfort | — | — | — | 1 (0.4) | — | — |
| Ocular hyperaemia | — | — | — | 1 (0.4) | — | — |
| Ocular toxicity | 1 (1.5) | — | — | — | — | — |
| Periorbital disorder | — | — | — | 1 (0.4) | — | — |
| Vitreous detachment | — | — | — | 1 (0.4) | — | — |
| **Gastrointestinal disorders** | 52 (76.5) | 11 (16.2) | — | 210 (74.2) | 24 (8.5) | 1 (0.4) |
| Diarrhoea | 45 (66.2) | 7 (10.3) | — | 176 (62.2) | 16 (5.7) | — |
| Nausea | 38 (55.9) | — | — | 106 (37.5) | 4 (1.4) | 1 (0.4) |
| Stomatitis | 23 (33.8) | 6 (8.8) | — | 82 (29.0) | 3 (1.1) | — |
| Vomiting | 21 (30.9) | 1 (1.5) | — | 63 (22.3) | 4 (1.4) | 1 (0.4) |
| Dyspepsia | 10 (14.7) | — | — | 38 (13.4) | — | — |
| Constipation | 7 (10.3) | — | — | 20 (7.1) | — | — |
| Abdominal pain upper | 7 (10.3) | 1 (1.5) | — | 15 (5.3) | 1 (0.4) | — |
| Haemorrhoids | 4 (5.9) | — | — | 11 (3.9) | — | — |
| Dry mouth | 6 (8.8) | — | — | 8 (2.8) | — | — |
| Abdominal pain | 2 (2.9) | — | — | 10 (3.5) | — | — |
| Odynophagia | 4 (5.9) | — | — | 8 (2.8) | — | — |
| Gastrooesophageal reflux disease | 1 (1.5) | — | — | 10 (3.5) | — | — |
| Abdominal discomfort | 1 (1.5) | — | — | 7 (2.5) | — | — |
| Gastritis | 1 (1.5) | — | — | 4 (1.4) | 2 (0.7) | — |
| Epigastric discomfort | — | — | — | 6 (2.1) | — | — |
| Gastrointestinal toxicity | 2 (2.9) | — | — | 2 (0.7) | 1 (0.4) | 1 (0.4) |
| Dysphagia | 1 (1.5) | — | — | 4 (1.4) | — | — |
| Rectal haemorrhage | 1 (1.5) | — | — | 4 (1.4) | — | — |
| Oesophagitis | 2 (2.9) | — | — | 2 (0.7) | — | — |
| Toothache | — | — | — | 3 (1.1) | — | — |
| Anal fissure | — | — | — | 2 (0.7) | — | — |
| Anal haemorrhage | 1 (1.5) | — | — | 1 (0.4) | — | — |
| Anal inflammation | 2 (2.9) | — | — | — | — | — |
| Flatulence | 1 (1.5) | — | — | 1 (0.4) | — | — |
| Gingival pain | — | — | — | 2 (0.7) | — | — |
| Proctalgia | — | — | — | 2 (0.7) | — | — |
| Regurgitation | 1 (1.5) | — | — | 1 (0.4) | — | — |
| Salivary hypersecretion | 1 (1.5) | — | — | 1 (0.4) | — | — |
| Tongue ulceration | — | — | — | 2 (0.7) | — | — |
| Abdominal pain lower | — | — | — | 1 (0.4) | — | — |
| Chapped lips | — | — | — | 1 (0.4) | — | — |
| Chronic gastritis | — | — | — | 1 (0.4) | — | — |
| Colitis | 1 (1.5) | — | — | — | — | — |
| Defaecation urgency | — | — | — | 1 (0.4) | — | — |
| Enteritis | — | — | — | 1 (0.4) | — | — |
| Faecaloma | — | — | — | 1 (0.4) | — | — |
| Faeces soft | — | — | — | 1 (0.4) | — | — |
| Gastrointestinal pain | — | — | — | 1 (0.4) | — | — |
| Gastrointestinal wall thickening | — | — | — | 1 (0.4) | — | — |
| Gingival bleeding | — | — | — | 1 (0.4) | — | — |
| Haemorrhoidal haemorrhage | — | — | — | 1 (0.4) | — | — |
| Lip swelling | — | — | — | 1 (0.4) | — | — |
| Periodontal disease | 1 (1.5) | — | — | — | — | — |
| **General disorders and administration site conditions** | 46 (67.6) | 11 (16.2) | 2 (2.9) | 196 (69.3) | 19 (6.7) | — |
| Fatigue | 47 (69.1) | 11 (16.2) | — | 170 (60.1) | 19 (6.7) | — |
| Pyrexia | 6 (8.8) | — | 1 (1.5) | 52 (18.4) | 1 (0.4) | — |
| Oedema | 3 (4.4) | — | — | 17 (6.0) | — | — |
| Influenza like illness | 2 (2.9) | — | — | 15 (5.3) | — | — |
| Pain | 3 (4.4) | — | — | 11 (3.9) | — | — |
| Mucosal dryness | 2 (2.9) | — | — | 9 (3.2) | — | — |
| Ill-defined disorder | 2 (2.9) | — | — | 5 (1.8) | — | — |
| Chills | 1 (1.5) | — | — | 5 (1.8) | — | — |
| Xerosis | — | — | — | 5 (1.8) | — | — |
| Axillary pain | 1 (1.5) | — | — | 2 (0.7) | — | — |
| Feeling hot | 2 (2.9) | — | — | 1 (0.4) | — | — |
| Fibrosis | 1 (1.5) | — | — | 2 (0.7) | — | — |
| Hyperthermia | — | — | 1 (1.5) | 1 (0.4) | — | — |
| Swelling | 1 (1.5) | — | — | 1 (0.4) | — | — |
| Administration site phlebitis | — | — | — | 1 (0.4) | — | — |
| Chest pain | — | — | — | 1 (0.4) | — | — |
| Crepitations | — | — | — | 1 (0.4) | — | — |
| Discomfort | — | — | — | 1 (0.4) | — | — |
| Dysplasia | — | — | — | 1 (0.4) | — | — |
| Face oedema | — | — | — | 1 (0.4) | — | — |
| Fat necrosis | — | — | — | 1 (0.4) | — | — |
| Feeling cold | — | — | — | 1 (0.4) | — | — |
| Gait deviation | 1 (1.5) | — | — | — | — | — |
| Impaired healing | — | — | — | 1 (0.4) | — | — |
| Implant site pain | — | — | — | 1 (0.4) | — | — |
| Inflammation | — | — | — | 1 (0.4) | — | — |
| Infusion site extravasation | — | — | — | 1 (0.4) | — | — |
| Infusion site reaction | 1 (1.5) | — | — | — | — | — |
| Injection site rash | — | — | — | 1 (0.4) | — | — |
| Injection site reaction | — | — | — | 1 (0.4) | — | — |
| Localised oedema | — | — | — | 1 (0.4) | — | — |
| Malaise | — | — | — | 1 (0.4) | — | — |
| Maxillofacial pain | — | — | — | 1 (0.4) | — | — |
| Medical device pain | — | — | — | 1 (0.4) | — | — |
| Mucosal pain | — | — | — | 1 (0.4) | — | — |
| Necrosis | — | — | — | 1 (0.4) | — | — |
| Peripheral swelling | — | — | — | 1 (0.4) | — | — |
| Sense of oppression | — | — | — | 1 (0.4) | — | — |
| **Hepatobiliary disorders** | 3 (4.4) | 3 (4.4) | — | 4 (1.4) | 2 (0.7) | — |
| Hypertransaminasaemia | 3 (4.4) | 2 (2.9) | — | 3 (1.1) | 2 (0.7) | — |
| Acute hepatic failure | — | 1 (1.5) | — | — | — | — |
| Cholestasis | — | — | — | 1 (0.4) | — | — |
| Hepatic cytolysis | — | — | — | 1 (0.4) | — | — |
| Hepatotoxicity | — | 1 (1.5) | — | — | — | — |
| **Immune system disorders** | — | — | — | 7 (2.5) | 1 (0.4) | — |
| Hypersensitivity | — | — | — | 4 (1.4) | 1 (0.4) | — |
| Allergic reaction to excipient | — | — | — | 2 (0.7) | — | — |
| Food allergy | — | — | — | 1 (0.4) | — | — |
| **Infections and infestations** | 29 (42.6) | 2 (2.9) | — | 130 (45.9) | 13 (4.6) | 3 (1.1) |
| Nasopharyngitis | 6 (8.8) | — | — | 28 (9.9) | — | — |
| Urinary tract infection | 6 (8.8) | — | — | 14 (4.9) | 2 (0.7) | — |
| Conjunctivitis | 5 (7.4) | — | — | 10 (3.5) | — | — |
| Respiratory tract infection | 3 (4.4) | — | — | 11 (3.9) | — | — |
| Cystitis | 2 (2.9) | — | — | 8 (2.8) | — | — |
| Folliculitis | 2 (2.9) | — | — | 8 (2.8) | — | — |
| Pharyngitis | 1 (1.5) | — | — | 7 (2.5) | — | — |
| Rhinitis | — | — | — | 8 (2.8) | — | — |
| Upper respiratory tract infection | — | — | — | 8 (2.8) | — | — |
| Influenza | 2 (2.9) | — | — | 4 (1.4) | — | — |
| Mastitis | 1 (1.5) | — | — | 4 (1.4) | — | 1 (0.4) |
| Paronychia | 2 (2.9) | — | — | 4 (1.4) | — | — |
| Pneumonia | — | 2 (2.9) | — | 3 (1.1) | — | — |
| Postoperative wound infection | — | — | — | 4 (1.4) | 1 (0.4) | — |
| Vaginal infection | 1 (1.5) | — | — | 4 (1.4) | — | — |
| Bronchitis | — | — | — | 4 (1.4) | — | — |
| Oral herpes | 1 (1.5) | — | — | 3 (1.1) | — | — |
| Cellulitis | 2 (2.9) | — | — | 1 (0.4) | — | — |
| Gastroenteritis | 1 (1.5) | — | — | 2 (0.7) | — | — |
| Herpes virus infection | 1 (1.5) | — | — | 2 (0.7) | — | — |
| Subcutaneous abscess | 1 (1.5) | — | — | — | 2 (0.7) | — |
| Tooth infection | — | — | — | 3 (1.1) | — | — |
| Breast abscess | 1 (1.5) | — | — | 1 (0.4) | — | — |
| Clostridium difficile infection | — | — | — | — | 2 (0.7) | — |
| Device related infection | — | — | — | 1 (0.4) | 1 (0.4) | — |
| Ear infection | 1 (1.5) | — | — | 1 (0.4) | — | — |
| Gastroenteritis viral | — | — | — | 2 (0.7) | — | — |
| Gingivitis | — | — | — | 2 (0.7) | — | — |
| Herpes zoster | — | — | — | 2 (0.7) | — | — |
| Hordeolum | — | — | — | 2 (0.7) | — | — |
| Infection | — | — | — | 2 (0.7) | — | — |
| Localised infection | — | — | — | 2 (0.7) | — | — |
| Oropharyngeal candidiasis | — | — | — | 2 (0.7) | — | — |
| Pharyngotonsillitis | — | — | — | 2 (0.7) | — | — |
| Sweating fever | — | — | — | 2 (0.7) | — | — |
| Viral infection | 1 (1.5) | — | — | 1 (0.4) | — | — |
| Adenoviral upper respiratory infection | — | — | — | 1 (0.4) | — | — |
| Anal abscess | — | — | — | — | 1 (0.4) | — |
| Atypical pneumonia | — | — | — | — | 1 (0.4) | — |
| Avian influenza | — | — | — | — | 1 (0.4) | — |
| Bacteraemia | — | — | — | 1 (0.4) | — | — |
| Brain abscess | — | — | — | 1 (0.4) | — | — |
| Candida infection | — | — | — | 1 (0.4) | — | — |
| Clostridium bacteraemia | — | — | — | 1 (0.4) | — | — |
| Clostridium difficile colitis | — | — | — | — | 1 (0.4) | — |
| Conjunctivitis viral | — | — | — | 1 (0.4) | — | — |
| Fungal skin infection | — | — | — | 1 (0.4) | — | — |
| Furuncle | — | — | — | 1 (0.4) | — | — |
| Genitourinary tract infection | — | — | — | 1 (0.4) | — | — |
| Groin abscess | — | — | — | 1 (0.4) | — | — |
| H1N1 influenza | — | — | — | 1 (0.4) | — | — |
| Herpes simplex | — | — | — | 1 (0.4) | — | — |
| Impetigo | — | — | — | 1 (0.4) | — | — |
| Infected bite | — | — | — | 1 (0.4) | — | — |
| Infected lymphocele | — | — | — | — | 1 (0.4) | — |
| Large intestine infection | — | — | — | 1 (0.4) | — | — |
| Lip infection | — | — | — | 1 (0.4) | — | — |
| Medical device site cellulitis | — | — | — | 1 (0.4) | — | — |
| Nail infection | 1 (1.5) | — | — | — | — | — |
| Omphalitis | — | — | — | 1 (0.4) | — | — |
| Oral infection | — | — | — | 1 (0.4) | — | — |
| Otitis externa | — | — | — | 1 (0.4) | — | — |
| Pericoronitis | — | — | — | — | — | 1 (0.4) |
| Pharyngitis bacterial | 1 (1.5) | — | — | — | — | — |
| Post procedural infection | — | — | — | — | — | 1 (0.4) |
| Pseudomonas infection | — | — | — | 1 (0.4) | — | — |
| Rash pustular | — | — | — | 1 (0.4) | — | — |
| Sinusitis | — | — | — | 1 (0.4) | — | — |
| Skin infection | — | — | — | 1 (0.4) | — | — |
| Staphylococcal infection | — | — | — | 1 (0.4) | — | — |
| Tonsillitis | — | — | — | 1 (0.4) | — | — |
| Vulvitis | 1 (1.5) | — | — | — | — | — |
| Vulvovaginal candidiasis | — | — | — | 1 (0.4) | — | — |
| Vulvovaginitis | — | — | — | 1 (0.4) | — | — |
| Wound infection | 1 (1.5) | — | — | — | — | — |
| **Injury, poisoning and procedural complications** | 13 (19.1) | 1 (1.5) | — | 66 (23.3) | 4 (1.4) | — |
| Radiation skin injury | 8 (11.8) | — | — | 35 (12.4) | 1 (0.4) | — |
| Infusion related reaction | 3 (4.4) | 1 (1.5) | — | 8 (2.8) | — | — |
| Seroma | — | — | — | 8 (2.8) | — | — |
| Arthropod bite | — | — | — | 2 (0.7) | — | — |
| Ligament sprain | — | — | — | 2 (0.7) | — | — |
| Nasal injury | 1 (1.5) | — | — | 1 (0.4) | — | — |
| Post breast therapy pain syndrome | — | — | — | 2 (0.7) | — | — |
| Postoperative wound complication | — | — | — | 1 (0.4) | 1 (0.4) | — |
| Scar | — | — | — | 2 (0.7) | — | — |
| Toxicity to various agents | — | — | — | 1 (0.4) | 1 (0.4) | — |
| Animal bite | — | — | — | 1 (0.4) | — | — |
| Ankle fracture | — | — | — | — | 1 (0.4) | — |
| Cervical vertebral fracture | 1 (1.5) | — | — | — | — | — |
| Contusion | — | — | — | 1 (0.4) | — | — |
| Epicondylitis | — | — | — | 1 (0.4) | — | — |
| Facial bones fracture | — | — | — | 1 (0.4) | — | — |
| Foot fracture | — | — | — | 1 (0.4) | — | — |
| Incision site haemorrhage | — | — | — | 1 (0.4) | — | — |
| Muscle rupture | — | — | — | 1 (0.4) | — | — |
| Post procedural contusion | — | — | — | 1 (0.4) | — | — |
| Post procedural haematoma | — | — | — | — | 1 (0.4) | — |
| Procedural pain | — | — | — | 1 (0.4) | — | — |
| Radiation mucositis | — | — | — | 1 (0.4) | — | — |
| **Investigations** | 12 (17.6) | 3 (4.4) | — | 43 (15.2) | 2 (0.7) | — |
| Alanine aminotransferase increased | 4 (5.9) | 1 (1.5) | — | 11 (3.9) | 1 (0.4) | — |
| Aspartate aminotransferase increased | 3 (4.4) | 1 (1.5) | — | 8 (2.8) | — | — |
| Ejection fraction decreased | 2 (2.9) | — | — | 7 (2.5) | — | — |
| Blood magnesium decreased | 1 (1.5) | — | — | 6 (2.1) | — | — |
| Gamma-glutamyltransferase increased | — | 1 (1.5) | — | 6 (2.1) | — | — |
| Blood alkaline phosphatase increased | 1 (1.5) | — | — | 4 (1.4) | — | — |
| Blood lactate dehydrogenase increased | — | — | — | 5 (1.8) | — | — |
| Transaminases increased | — | — | — | 3 (1.1) | — | — |
| Weight decreased | — | — | — | 3 (1.1) | — | — |
| Blood calcium decreased | 1 (1.5) | — | — | 1 (0.4) | — | — |
| Blood phosphorus increased | 1 (1.5) | — | — | 1 (0.4) | — | — |
| Blood triglycerides increased | — | — | — | 2 (0.7) | — | — |
| Cardiac function test abnormal | — | — | — | 2 (0.7) | — | — |
| Red blood cell count abnormal | — | — | — | 2 (0.7) | — | — |
| Red blood cell count decreased | 1 (1.5) | — | — | 1 (0.4) | — | — |
| Weight increased | — | — | — | 2 (0.7) | — | — |
| Activated partial thromboplastin time prolonged | — | — | — | 1 (0.4) | — | — |
| Adjusted calcium decreased | — | — | — | 1 (0.4) | — | — |
| Amylase increased | 1 (1.5) | — | — | — | — | — |
| Blood bilirubin increased | 1 (1.5) | — | — | — | — | — |
| Blood cholesterol increased | — | — | — | 1 (0.4) | — | — |
| Blood creatinine increased | — | — | — | 1 (0.4) | — | — |
| Blood iron decreased | 1 (1.5) | — | — | — | — | — |
| Blood lactate dehydrogenase abnormal | — | — | — | 1 (0.4) | — | — |
| Blood phosphorus decreased | — | — | — | 1 (0.4) | — | — |
| Blood potassium abnormal | — | — | — | 1 (0.4) | — | — |
| Blood potassium increased | — | — | — | 1 (0.4) | — | — |
| C-reactive protein increased | — | — | — | 1 (0.4) | — | — |
| Cardiac murmur | — | — | — | 1 (0.4) | — | — |
| Ejection fraction abnormal | — | — | — | 1 (0.4) | — | — |
| Full blood count abnormal | — | 1 (1.5) | — | — | — | — |
| Gamma-glutamyltransferase | — | — | — | — | 1 (0.4) | — |
| Glomerular filtration rate abnormal | 1 (1.5) | — | — | — | — | — |
| Hepatic enzyme increased | — | 1 (1.5) | — | — | — | — |
| International normalised ratio increased | — | — | — | 1 (0.4) | — | — |
| Vitamin D decreased | — | — | — | 1 (0.4) | — | — |
| **Metabolism and nutrition disorders** | 24 (35.3) | 1 (1.5) | 1 (1.5) | 67 (23.7) | 9 (3.2) | 2 (0.7) |
| Decreased appetite | 12 (17.6) | — | — | 33 (11.7) | 2 (0.7) | — |
| Hypomagnesaemia | 8 (11.8) | 1 (1.5) | — | 17 (6.0) | 4 (1.4) | 1 (0.4) |
| Hyperglycaemia | 3 (4.4) | — | — | 13 (4.6) | — | — |
| Hypokalaemia | 2 (2.9) | — | 1 (1.5) | 6 (2.1) | 2 (0.7) | 2 (0.7) |
| Hypophosphataemia | — | — | — | 9 (3.2) | — | — |
| Hypoalbuminaemia | — | — | — | 7 (2.5) | — | — |
| Fluid retention | 1 (1.5) | — | — | 2 (0.7) | — | — |
| Hypercholesterolaemia | — | — | — | 3 (1.1) | — | — |
| Hypertriglyceridaemia | 1 (1.5) | — | — | 2 (0.7) | — | — |
| Magnesium deficiency | 1 (1.5) | — | — | 2 (0.7) | — | — |
| Cell death | 1 (1.5) | — | — | 1 (0.4) | — | — |
| Hyperuricaemia | — | — | — | 2 (0.7) | — | — |
| Hypocalcaemia | — | — | — | 2 (0.7) | — | — |
| Hyponatraemia | — | — | — | 2 (0.7) | — | — |
| Diabetes mellitus | — | — | — | — | 1 (0.4) | — |
| Dyslipidaemia | — | — | — | 1 (0.4) | — | — |
| Hypercalcaemia | — | — | — | 1 (0.4) | — | — |
| Hyperphosphatasaemia | — | — | — | 1 (0.4) | — | — |
| Hypoglycaemia | 1 (1.5) | — | — | — | — | — |
| Vitamin D deficiency | — | — | — | 1 (0.4) | — | — |
| **Musculoskeletal and connective tissue disorders** | 37 (54.4) | — | — | 119 (42.0) | 1 (0.4) | — |
| Arthralgia | 20 (29.4) | — | — | 50 (17.7) | — | — |
| Myalgia | 9 (13.2) | — | — | 29 (10.2) | — | — |
| Muscle spasms | 3 (4.4) | — | — | 18 (6.4) | — | — |
| Musculoskeletal pain | 8 (11.8) | — | — | 12 (4.2) | 1 (0.4) | — |
| Back pain | 3 (4.4) | — | — | 13 (4.6) | — | — |
| Pain in extremity | 1 (1.5) | — | — | 10 (3.5) | — | — |
| Bone pain | 2 (2.9) | — | — | 3 (1.1) | — | — |
| Neck pain | — | — | — | 4 (1.4) | — | — |
| Flank pain | — | — | — | 3 (1.1) | — | — |
| Muscle contracture | — | — | — | 2 (0.7) | — | — |
| Musculoskeletal chest pain | — | — | — | 2 (0.7) | — | — |
| Osteoporosis | — | — | — | 2 (0.7) | — | — |
| Arthritis | — | — | — | 1 (0.4) | — | — |
| Arthropathy | — | — | — | 1 (0.4) | — | — |
| Costochondritis | 1 (1.5) | — | — | — | — | — |
| Joint stiffness | — | — | — | 1 (0.4) | — | — |
| Limb discomfort | 1 (1.5) | — | — | — | — | — |
| Muscle rigidity | — | — | — | 1 (0.4) | — | — |
| Muscular weakness | 1 (1.5) | — | — | — | — | — |
| Musculoskeletal discomfort | — | — | — | 1 (0.4) | — | — |
| Musculoskeletal stiffness | 1 (1.5) | — | — | — | — | — |
| Osteoarthritis | — | — | — | 1 (0.4) | — | — |
| Osteopenia | — | — | — | 1 (0.4) | — | — |
| Pain in jaw | — | — | — | 1 (0.4) | — | — |
| Pseudothrombophlebitis | — | — | — | 1 (0.4) | — | — |
| Rotator cuff syndrome | — | — | — | 1 (0.4) | — | — |
| Spinal pain | — | — | — | 1 (0.4) | — | — |
| Tendonitis | — | — | — | 1 (0.4) | — | — |
| **Neoplasms benign, malignant and unspecified (incl cysts and polyps)** | 1 (1.5) | — | — | — | — | — |
| Benign neoplasm of skin | 1 (1.5) | — | — | — | — | — |
| **Nervous system disorders** | 38 (55.9) | — | — | 119 (42.0) | 4 (1.4) | — |
| Dysgeusia | 14 (20.6) | — | — | 40 (14.1) | — | — |
| Headache | 11 (16.2) | — | — | 34 (12.0) | — | — |
| Neuropathy peripheral | 11 (16.2) | — | — | 19 (6.7) | — | — |
| Dizziness | 5 (7.4) | — | — | 17 (6.0) | 1 (0.4) | — |
| Paraesthesia | 5 (7.4) | — | — | 16 (5.7) | — | — |
| Neurotoxicity | 5 (7.4) | — | — | 6 (2.1) | 1 (0.4) | — |
| Syncope | — | — | — | 9 (3.2) | 1 (0.4) | — |
| Dysaesthesia | — | — | — | 6 (2.1) | 1 (0.4) | — |
| Polyneuropathy | 1 (1.5) | — | — | 4 (1.4) | 1 (0.4) | — |
| Taste disorder | 2 (2.9) | — | — | 3 (1.1) | — | — |
| Hypoaesthesia | 1 (1.5) | — | — | 2 (0.7) | — | — |
| Presyncope | — | — | — | 3 (1.1) | — | — |
| Tremor | — | — | — | 3 (1.1) | — | — |
| Migraine | — | — | — | 2 (0.7) | — | — |
| Neuralgia | 1 (1.5) | — | — | 1 (0.4) | — | — |
| Ageusia | — | — | — | 1 (0.4) | — | — |
| Amnesia | 1 (1.5) | — | — | — | — | — |
| Brachial plexopathy | — | — | — | 1 (0.4) | — | — |
| Facial paresis | — | — | — | 1 (0.4) | — | — |
| Memory impairment | — | — | — | 1 (0.4) | — | — |
| Peripheral motor neuropathy | — | — | — | 1 (0.4) | — | — |
| Psychomotor hyperactivity | — | — | — | 1 (0.4) | — | — |
| Sciatica | — | — | — | 1 (0.4) | — | — |
| Somnolence | — | — | — | 1 (0.4) | — | — |
| Tension headache | — | — | — | 1 (0.4) | — | — |
| **Pregnancy, puerperium and perinatal conditions** | 1 (1.5) | — | — | — | — | — |
| Pregnancy | 1 (1.5) | — | — | — | — | — |
| **Psychiatric disorders** | 12 (17.6) | — | — | 41 (14.5) | — | — |
| Insomnia | 5 (7.4) | — | — | 22 (7.8) | — | — |
| Anxiety | 4 (5.9) | — | — | 11 (3.9) | — | — |
| Depressed mood | — | — | — | 4 (1.4) | — | — |
| Depression | 1 (1.5) | — | — | 3 (1.1) | — | — |
| Agitation | — | — | — | 2 (0.7) | — | — |
| Mood altered | — | — | — | 2 (0.7) | — | — |
| Affect lability | — | — | — | 1 (0.4) | — | — |
| Confusional state | — | — | — | 1 (0.4) | — | — |
| Mood swings | — | — | — | 1 (0.4) | — | — |
| Nervousness | 1 (1.5) | — | — | — | — | — |
| Onychophagia | — | — | — | 1 (0.4) | — | — |
| Tearfulness | 1 (1.5) | — | — | — | — | — |
| **Renal and urinary disorders** | 3 (4.4) | — | — | 15 (5.3) | 2 (0.7) | — |
| Dysuria | 3 (4.4) | — | — | 9 (3.2) | — | — |
| Micturition disorder | — | — | — | 3 (1.1) | — | — |
| Acute kidney injury | — | — | — | 1 (0.4) | 1 (0.4) | — |
| Renal failure | — | — | — | 1 (0.4) | 1 (0.4) | — |
| Haematuria | 1 (1.5) | — | — | — | — | — |
| Micturition urgency | — | — | — | 1 (0.4) | — | — |
| Nocturia | — | — | — | 1 (0.4) | — | — |
| Pollakiuria | — | — | — | 1 (0.4) | — | — |
| Renal colic | — | — | — | 1 (0.4) | — | — |
| Urethral pain | — | — | — | 1 (0.4) | — | — |
| Urinary tract disorder | — | — | — | 1 (0.4) | — | — |
| **Reproductive system and breast disorders** | 15 (22.1) | — | — | 35 (12.4) | — | — |
| Breast pain | 6 (8.8) | — | — | 18 (6.4) | — | — |
| Vulvovaginal dryness | 2 (2.9) | — | — | 7 (2.5) | — | — |
| Vulvovaginal inflammation | 1 (1.5) | — | — | 5 (1.8) | — | — |
| Amenorrhoea | 1 (1.5) | — | — | 4 (1.4) | — | — |
| Breast cyst | 1 (1.5) | — | — | 1 (0.4) | — | — |
| Breast discomfort | 1 (1.5) | — | — | 1 (0.4) | — | — |
| Vaginal haemorrhage | 1 (1.5) | — | — | 1 (0.4) | — | — |
| Vulvovaginal pruritus | 1 (1.5) | — | — | 1 (0.4) | — | — |
| Breast haematoma | — | — | — | 1 (0.4) | — | — |
| Breast oedema | 1 (1.5) | — | — | — | — | — |
| Dysmenorrhoea | — | — | — | 1 (0.4) | — | — |
| Genital pain | 1 (1.5) | — | — | — | — | — |
| Menopausal symptoms | — | — | — | 1 (0.4) | — | — |
| Menstruation irregular | — | — | — | 1 (0.4) | — | — |
| Nipple inflammation | 1 (1.5) | — | — | — | — | — |
| Perineal erythema | — | — | — | 1 (0.4) | — | — |
| Uterine disorder | — | — | — | 1 (0.4) | — | — |
| Uterine stenosis | — | — | — | 1 (0.4) | — | — |
| Vaginal discharge | — | — | — | 1 (0.4) | — | — |
| **Respiratory, thoracic and mediastinal disorders** | 19 (27.9) | 1 (1.5) | — | 79 (27.9) | — | — |
| Epistaxis | 10 (14.7) | — | — | 22 (7.8) | — | — |
| Cough | 3 (4.4) | — | — | 24 (8.5) | — | — |
| Dyspnoea | 2 (2.9) | — | — | 13 (4.6) | — | — |
| Rhinorrhoea | 1 (1.5) | — | — | 11 (3.9) | — | — |
| Nasal inflammation | 2 (2.9) | — | — | 9 (3.2) | — | — |
| Dysphonia | 1 (1.5) | — | — | 4 (1.4) | — | — |
| Nasal congestion | — | — | — | 4 (1.4) | — | — |
| Nasal dryness | 1 (1.5) | — | — | 3 (1.1) | — | — |
| Rhinitis allergic | — | — | — | 4 (1.4) | — | — |
| Productive cough | — | — | — | 3 (1.1) | — | — |
| Allergic cough | — | — | — | 2 (0.7) | — | — |
| Pulmonary embolism | — | 1 (1.5) | — | 1 (0.4) | — | — |
| Aphonia | — | — | — | 1 (0.4) | — | — |
| Bronchospasm | — | — | — | 1 (0.4) | — | — |
| Catarrh | — | — | — | 1 (0.4) | — | — |
| Nasal discomfort | — | — | — | 1 (0.4) | — | — |
| Pharyngeal disorder | — | — | — | 1 (0.4) | — | — |
| Pharyngeal inflammation | — | — | — | 1 (0.4) | — | — |
| Pneumonitis | — | — | — | 1 (0.4) | — | — |
| Pulmonary hypertension | — | — | — | 1 (0.4) | — | — |
| Rhinalgia | — | — | — | 1 (0.4) | — | — |
| Sinus pain | — | — | — | 1 (0.4) | — | — |
| Throat irritation | 1 (1.5) | — | — | — | — | — |
| Upper-airway cough syndrome | 1 (1.5) | — | — | — | — | — |
| Wheezing | 1 (1.5) | — | — | — | — | — |
| **Skin and subcutaneous tissue disorders** | 40 (58.8) | 2 (2.9) | — | 167 (59.0) | 5 (1.8) | — |
| Alopecia | 23 (33.8) | 1 (1.5) | — | 76 (26.9) | 2 (0.7) | — |
| Rash | 13 (19.1) | 1 (1.5) | — | 70 (24.7) | 1 (0.4) | — |
| Pruritus | 5 (7.4) | — | — | 33 (11.7) | 1 (0.4) | — |
| Dry skin | 5 (7.4) | — | — | 20 (7.1) | — | — |
| Erythema | 2 (2.9) | — | — | 21 (7.4) | — | — |
| Onycholysis | 2 (2.9) | — | — | 15 (5.3) | — | — |
| Nail toxicity | 4 (5.9) | — | — | 10 (3.5) | — | — |
| Nail dystrophy | 1 (1.5) | — | — | 7 (2.5) | — | — |
| Urticaria | 1 (1.5) | — | — | 4 (1.4) | 1 (0.4) | — |
| Acne | 2 (2.9) | — | — | 3 (1.1) | — | — |
| Eczema | 2 (2.9) | — | — | 3 (1.1) | — | — |
| Skin toxicity | — | — | — | 4 (1.4) | — | — |
| Onychoclasis | — | — | — | 3 (1.1) | — | — |
| Palmar-plantar erythrodysaesthesia syndrome | 1 (1.5) | — | — | 2 (0.7) | — | — |
| Skin hyperpigmentation | — | — | — | 3 (1.1) | — | — |
| Skin reaction | 1 (1.5) | — | — | 2 (0.7) | — | — |
| Hyperhidrosis | — | — | — | 2 (0.7) | — | — |
| Nail discomfort | — | — | — | 2 (0.7) | — | — |
| Onychalgia | 1 (1.5) | — | — | 1 (0.4) | — | — |
| Rash macular | — | — | — | 2 (0.7) | — | — |
| Skin fissures | 1 (1.5) | — | — | 1 (0.4) | — | — |
| Skin irritation | — | — | — | 2 (0.7) | — | — |
| Xeroderma | — | — | — | 2 (0.7) | — | — |
| Blister | — | — | — | 1 (0.4) | — | — |
| Dermatitis atopic | — | — | — | 1 (0.4) | — | — |
| Hand dermatitis | — | — | — | 1 (0.4) | — | — |
| Hangnail | — | — | — | 1 (0.4) | — | — |
| Hirsutism | — | — | — | 1 (0.4) | — | — |
| Itching scar | — | — | — | 1 (0.4) | — | — |
| Nail atrophy | — | — | — | 1 (0.4) | — | — |
| Nail disorder | 1 (1.5) | — | — | — | — | — |
| Night sweats | — | — | — | 1 (0.4) | — | — |
| Onychomadesis | — | — | — | 1 (0.4) | — | — |
| Perioral dermatitis | — | — | — | 1 (0.4) | — | — |
| Petechiae | — | — | — | 1 (0.4) | — | — |
| Prurigo | 1 (1.5) | — | — | — | — | — |
| Scar pain | — | — | — | 1 (0.4) | — | — |
| Skin burning sensation | — | — | — | 1 (0.4) | — | — |
| Skin exfoliation | — | — | — | 1 (0.4) | — | — |
| Skin ulcer | — | — | — | 1 (0.4) | — | — |
| Trichodynia | 1 (1.5) | — | — | — | — | — |
| **Social circumstances** | — | — | — | — | 1 (0.4) | — |
| Breast prosthesis user | — | — | — | — | 1 (0.4) | — |
| **Surgical and medical procedures** | — | — | — | 2 (0.7) | — | — |
| Breast tumour excision | — | — | — | 1 (0.4) | — | — |
| Nail operation | — | — | — | 1 (0.4) | — | — |
| Probiotic therapy | — | — | — | 1 (0.4) | — | — |
| **Vascular disorders** | 12 (17.6) | — | — | 71 (25.1) | 5 (1.8) | — |
| Hot flush | 10 (14.7) | — | — | 38 (13.4) | 1 (0.4) | — |
| Hypertension | — | — | — | 14 (4.9) | 3 (1.1) | — |
| Lymphoedema | — | — | — | 6 (2.1) | — | — |
| Flushing | 1 (1.5) | — | — | 3 (1.1) | — | — |
| Circulatory collapse | 1 (1.5) | — | — | 2 (0.7) | — | — |
| Embolism | — | — | — | 2 (0.7) | — | — |
| Hypotension | — | — | — | 2 (0.7) | — | — |
| Phlebitis | 1 (1.5) | — | — | 1 (0.4) | — | — |
| Thrombophlebitis | — | — | — | 2 (0.7) | — | — |
| Venous thrombosis | — | — | — | 2 (0.7) | — | — |
| Axillary vein thrombosis | — | — | — | 1 (0.4) | — | — |
| Deep vein thrombosis | — | — | — | 1 (0.4) | — | — |
| Haematoma | — | — | — | 1 (0.4) | — | — |
| Hypertensive crisis | — | — | — | — | 1 (0.4) | — |
| Lymphocele | — | — | — | 1 (0.4) | — | — |
| Neurogenic shock | 1 (1.5) | — | — | — | — | — |
| Peripheral venous disease | 1 (1.5) | — | — | — | — | — |
| Phlebitis superficial | — | — | — | 1 (0.4) | — | — |
| Superficial vein thrombosis | — | — | — | 1 (0.4) | — | — |
| Thrombosis | — | — | — | 1 (0.4) | — | — |
| Vena cava thrombosis | — | — | — | — | 1 (0.4) | — |