**Table e-2** Patients with AEs leading to treatment discontinuation in the OCR all-exposure populationa

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| --- | --- |
| **MedDRA SOC** **MedDRA preferred term** | **Number of patients** |
| **Overall total number of patients**  | **181** |
| **Neoplasms benign, malignant and unspecified (including cysts and polyps)** Invasive ductal breast carcinoma Breast cancer Malignant melanoma Papillary thyroid cancer Prostate cancer Adenocarcinoma of colon  Anaplastic large-cell lymphoma Basal cell carcinoma Carcinoma *in situ* of penis  Cervix carcinoma stage II Chondrosarcoma Endometrial adenocarcinoma Endometrial cancer Hypergammaglobulinemia benign monoclonal  Invasive breast carcinoma Lobular breast carcinoma *in situ* Lung neoplasm malignant Malignant fibrous histiocytoma Metastatic malignant melanoma Nodular melanoma Pancreatic carcinoma metastatic Renal cell carcinoma Squamous cell carcinoma Transitional cell carcinoma | **40**854221111111111111111111 |
| **Injury, poisoning and procedural complications** Infusion-related reaction Lumbar vertebral fracture Subdural hematoma | **35**3311 |
| **Infections and infestations** Urinary tract infection Herpes zoster Infectionb Sepsis Septic shock Acute hepatitis C Anal abscess Bacterial vaginosis Bronchitis Cellulitis *Clostridium difficile* colitis  Coccidioidomycosis Large intestine infection Latent tuberculosis Mastoiditis  Esophageal candidiasis Periodontitis Pneumonia  Pulmonary tuberculoma Viral infection | **27**42222111111111111111 |
| **Psychiatric disorders** Depression Anxiety Completed suicide Delusion Depressive symptom Hallucination Mental disorder Suicidal ideation Suicide attempt | **13**322111111 |
| **Skin and subcutaneous tissue disorders** Rash  Alopecia Asteatosis Decubitus ulcer Dermatitis allergic Dermatitis bullous Erythema nodosum Guttate psoriasis Interstitial granulomatous dermatitis Pruritis allergic Skin lesion | **12**21111111111 |
| **Investigations** Neutrophil count decreased B lymphocyte count decreased Blood creatine increased Blood immunoglobulin G decreased CD4 lymphocytes decreased Electrocardiogram QT prolonged Gamma-glutamyltransferase increased Transaminases increased | **9**21111111 |
| **Gastrointestinal disorders** Crohn’s disease Colitis Colitis ulcerative Diarrhea Enterocolitis | **8**41111 |
| **General disorders and administration site conditions** Fatigue Asthenia Chest pain Chills Influenza-like illness Pyrexia | **7**211111 |
| **Nervous system disorders** Multiple sclerosis relapse Headache Optic neuritis Secondary progressive multiple sclerosis Speech disorder | **6**21111 |
| **Musculoskeletal and connective tissue disorders** Arthralgia Osteonecrosis Pain in extremity Psoriatic arthropathy Seronegative arthritis | **5**11111 |
| **Blood and lymphatic system disorders** Lymphocytosis Lymphopenia Neutropenia | **3**111 |
| **Hepatobiliary disorders** Hepatitis Hepatitis fulminant Portal vein thrombosis | **3**111 |
| **Immune system disorders** Hemophagocytic lymphohistiocytosis Hypersensitivity Hypogammaglobulinemia | **3**111 |
| **Metabolism and nutrition disorders** Diabetes mellitus inadequate control Hypoproteinemia Lactic acidosis | **3**111 |
| **Cardiac disorders** Aortic valve incompetence Congestive cardiomyopathy | **2**11 |
| **Reproductive system and breast disorders** Cervical dysplasia Metrorrhagia | **2**11 |
| **Respiratory, thoracic and mediastinal disorders** Dysphonia Sinus congestion | **2**11 |
| **Eye disorders** Vitreous floaters | **1**1 |

Investigator text for AEs was encoded using MedDRA version 22.1. Multiple occurrences of the same AE in 1 patient are counted only once.
a Includes patients who received any dose of OCR during the CTP and associated OLE periods of the phase 2 and phase 3 studies, including patients originally randomized to comparator (IFN β-1a or placebo) who switched to open-label OCR treatment, plus VELOCE, CHORDS, CASTING, OBOE, ENSEMBLE, CONSONANCE, and LIBERTO.
b Reported terms: Infection-suspicion, WBC count 18.4 x 109/L, and Infectious syndrome of unknown cause.
AE = adverse event; CTP = controlled treatment period; IFN = interferon; MedDRA = Medical Dictionary for Regulatory Activities; OCR = ocrelizumab; OLE = open-label extension; SOC = system organ class; WBC = white blood cell.