

Supplemental Table for:

FDA Supplemental Approval: Blinatumomab for treatment of relapsed and refractory precursor B-cell acute lymphoblastic leukemia

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Table S1: Definition of Grouped Terms

Term	Preferred terms included in grouped term
Abdominal pain	Abdominal pain, abdominal pain lower, abdominal pain upper, gastrointestinal pain, abdominal discomfort
Anemia	Anaemia, erythropenia, haematocrit decreased, haemoglobin decreased, red blood cell count decreased
Cytokine release syndrome	Cytokine release syndrome, cytokine storm, macrophage activation
Depression	Depressed mood, depression, depression suicidal, major depression, completed suicide, suicide attempt, adjustment disorder with depressed mood, adjustment disorder with mixed anxiety and depression, agitated depression, Columbia suicide severity rating abnormal, suicidal ideation, suicidal behavior
Device related infection	Device related infection, device related sepsis
Diarrhea	Colitis, diarrhea, diarrhea infectious, enteritis, gastroenteritis, gastroenteritis viral, neutropenic colitis, viral diarrhea
Encephalopathy	Altered state of consciousness, cognitive disorder, confusional state, depressed level of consciousness, disturbance in attention, encephalopathy, lethargy, leukoencephalopathy, memory

	impairment, mental status changes, somnolence
Headache	Cluster headache, headache, sinus headache, tension headache
Mucosal inflammation	Glossitis, mucosal inflammation, pharyngeal inflammation, stomatitis
Neutropenia	Agranulocytosis, febrile neutropenia, granulocytopenia, neutropenia, neutrophil count decreased
Pyrexia	Pyrexia, body temperature increased
Rash	Dermatitis, dermatitis contact, erythema, rash, rash erythematous, rash generalized, rash macular, rash maculopapular, rash macrovascular, rash papular, rash vesicular, skin exfoliation, skin reaction, toxic skin eruption
Sepsis	Abdominal sepsis, bacteremia, bacterial sepsis, candida sepsis, device related sepsis, enterococcal sepsis, Enterobacter sepsis, Escherichia sepsis, fungal sepsis, neutropenic sepsis, post-procedural sepsis, pulmonary sepsis, sepsis, sepsis syndrome, septic shock, viral sepsis
Seizure	Atonic seizures, partial seizures, partial seizures with secondary generalization, seizure, simple partial seizures
Sensory issues	Anosmia, bruxism, carpal tunnel syndrome, dysaesthesia, dysgeusia, hemianopia, hyperaesthesia, hypoaesthesia, neuralgia, paresthesia, peripheral sensory neuropathy, sciatica, sensory disturbance, trigeminal neuralgia, visual field defect
Syncope	Dizziness, presyncope, syncope

Thrombocytopenia

Platelet count decreased, thrombocytopenia

Tremor

Action tremor, essential tremor, intention tremor, resting tremor, tremor
