

Supplemental Table S1: FDA Approval Summary: (Daunorubicin and Cytarabine) Liposome for Injection for the Treatment of Adults with High-Risk Acute Myeloid Leukemia

Supplemental Table S1: Grouped Terms for Adverse Reactions on Study 301

Grouped Term	Preferred Terms
Hemorrhage	Anal hemorrhage, Blood blister, Blood urine present, Breast hematoma, Catheter site bruise, Catheter site hemorrhage, Central nervous system hemorrhage, Cerebral hematoma, Cerebral hemorrhage, Coagulopathy, Conjunctival hemorrhage, Contusion, Ecchymosis, Enterocolitis hemorrhagic, Epistaxis, Gastric hemorrhage, Gastrointestinal hemorrhage, Gingival bleeding, Hematemesis, Hematochezia, Hematoma, Hematuria, Hemoptysis, Hemorrhage, Hemorrhage intracranial, Hemorrhage subcutaneous, Hemorrhage urinary tract, Hemorrhoidal hemorrhage, Lip hematoma, Lip hemorrhage, Lower gastrointestinal hemorrhage, Melena, Mouth hemorrhage, Mucosal hemorrhage, Periorbital hematoma, Periorbital hemorrhage, Pharyngeal hematoma, Pharyngeal hemorrhage, Post procedural contusion, Post procedural hematoma, Post procedural hemorrhage, Pulmonary alveolar hemorrhage, Pulmonary hemorrhage, Purpura, Rectal hemorrhage, Retinal hemorrhage, Scleral hemorrhage, Scrotal hematoma, Skin ulcer hemorrhage, Small intestinal hemorrhage, Stomatitis hemorrhagic, Subdural hematoma, Subdural hemorrhage, Subgaleal hematoma, Tongue hemorrhage, Traumatic hematoma, Upper gastrointestinal hemorrhage, Urethral hemorrhage, Vaginal hemorrhage, Vessel puncture site hemorrhage, Vitreous hemorrhage
Rash	Dermatitis, Dermatitis acneiform, Dermatitis allergic, Dermatitis contact, Eczema, Erythema nodosum, Exfoliative rash, Psoriasis, Rash, Rash erythematous, Rash follicular, Rash generalized, Rash macular, Rash maculopapular, Rash papular, Rash pruritic, Rash pustular, Skin exfoliation
Edema	Face edema, Fluid overload, Fluid retention, Generalized edema, Localized edema, Edema, Edema peripheral, Penile edema, Scrotal edema, Swelling, Swelling face
Diarrhea/colitis	Cecitis, Colitis, Diarrhea, Enterocolitis, Ileitis, Neutropenic colitis, Enteritis, Enterocolitis
Mucositis	Anal erosion, Anorectal discomfort, Duodenitis, Gastric ulcer, Gastrointestinal inflammation, Gingival pain, Gingival swelling, Gingivitis, Glossodynia, Laryngeal inflammation, Lip ulceration, Mouth ulceration, Mucosal inflammation, Mucosal ulceration, Odynophagia, Edema mouth, Esophageal ulcer, Esophagitis, Oral mucosa erosion, Oral mucosal blistering, Oral mucosal erythema, Pharyngeal ulceration, Proctalgia, Proctitis, Rectal ulcer, Stomatitis, Tongue ulceration, Oropharyngeal pain, Oral pain, Oropharyngeal discomfort, Pharyngeal erythema
Musculoskeletal pain	Arthralgia, Back pain, Bone pain, Coccydynia, Limb discomfort, Musculoskeletal chest pain, Musculoskeletal pain, Myalgia, Neck pain, Pain in extremity, Pain in jaw
Abdominal pain	Abdominal pain, Abdominal distension, Abdominal pain upper, Abdominal discomfort, Abdominal pain lower, Abdominal tenderness
Cough	Cough, Productive Cough
Headache	Headache, Sinus Headache
Dyspnea	Acute respiratory distress syndrome, Acute respiratory failure, Bronchospasm, Dyspnea, Dyspnea exertional, Respiratory distress, Respiratory failure, Wheezing

Grouped Term	Preferred Terms
Fatigue	Fatigue, Asthenia
Arrhythmia	Arrhythmia, Arrhythmia supraventricular, Atrial fibrillation, Atrial flutter, Atrial tachycardia, Atrioventricular block first degree, Atrioventricular block second degree, Bradycardia, Bundle branch block right, Extrasystoles, Heart rate increased, Nodal arrhythmia, Nodal rhythm, Sinus arrest, Sinus arrhythmia, Sinus bradycardia, Sinus tachycardia, Supraventricular tachycardia, Tachycardia, Ventricular extrasystoles, Ventricular tachycardia
Pneumonia (excluding fungal)	Lung consolidation, Lung infection, Lung infiltration, Pneumonia, Pneumonia aspiration, Pneumonia bacterial, Pneumonia klebsiella, Pneumonia pseudomonas aeruginosa, Pneumonia viral
Sleep disorders	Abnormal dreams, Insomnia, Nightmare, Sleep apnea syndrome, Sleep disorder
Bacteremia (excluding sepsis)	Bacillus test positive, Bacteremia, Bacteroides bacteremia, Corynebacterium test positive, Enterobacter bacteremia, Enterococcal bacteremia, Enterococcus test positive, Escherichia bacteremia, Klebsiella bacteremia, Pseudomonal bacteremia, Pseudomonas test positive, Staphylococcal bacteremia, Staphylococcus test positive, Stomatococcus test positive, Streptococcal bacteremia, Streptococcus test positive, Escherichia test positive, Klebsiella test positive
Vomiting	Retching, Vomiting
Hypotension	Hypotension, Orthostatic hypotension
Non-conduction cardiotoxicity	Acute coronary syndrome, Acute endocarditis, Acute myocardial infarction, Angina pectoris, Aortic valve incompetence, Cardiac arrest, Cardiac failure, Cardiac failure congestive, Cardiac murmur, Cardiogenic shock, Cardiomegaly, Cardiomyopathy, Cardiotoxicity, Cytotoxic cardiomyopathy, Diastolic dysfunction, Dilatation atrial, Dilatation ventricular, Ejection fraction decreased, Endocarditis, Left ventricular dysfunction, Mitral valve incompetence, Myocardial infarction, Pericardial effusion, Pericarditis, Restrictive cardiomyopathy, Right ventricular hypertrophy
Dizziness	Dizziness, Dizziness postural, Dizziness exertional
Fungal infection	Aspergillosis, Bronchopulmonary aspergillosis, Candida test positive, Candidiasis, Fungemia, Fungal infection, Fungal skin infection, Intertrigo candida, Lower respiratory tract infection fungal, Oral candidiasis, Pneumonia fungal, Pulmonary mycosis, Sinusitis fungal, Skin candida, Tinea cruris, Tinea infection, Vulvovaginal mycotic infection, Wound infection fungal, Zygomycosis, Mycotic aneurysm
Hypertension	Blood pressure increased, Hypertension
Hypoxia	Hypoxia, Oxygen saturation decreased
Upper respiratory infection (excluding fungal)	Acute sinusitis, Chronic sinusitis, Increased upper airway secretion, Nasal congestion, Pharyngitis, Rhinitis, Rhinorrhea, Sinus congestion, Sinusitis, Sinusitis bacterial, Upper respiratory tract congestion, Upper respiratory tract infection, Upper-airway cough syndrome, Viral upper respiratory tract infection
Chest pain	Chest discomfort, Chest pain, Non-cardiac chest pain, Pleuritic pain
Catheter/device/injection site reaction	Catheter site discharge, Catheter site erosion, Catheter site erythema, Catheter site inflammation, Catheter site edema, Catheter site pain, Catheter site pruritus, Catheter site rash, Infusion site edema, Infusion site pain, Infusion site vesicles, Catheter site related reaction
Delirium	Cognitive disorder, Confusional state, Delirium
Pruritis	Anal pruritis, Ear pruritis, Pruritis, Pruritis generalized
Sepsis (excluding fungal)	Enterobacter sepsis, Escherichia sepsis, Klebsiella sepsis, Neutropenic sepsis, Sepsis, Septic shock, Staphylococcal sepsis, Streptococcal sepsis, Urosepsis, Viral sepsis

Grouped Term	Preferred Terms
Renal insufficiency	Acute prerenal failure, Azotemia, Oliguria, Renal failure, Renal failure acute, Renal failure chronic
Transfusion reaction	Allergic transfusion reaction, Febrile non-hemolytic transfusion reaction, Transfusion reaction
Visual impairment (except bleeding)	Photophobia, Photopsia, Photosensitivity reaction, Retinal tear, Scintillating scotoma, Uveitis, Vision blurred, Visual acuity reduced, Visual impairment, Vitreous detachment, Vitreous floaters

Adverse reactions graded using NCI CTCAE version 3.0.