

CY 2014 CDER Fast Track Calendar Year Approvals*

Data as of 12/31/2014

Total of 21 Approvals

Appl Type Number	Submission Type and Number	Propriety Name	Established Name	Applicant	Approval Date	Use
NDA 204114	SUPP-1	MEKINIST	TRAMETINIB	GLAXO SMITH KLINE	8-Jan-2014	In combination with dabrafenib, for the treatment of patients with melanomas as detected by an FDA-approved test.
NDA 205552	ORIG - 2	IMBRUVICA	IBRUTINIB	PHARMACYCLICS LLC	12-Feb-2014	Treatment of patients with Chronic Lymphocytic Leukemia (CLL) who have received at least one prior therapy
BLA 125460	ORIG - 1	VIMIZIM	ELOSULFASE ALFA	BIOMARIN PHARMACEUTICAL INC	14-Feb-2014	Treatment of patients with Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome)
NDA 203202	ORIG - 1	NORTHERA	DROXIDOPA	LUNDBECK NA LTD	18-Feb-2014	Treatment of orthostatic dizziness, lightheadedness, or the "feeling that you are about to black out" in adult patients with symptomatic neurogenic orthostatic hypotension caused by primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy.
BLA 125390	ORIG - 1	MYALEPT	METRELEPTIN	AEGERION PHARMACEUTICALS INC	24-Feb-2014	Treatment of the complications of leptin deficiency in patients with congenital or acquired generalized lipodystrophy
NDA 204684	ORIG - 1	IMPAVIDO	MILTEFOSINE	KNIGHT THERAPEUTICS USA INC	19-Mar-2014	Treatment of visceral leishmaniasis due to Leishmania donovani, cutaneous leishmaniasis due to Leishmania braziliensis, Leishmania guyanensis, and Leishmania panamensis and mucosal leishmaniasis due to Leishmania braziliensis
NDA 205787	ORIG - 1	EVZIO	NALOXONE HYDROCHLORIDE	KALEO INC	03-Apr-2014	Treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression, and for immediate administration as emergency therapy in settings where opioids may be present
BLA 125477	ORIG - 1	CYRAMZA	RAMUCIRUMAB	ELI LILLY AND COMPANY	21-Apr-2014	Treatment of advanced gastric cancer or gastro-esophageal junction adenocarcinoma, as a single-agent after prior fluoropyrimidine-or platinum-containing therapy
NDA 204886	ORIG - 1	ZONTIVITY	VORAPAXAR SULFATE	ARALEZ PHARMACEUTICALS	08-May-2014	Reduction of thrombotic cardiovascular events in patients with a history of myocardial infarction (MI) or with peripheral arterial disease (PAD)
BLA 125476	ORIG - 1	ENTYVIO	VEDOLIZUMAB	TAKEDA PHARMACEUTICALS USA INC	20-May-2014	Inducing and maintaining clinical response, inducing and maintaining clinical remission, improving the endoscopic appearance of the mucosa, and achieving corticosteroid-free remission in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids
NDA 021883	ORIG - 1	DALVANCE	DALBAVANCIN HYDROCHLORIDE	ALLERGAN SALES LLC	23-May-2014	Treatment of acute bacterial skin and skin structure infections (ABSSSI)
NDA 206256	ORIG - 1	BELEODAQ	BELINOSTAT	ACROTECH BIOPHARMA LLC	03-Jul-2014	Treatment of patients with relapsed or refractory peripheral t-cell lymphoma
NDA 206545	ORIG - 1	ZYDELIG	IDELALISIB	GILEAD SCIENCES INC	23-Jul-2014	Treatment of relapsed chronic lymphocytic leukemia (CLL), in combination with rituximab, in patients for whom rituximab alone would be considered appropriate therapy due to other co-morbidities

NDA 203094	ORIG - 1	TYBOST	COBICISTAT	GILEAD SCIENCES INC	24-Sep-2014	Use as a CYP3A inhibitor indicated to increase systemic exposures of atazanavir in combination with other antiretroviral agents in the treatment of HIV-1 infection
NDA 205834	ORIG - 1	HARVONI	LEDIPASVIR AND SOFOBUVIR	GILEAD SCIENCES INC	10-Oct-2014	Treatment of chronic hepatitis C, genotype 1 infection
NDA 022535	ORIG - 1	ESBRIET	PIRFENIDONE	GENENTECH INC	15-Oct-2014	Treatment of idiopathic pulmonary fibrosis (IPF)
NDA 205832	ORIG - 1	OFEV	NINTEDANIB	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	15-Oct-2014	Treatment of idiopathic pulmonary fibrosis (IPF)
NDA 206426	ORIG - 1	RAPIVAB	PERAMIVIR	BIOCRYST PHARMACEUTICALS INC	19-Dec-2014	Treatment of influenza infections
NDA 206619	ORIG - 1	VIEKIRA PAK	DASABUVIR, OMBITASVIR, PARITAPREVIR, AND RITONAVIR	ABBVIE INC	19-Dec-2014	Treatment of patients with genotype 1 chronic hepatitis C virus (HCV) infection including those with compensated cirrhosis
NDA 206829	ORIG - 1	ZERBAXA	CEFTOLOZANE AND TAZOBACTAM	CUBIST PHARMACEUTICALS LLC	19-Dec-2014	Treatment of complicated Urinary Tract Infections (cUTI) and complicated Intra-Abdominal Infections (cIAI)
BLA 125554	ORIG - 1	OPDIVO	NIVOLUMAB	BRISTOL-MYERS SQUIBB COMPANY	22-Dec-2014	Treatment of unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor

NOTE: Approvals with Fast Track granted because the drug was qualified as a PEPFAR drug are excluded.