

CDER Breakthrough Therapy Designation Approvals

As of December 31, 2017

Application Number	Submission Type and Number	Proprietary Name	Established Name	Applicant*	Approval Date	Use
BLA 125554	SUPPLEMENT-55	OPDIVO	NIVOLUMAB	BRISTOL-MYERS SQUIBB COMPANY	20-Dec-2017	Adjuvant treatment of patients with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection
BLA 761083	ORIGINAL-1	HEMLIBRA	EMICIZUMAB-KXWH	GENENTECH INC	16-Nov-2017	Prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients with hemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors
BLA 125388	SUPPLEMENT-94	ADCETRIS	BRENTUXIMAB VEDOTIN	SEATTLE GENETICS INC	09-Nov-2017	Treatment of patients with primary cutaneous anaplastic large cell lymphoma or CD30-expressing mycosis fungoides who have received prior systemic therapy
NDA 209939	ORIGINAL-1	PREVYMIS	LETERMOVIR	MERCK SHARP AND DOHME CORP	08-Nov-2017	Prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT)
NDA 209940	ORIGINAL-1	PREVYMIS	LETERMOVIR	MERCK SHARP AND DOHME CORP	08-Nov-2017	Prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT)
NDA 202429	SUPPLEMENT-16	ZELBORAF	VEMURAFENIB	HOFFMANN-LA ROCHE INC	06-Nov-2017	Treatment of Erdheim-Chester disease with BRAF V600 mutation
NDA 208434	SUPPLEMENT-3	ALECENSA	ALECTINIB	HOFFMANN-LA ROCHE INC	06-Nov-2017	Treatment of patients with anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test
NDA 210259	ORIGINAL-1	CALQUENCE	ACALABRUTINIB	ASTRAZENECA UK LTD	31-Oct-2017	Treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy
NDA 208716	ORIGINAL-1	VERZENIO	ABEMACICLIB	ELI LILLY AND CO	28-Sep-2017	Treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting
NDA 209885	ORIGINAL-1	AUSTEDO	DEUTETRABENAZINE	TEVA BRANDED PHARMACEUTICAL PRODUCTS R AND D INC	30-Aug-2017	Treatment of tardive dyskinesia

BLA 761040	ORIGINAL-1	BESPOLSA	INOTUZUMAB OZOGAMICIN	WYETH PHARMACEUTICALS INC	17-Aug-2017	Treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)
NDA 209394	ORIGINAL-1	MAVYRET	GLECAPREVIR AND PIBRENTASVIR	ABBVIE INC	03-Aug-2017	Treatment of patients with chronic hepatitis C virus (HCV) genotype (GT) 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis; and also for patients with HCV GT1 infection who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both.
NDA 209401	ORIGINAL-1	VYXEOS	CYTARABINE AND DAUNORUBICIN	CELATOR PHARMACEUTICALS INC	03-Aug-2017	Treatment of adults with newly-diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC)
NDA 205552	SUPPLEMENT-17	IMBRUVICA	IBRUTINIB	PHARMACYCLICS LLC	02-Aug-2017	Treatment of adult patients with chronic graft versus host disease (cGVHD) after failure of one or more lines of systemic therapy
NDA 202806	SUPPLEMENT-6	TAFINLAR	DABRAFENIB	NOVARTIS PHARMACEUTICALS CORP	22-Jun-2017	Treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test
NDA 204114	SUPPLEMENT-5	MEKINIST	TRAMETINIB	NOVARTIS PHARMACEUTICALS CORP	22-Jun-2017	Treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test
NDA 205755	SUPPLEMENT-9	ZYKADIA	CERITINIB	NOVARTIS PHARMACEUTICALS CORP	26-May-2017	Treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test
BLA 125514	SUPPLEMENT-14	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME CORP	23-May-2017	Treatment of adult and pediatric patients with: • unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, or • metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.
BLA 125472	SUPPLEMENT-24	ACTEMRA	TOCILIZUMAB	GENENTECH INC	22-May-2017	Treatment of adult patients with giant cell arteritis (GCA)

BLA 125514	SUPPLEMENT-18	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME CORP	18-May-2017	Treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy
NDA 209935	ORIGINAL-1	KISQALI FEMARA CO-PACK	LETROZOLE AND RIBOCICLIB	NOVARTIS PHARMACEUTICALS CORP	04-May-2017	Treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer
BLA 761069	ORIGINAL-1	IMFINZI	DURVALUMAB	ASTRAZENECA UK LTD	01-May-2017	Treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy
NDA 207997	ORIGINAL-2	RYDAPT	MIDOSTAURIN	NOVARTIS PHARMACEUTICALS CORP	28-Apr-2017	Treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) that is FLT3 mutation-positive as detected by an FDA approved test, in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation
NDA 208772	ORIGINAL-1	ALUNBRIG	BRIGATINIB	ARIAD PHARMACEUTICALS INC	28-Apr-2017	Treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib
BLA 761052	ORIGINAL-1	BRINEURA	CERLIPONASE ALFA	BIOMARIN PHARMACEUTICAL INC	27-Apr-2017	Treatment of pediatric patients 3 years of age and older with late infantile neuronal ceroid lipofuscinosis type 2 (CLN2), also known as tripeptidyl peptidase 1 (TPP1) deficiency
NDA 209241	ORIGINAL-1	INGREZZA	VALBENAZINE	NEUROCRINE BIOSCIENCES INC	11-Apr-2017	Treatment of tardive dyskinesia
NDA 207103	SUPPLEMENT-4	IBRANCE	PALBOCICLIB	PFIZER INC	31-Mar-2017	Treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer, In combination with an aromatase inhibitor as initial endocrine-based therapy

BLA 761053	ORIGINAL-1	OCREVUS	OCRELIZUMAB	GENENTECH INC	28-Mar-2017	Treatment of adult patients with relapsing or primary progressive forms of multiple sclerosis
BLA 761055	ORIGINAL-1	DUPIXENT	DUPIUMAB	REGENERON PHARMACEUTICALS INC	28-Mar-2017	Treatment of adult patients with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. DUPIXENT can be used with or without topical corticosteroids
NDA 208447	ORIGINAL-1	ZEJULA	NIRAPARIB	TESARO INC	27-Mar-2017	Maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy
BLA 761049	ORIGINAL-1	BAVENCIO	AVELUMAB	EMD SERONO INC	23-Mar-2017	Treatment of adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma (MCC)
BLA 125514	SUPPLEMENT-15	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME CORP	14-Mar-2017	Treatment of patients with hematological malignancies: Hodgkin Lymphoma
NDA 209092	ORIGINAL-1	KISQALI	RIBOCICLIB	NOVARTIS PHARMACEUTICALS CORP	13-Mar-2017	Treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer as initial endocrine-based therapy
BLA 125554	SUPPLEMENT-24	OPDIVO	NIVOLUMAB	BRISTOL-MYERS SQUIBB COMPANY	02-Feb-2017	Treatment of locally advanced or metastatic urothelial carcinoma in patients who have disease progression during or following platinum-containing chemotherapy; have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy
NDA 209115	ORIGINAL-1	RUBRACA	RUCAPARIB	CLOVIS ONCOLOGY INC	19-Dec-2016	Treatment of patients with deleterious BRCA mutation (germline and/or somatic) associated advanced ovarian cancer who have been treated with two or more chemotherapies
BLA 761036	SUPPLEMENT-3	DARZALEX	DARATUMUMAB	JANSSEN BIOTECH INC	21-Nov-2016	Treatment of patients with multiple myeloma who have received at least one prior therapy, in combination with lenalidomide and dexamethasone

BLA 761036	SUPPLEMENT-4	DARZALEX	DARATUMUMAB	JANSSEN BIOTECH INC	21-Nov-2016	Treatment of patients with multiple myeloma who have received at least one prior therapy, combination with bortezomib and dexamethasone
BLA 125554	SUPPLEMENT-22	OPDIVO	NIVOLUMAB	BRISTOL-MYERS SQUIBB COMPANY	10-Nov-2016	Treatment of patients with recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN) with disease progression on or after platinum based therapy
BLA 761038	ORIGINAL-1	LARTRUVO	OLARATUMAB	ELI LILLY AND COMPANY	19-Oct-2016	Treatment of adult patients with soft tissue sarcoma (STS) with a histologic subtype, in combination with doxorubicin, for which an anthracycline-containing regimen is appropriate and which is not amenable to curative treatment with radiotherapy or surgery
BLA 761041	ORIGINAL-1	TECENTRIQ	ATEZOLIZUMAB	GENENTECH INC	18-Oct-2016	Treatment of patients with metastatic non-small cell lung cancer who have disease progression during or following platinum-containing chemotherapy
NDA 206038	SUPPLEMENT-5	ORKAMBI	LUMACAFITOR and IVACAFITOR	VERTEX PHARMACEUTICALS INC	28-Sep-2016	Treatment of cystic fibrosis patients who are homozygous for the F508del mutation in the CFTR gene, ages 6-11
BLA 125319	SUPPLEMENT-85	ILARIS	CANAKINUMAB	NOVARTIS PHARMACEUTICALS CORPORATION	23-Sep-2016	Treatment of Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)
BLA 125319	SUPPLEMENT-86	ILARIS	CANAKINUMAB	NOVARTIS PHARMACEUTICALS CORPORATION	23-Sep-2016	Treatment of Hyperimmunoglobulin D Syndrome (HIDS)
BLA 125319	SUPPLEMENT-87	ILARIS	CANAKINUMAB	NOVARTIS PHARMACEUTICALS CORPORATION	23-Sep-2016	Treatment of Familial Mediterranean Fever (FMF)
NDA 208341	ORIGINAL-1	EPCLUSA	SOFOSBUVIR and VELPATASVIR	GILEAD SCIENCES INC	28-Jun-2016	Treatment of adult patients with chronic hepatitis C virus (HCV) genotypes 1, 2, 3, 4, 5 or 6 infection: - without cirrhosis or with compensated cirrhosis - with decompensated cirrhosis for use in combination with ribavirin
BLA 761034	ORIGINAL-1	TECENTRIQ	ATEZOLIZUMAB	GENENTECH INC	18-May-2016	Treatment of locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy

BLA 125554	SUPPLEMENT-19	OPDIVO	NIVOLUMAB	BRISTOL-MYERS SQUIBB COMPANY	17-May-2016	Treatment of Hodgkin Lymphoma
NDA 206947	SUPPLEMENT-3	LENVIMA	LENVATINIB MESYLATEL	EISAI INC	13-May-2016	Treatment of renal cell cancer (RCC): in combination with everolimus, for patients with advanced RCC following one prior anti-angiogenic therapy
NDA 207318	ORIGINAL-1	NUPLAZID	PIMAVANSERIN	ACADIA PHARMACEUTICALS INC	29-Apr-2016	Treatment of hallucinations and delusions associated with Parkinson's disease psychosis
NDA 208692	ORIGINAL-1	CABOTETYX	CABOZANTINIB	EXELIXIS INC	25-Apr-2016	Treatment of patients with advanced renal cell carcinoma (RCC) who have received prior anti-angiogenic therapy
NDA 208573	ORIGINAL-1	VENCLEXTA	VENETOCLAX	ABBVIE INC	11-Apr-2016	Treatment of patients with chronic lymphocytic leukemia (CLL) with 17p deletion who have received at least one prior therapy
NDA 202570	SUPPLEMENT-16	XALKORI	CRIZOTINIB	PF PRISM CV	11-Mar-2016	Treatment of patients with non-small cell lung cancer whose tumors are ROS-1 positive
NDA 207103	SUPPLEMENT-2	IBRANCE	PALBOCICLIB	PFIZER INC	19-Feb-2016	Treatment hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with fulvestrant in women with disease progression following endocrine therapy
NDA 208261	ORIGINAL-1	ZEPATIER	GRAZOPREVIR and ELBASVIR	MERCK SHARP AND DOHME CORP	28-Jan-2016	Treatment of chronic hepatitis C virus (HCV) genotypes 1 and 4 infections in adults
BLA 125514	SUPPLEMENT-6	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME CORP	18-Dec-2015	Treatment of patients with unresectable or metastatic melanoma
NDA 208434	ORIGINAL-1	ALECENSA	ALECTINIB	HOFFMANN-LA ROCHE INC	11-Dec-2015	Treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC), who have progressed on or are intolerant to crizotinib
BLA 125561	ORIGINAL-1	KANUMA	SEBELIPASE ALFA	SYNAGEVA BIOPHARMA CORP	08-Dec-2015	Treatment of patients with a diagnosis of lysosomal acid lipase (LAL) deficiency
BLA 761035	ORIGINAL-1	EMPLICITI	ELOTUZUMAB	BRISTOL-MYERS SQUIBB COMPANY	30-Nov-2015	Treatment of patients with multiple myeloma who have received one to three prior therapies
BLA 125554	SUPPLEMENT-12	OPDIVO	NIVOLUMAB	BRISTOL-MYERS SQUIBB COMPANY	23-Nov-2015	Treatment of advanced renal cell carcinoma patients who have received prior antiangiogenic therapy

BLA 761036	ORIGINAL-1	DARZALEX	DARATUMUMAB	JANSSEN BIOTECH INC	16-Nov-2015	Treatment of patients with multiple myeloma who have received at least 3 prior lines of therapy including a proteasome inhibitor and an immunomodulatory agent or are double refractory to a proteasome inhibitor and an immunomodulatory agent
NDA 208065	ORIGINAL-1	TAGRISSO	OSIMERTINIB	ASTRAZENECA PHARMACEUTICALS LP	13-Nov-2015	Treatment of patients with metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive-non-small-cell lung cancer (NSCLC), as detected by an FDA approved test, who have progressed on or after EGFR TKI therapy
BLA 125513	ORIGINAL-1	STRENSIQ	ASFOTASE ALFA	ALEXION PHARMACEUTICALS INC	23-Oct-2015	Treatment of patients with perinatal/infantile- and juvenile-onset hypophosphatasia (HPP)
BLA 761025	ORIGINAL-1	PRAXBIND	IDARUCIZUMAB	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	16-Oct-2015	Treatment of patients treated with Pradaxa® when reversal of the anticoagulant effects of dabigatran is needed for emergency surgery/urgent procedures and in life-threatening or uncontrolled bleeding
BLA 125554	SUPPLEMENT-5	OPDIVO	NIVOLUMAB	BRISTOL-MYERS SQUIBB COMPANY	09-Oct-2015	Treatment of patients with metastatic non-squamous non-small cell lung cancer (NSCLC) with progression on or after platinum-based chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving OPDIVO
BLA 125514	SUPPLEMENT-5	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME CORP	02-Oct-2015	Treatment of patients with metastatic, PD-L1 positive, non-small cell lung cancer (NSCLC), as determined by an FDA-approved test, with disease progression on or after platinum-containing chemotherapy
NDA 208169	ORIGINAL-1	XURIDEN	URIDINE TRIACETATE	WELLSTAT THERAPEUTICS CORP	04-Sep-2015	Treatment of hereditary orotic aciduria
NDA 207931	ORIGINAL-1	TECHNIVIE	OMBITASVIR, PARITAPREVIR, RITONAVIR	ABBVIE INC	24-Jul-2015	Treatment of patients with genotype 4 chronic hepatitis C virus (HCV) infection without cirrhosis
NDA 206038	ORIGINAL-1	ORKAMBI	LUMACAFTOR/IVACAFTOR	VERTEX PHARMACEUTICALS INC	02-Jul-2015	Treatment of cystic fibrosis (CF) in patients age 12 years and older who are homozygous for the F508del mutation in the CFTR gene
NDA 021083	SUPPLEMENT-55	RAPAMUNE	SIROLIMUS	PF PRISM CV	28-May-2015	Treatment of patients with lymphangioleiomyomatosis (LAM)
NDA 021110	SUPPLEMENT-73	RAPAMUNE	SIROLIMUS	PF PRISM CV	28-May-2015	Treatment of patients with lymphangioleiomyomatosis (LAM)

BLA 125387	SUPPLEMENT-48	EYLEA	AFLIBERCEPT	REGENERON PHARMACEUTICALS INC	25-Mar-2015	Treatment of diabetic retinopathy (DR) in patients with diabetic macular edema (DME)
NDA 207925	ORIGINAL-1	KALYDECO	IVACAFTOR	VERTEX PHARMACEUTICALS INC	17-Mar-2015	Treatment of cystic fibrosis patients 2 years and older who have one of the following mutations in CFTR gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, S549R, and R117H
BLA 125156	SUPPLEMENT-106	LUCENTIS	RANIBIZUMAB	GENENTECH INC	06-Feb-2015	Treatment of Diabetic Retinopathy (DR) in patients with Diabetic Macula Edema (DME)
NDA 207103	ORIGINAL-1	IBRANCE	PALBOCICLIB	PFIZER INC	03-Feb-2015	Treatment of postmenopausal women with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer as initial endocrine-based therapy for their metastatic disease
NDA 205552	SUPPLEMENT-2	IMBRUVICA	IBRUTINIB	PHARMACYCLICS LLC	29-Jan-2015	Treatment of patients with Waldenström's macroglobulinemia
NDA 203188	SUPPLEMENT-14	KALYDECO	IVACAFTOR	VERTEX PHARMACEUTICALS INC	29-Dec-2014	Treatment of cystic fibrosis in patients age 6 years and older who have the R117H mutation in the CF transmembrane conductance regulator (CFTR) gene
BLA 125554	ORIGINAL-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
NDA 206619	ORIGINAL-1	VIEKIRA PAK	OMBITASVIR, PARITAPREVIR, RITONAVIR	ABBVIE INC	19-Dec-2014	Treatment of patients with genotype 1 chronic hepatitis C virus (HCV) infection including those with compensated cirrhosis
BLA 125557	ORIGINAL-1	BLINCYTO	BLINTUMOMAB	AMGEN INC	03-Dec-2014	Treatment of Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)
NDA 022535	ORIGINAL-1	ESBRIET	PIRFENIDONE	GENENTECH INC	15-Oct-2014	Treatment of idiopathic pulmonary fibrosis (IPF)
NDA 205832	ORIGINAL-1	OFEV	NINTEDANIB	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	15-Oct-2014	Treatment of idiopathic pulmonary fibrosis (IPF)
NDA 205834	ORIGINAL-1	HARVONI	SOFOSBUVIR/LEDIPASVIR	GILEAD SCIENCES INC	10-Oct-2014	Treatment of chronic hepatitis C, genotype 1 infection
BLA 125514	ORIGINAL-1	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME CORP	04-Sep-2014	Treatment of patients with unresectable or metastatic melanoma & disease progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor

NDA 022291	SUPPLEMENT-12	PROMACTA	ELTROMBOPAG	NOVARTIS PHARMACEUTICALS CORP	26-Aug-2014	Treatment of cytopenias in patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy
NDA 205552	SUPPLEMENT-1	IMBRUVICA	IBRUTINIB	PHARMACYCLICS LLC	28-Jul-2014	Treatment of patients with chronic lymphocytic leukemia (CLL) who have received at least one prior therapy and CLL with 17p deletion
NDA 206545	ORIGINAL-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 205755	ORIGINAL-1	ZYKADIA	CERITINIB	NOVARTIS PHARMACEUTICALS CORP	29-Apr-2014	Treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib
BLA 125326	SUPPLEMENT-60	ARZERRA	OFATUMUMAB	NOVARTIS PHARMACEUTICALS CORPORATION	17-Apr-2014	Treatment of previously untreated patients with chronic lymphocytic leukemia (CLL) for whom fludarabine-based therapy is considered inappropriate
NDA 203188	SUPPLEMENT-4	KALYDECO	IVACAFTOR	VERTEX PHARMACEUTICALS INC	21-Feb-2014	Treatment of cystic fibrosis patients age 6 years and older who have mutations in the CFTR gene
NDA 204671	ORIGINAL-1	SOVALDI	SOFOSBUVIR	GILEAD SCIENCES INC	06-Dec-2013	Treatment of chronic hepatitis C infection
NDA 205552	ORIGINAL-1	IMBRUVICA	IBRUTINIB	PHARMACYCLICS LLC	13-Nov-2013	Treatment of patients with mantle cell lymphoma (MCL)
BLA 125486	ORIGINAL-1	GAZYVA	OBINUTUZUMAB	GENENTECH INC	01-Nov-2013	Treatment of patients with previously untreated chronic lymphocytic leukemia in combination with chlorambucil

Breakthrough Therapy designation was enacted in the Food and Drug Administration Safety and Innovation Act on July 9, 2012. There were no approvals in CY 2012.