CDER Drug and Biologic Accelerated Approvals Based on a Surrogate Endpoint
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Total Approvals 333

NDA and BLA Accelerated Approvals

Application Number	Proprietary Name	Established Name	Applicant	FDA Received Date	Accelerated Approval Date	Total Time to Accelerated Approval (Months)	Accelerated Approval Indication	Conversion-Withdrawal Status	Full Approval Conversion-Withdrawal Date
BLA 761464	DATROWAY	DATOPOTAMAB DERUXTECAN-DLNK	DAIICHI SANKYO, INC.	11/12/2024	6/23/2025	7.3	TREATMENT OF ADULT PATIENTS WITH LOCALLY ADVANCED OR METASTATIC EPIDERMAL GROWTH FACTOR RECEPTOR (EGFR)-MUTATED NON-SMALL CELL LUNG CANCER (NSCLC) WHO HAVE RECEIVED PRIOR EGFR DIRECTED THERAPY AND PLATINUM-BASED CHEMOTHERAPY	Not Yet Converted	
NDA 218785 Original 2	BRUKINSA (TABLET)	ZANUBRUTINIB	BEONE MEDICINES	8/30/2024	6/10/2025	9.3	TREATMENT OF ADULT PATIENTS WITH MANTLE CELL LYMPHOMA (MCL) WHO HAVE RECEIVED AT LEAST ONE PRIOR THERAPY; TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY MARGINAL ZONE LYMPHOMA (MZL) WHO HAVE RECEIVED AT LEAST ONE ANTI-CD20-BASED REGIMEN; TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY FOLLICULAR LYMPHOMA (FL), IN COMBINATION WITH OBINUTUZUMAB, AFTER TWO OR MORE LINES OF SYSTEMIC THERAPY	Not Yet Converted	
BLA 761384	EMRELIS	TELISOTUZUMAB VEDOTIN-TLLV	ABBVIE INC.	9/27/2024	5/14/2025	7.5	TREATMENT OF ADULT PATIENTS WITH LOCALLY ADVANCED OR METASTATIC, NON-SQUAMOUS NON-SMALL CELL LUNG CANCER (NSCLC) WITH HIGH C-MET PROTEIN OVEREXPRESSION [≥50% OF TUMOR CELLS WITH STRONG (3+) STAINING], AS DETERMINED BY AN FDA-APPROVED TEST, WHO HAVE RECEIVED A PRIOR SYSTEMIC THERAPY	Not Yet Converted	
NDA 219616	AVMAPKI FAKZYNJA CO-PACK	AVUTOMETINIB, DEFACTINIB	VERASTEM INC.	10/31/2024	5/8/2025	6.2	TREATMENT OF ADULT PATIENTS WITH KRAS-MUTATED RECURRENT LOW-GRADE SEROUS OVARIAN CANCER (LGSOC) WHO HAVE RECEIVED PRIOR SYSTEMIC THERAPY	Not Yet Converted	
NDA 219208	VANRAFIA	ATRASENTAN	NOVARTIS PHARMACEUTICALS CORP	4/2/2024	4/2/2025	12.0	TO REDUCE PROTEINURIA IN ADULTS WITH PRIMARY IMMUNOGLOBULIN A NEPHROPATHY (IGAN) AT RISK OF RAPID DISEASE PROGRESSION, GENERALLY A URINE PROTEIN-TO-CREATININE RATIO (UPCR) ≥ 1.5 G/G.	Not Yet Converted	
BLA 761381	OPDIVO QVANTIG	NIVOLUMAB HYALURONIDASE-NVHY	BRISTOL-MYERS SQUIBB COMPANY	2/29/2024	12/27/2024	9.9	FOR THE TREATMENT OF ADULT PATIENTS WITH MSI-H OR DMMR METASTATIC COLORECTAL CANCER (CRC) THAT HAS PROGRESSED FOLLOWING TREATMENT WITH A FLUOROPYRIMIDINE, OXALIPLATIN, AND IRINOTECAN, AS MONOTHERAPY OR AS MONOTHERAPY FOLLOWING COMBINATION TREATMENT WITH INTRAVENOUS NIVOLUMAB AND IPILIMUMAB	Not Yet Converted	
BLA 761381	OPDIVO QVANTIG	NIVOLUMAB HYALURONIDASE-NVHY	BRISTOL-MYERS SQUIBB COMPANY	2/29/2024	12/27/2024	9.9	FOR THE TREATMENT OF ADULT PATIENTS WITH HEPATOCELLULAR CARCINOMA (HCC) PREVIOUSLY TREATED WITH SORAFENIB AND FOLLOWING COMBINATION TREATMENT WITH INTRAVENOUS NIVOLUMAB AND IPILIMUMAB	Not Yet Converted	
NDA 210496 Supplement 17	BRAFTOVI	ENCORAFENIB	ARRAY BIOPHARMA INC	7/1/2024	12/20/2024	5.7	IN COMBINATION WITH CETUXIMAB AND MFOLFOX6, FOR THE TREATMENT OF PATIENTS WITH METASTATIC COLORECTAL CANCER (CRC) WITH A BRAF V600E MUTATION, AS DETECTED BY AN FDA-APPROVED TEST	Not Yet Converted	
BLA 761352	BIZENGRI	ZENOCUTUZUMAB-ZBCO	MERUS NV	3/4/2024	12/4/2024	9.0	FOR THE TREATMENT OF ADULTS WITH ADVANCED, UNRESECTABLE OR METASTATIC PANCREATIC ADENOCARCINOMA HARBORING AN NRG1 GENE FUSION WITH DISEASE PROGRESSION ON OR AFTER PRIOR SYSTEMIC THERAPY	Not Yet Converted	
BLA 761352	BIZENGRI	ZENOCUTUZUMAB-ZBCO	MERUS NV	3/4/2024	12/4/2024	9.0	FOR THE TREATMENT OF ADULTS WITH ADVANCED, UNRESECTABLE OR METASTATIC NON-SMALL CELL LUNG CANCER HARBORING A NEUREGULIN 1 (NRG1) GENE FUSION WITH DISEASE PROGRESSION ON OR AFTER PRIOR SYSTEMIC THERAPY	Not Yet Converted	
BLA 761416	ZIIHERA	ZANIDATAMAB-HRII	JAZZ PHARMACEUTICALS IRELAND LIMITED	3/29/2024	11/20/2024	7.8	FOR THE TREATMENT OF ADULTS WITH PREVIOUSLY TREATED, UNRESECTABLE OR METASTATIC HER2-POSITIVE (IHC3+) BILIARY TRACT CANCER AS DETECTED BY AN FDA APPROVED TEST	Not Yet Converted	
NDA 215358 Supplement 8	SCEMBLIX	ASCIMINIB	NOVARTIS PHARMACEUTICALS CORP	5/29/2024	10/29/2024	5.0	FOR THE TREATMENT OF ADULT PATIENTS WITH NEWLY DIAGNOSED PHILADELPHIA CHROMOSOME-POSITIVE CHRONIC MYELOID LEUKEMIA (PH+ CML) IN CHRONIC PHASE (CP)	Not Yet Converted	
NDA 217899	LIVDELZI	SELADELPAR	CYMABAY THERAPEUTICS INC	12/14/2023	8/14/2024	8.0	FOR THE TREATMENT OF PRIMARY BILIARY CHOLANGITIS (PBC) IN COMBINATION WITH URSODEOXYCHOLIC ACID (UDCA) IN ADULTS WHO HAVE AN INADEQUATE RESPONSE TO UDCA, OR AS MONOTHERAPY IN PATIENTS UNABLE TO TOLERATE UDCA	Not Yet Converted	
NDA 218276 Supplement 1	FABHALTA	IPTACOPAN	NOVARTIS PHARMACEUTICALS CORP	2/7/2024	8/7/2024	6.0	FOR THE REDUCTION OF PROTEINURIA IN ADULTS WITH PRIMARY IMMUNOGLOBULIN A NEPHROPATHY (IGAN) AT RISK OF RAPID DISEASE PROGRESSION, GENERALLY A URINE PROTEIN-TO-CREATININE RATIO (UPCR) ≥1.5 G/G	Not Yet Converted	

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BLA 761324 Supplement 3	EPKINLY	EPCORITAMAB-BYSP	GENMAB US INC	12/28/2023	6/26/2024	6.0	FOR THE TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY FOLLICULAR LYMPHOMA (FL) AFTER TWO OR MORE LINES OF SYSTEMIC THERAPY	Not Yet Converted	
NDA 216340 Supplement 5	KRAZATI	ADAGRASIB	MIRATI THERAPEUTICS INC	12/21/2023	6/21/2024	6.0	IN COMBINATION WITH CETUXIMAB FOR THE TREATMENT OF ADULT PATIENTS WITH KRAS G12C-MUTATED LOCALLY ADVANCED OR METASTATIC COLORECTAL CANCER WHO HAVE BEEN PREVIOUSLY TREATED WITH FLUOROPYRIMIDINE-, OXALIPLATIN-, AND IRINOTECAN-BASED CHEMOTHERAPY	Not Yet Converted	
NDA 218213 Supplement 1	AUGTYRO	REPOTRECTINIB	BRISTOL MYERS SQUIBB CO	12/15/2023	6/13/2024	6.0	FOR THE TREATMENT OF ADULT AND PEDIATRIC PATIENTS 12 YEARS OF AGE AND OLDER WITH SOLID TUMORS THAT: • HAVE A NEUROTROPHIC TYROSINE RECEPTOR KINASE (NTRK) GENE FUSION, • ARE LOCALLY ADVANCED OR METASTATIC OR WHERE SURGICAL RESECTION IS LIKELY TO RESULT IN SEVERE MORBIDITY, AND • HAVE PROGRESSED FOLLOWING TREATMENT OR HAVE NO SATISFACTORY ALTERNATIVE THERAPY	Not Yet Converted	
NDA 218860	IQIRVO	ELAFIBRANOR	IPSEN BIOPHARMACEUTICALS INC	10/10/2023	6/10/2024	8.0	FOR THE TREATMENT OF PRIMARY BILIARY CHOLANGITIS (PBC), IN COMBINATION WITH URSODEOXYCHOLIC ACID (UDCA) IN ADULTS WITH AN INADEQUATE RESPONSE TO UDCA, OR AS MONOTHERAPY IN ADULTS UNABLE TO TOLERATE UDCA	Not Yet Converted	
NDA 213246 Supplement 12	RETEVMO	SELPERCATINIB	LOXO ONCOLOGY INC	12/13/2023	5/29/2024	5.5	FOR THE TREATMENT OF PEDIATRIC PATIENTS 2 YEARS OF AGE AND OLDER WITH RET-ACTIVATED SOLID TUMORS	Not Yet Converted	
BLA 761344	IMDELLTRA	TARLATAMAB-DLLE	AMGEN INC	10/12/2023	5/16/2024	7.1	FOR THE TREATMENT OF ADULT PATIENTS WITH EXTENSIVE STAGE SMALL CELL LUNG CANCER (ES-SCLC) WITH DISEASE PROGRESSION ON OR AFTER PLATINUM-BASED CHEMOTHERAPY	Not Yet Converted	
NDA 218033	OJEMDA Oral Suspension	TOVORAFENIB	DAY ONE BIOPHARMACEUTICALS INC	8/31/2023	4/23/2024	7.8	FOR TREATMENT OF PATIENTS 6 MONTHS OF AGE AND OLDER WITH RELAPSED OR REFRACTORY PEDIATRIC LOW-GRADE GLIOMA (LGG) HARBORING A BRAF FUSION OR REARRANGEMENT, OR BRAF V600 MUTATION	Not Yet Converted	
NDA 217700	OJEMDA Tablets	TOVORAFENIB	DAY ONE BIOPHARMACEUTICALS INC	8/31/2023	4/23/2024	7.8	FOR TREATMENT OF PATIENTS 6 MONTHS OF AGE AND OLDER WITH RELAPSED OR REFRACTORY PEDIATRIC LOW-GRADE GLIOMA (LGG) HARBORING A BRAF FUSION OR REARRANGEMENT, OR BRAF V600 MUTATION	Not Yet Converted	
BLA 761139 Supplement 28	ENHERTU	FAM-TRASTUZUMAB DERUXTECAN-NXKI	DAIICHI SANKYO INC	11/30/2023	4/5/2024	4.2	FOR THE TREATMENT OF ADULT PATIENTS WITH UNRESECTABLE OR METASTATIC HER2-POSITIVE (IHC 3+) SOLID TUMORS WHO HAVE RECEIVED PRIOR SYSTEMIC TREATMENT AND HAVE NO SATISFACTORY ALTERNATIVE TREATMENT OPTIONS	Not Yet Converted	
NDA 203469 Supplement 37	ICLUSIG	PONATINIB	TAKEDA PHARMACEUTICALS USA INC	9/21/2023	3/19/2024	5.9	FOR THE TREATMENT OF ADULT PATIENTS WITH NEWLY DIAGNOSED PHILADELPHIA CHROMOSOME-POSITIVE ACUTE LYMPHOBLASTIC LEUKEMIA (PH+ ALL) IN COMBINATION WITH CHEMOTHERAPY	Not Yet Converted	
NDA 217785	REZDIFFRA	RESMETIROM	MADRIGAL PHARMACEUTICALS INC	7/14/2023	3/14/2024	8.0	IN CONJUNCTION WITH DIET AND EXERCISE, FOR THE TREATMENT OF ADULTS WITH NONCIRRHOTIC NONALCOHOLIC STEATOHEPATITIS (NASH) WITH MODERATE TO ADVANCED LIVER FIBROSIS (CONSISTENT WITH STAGES F2 TO F3 FIBROSIS)	Not Yet Converted	
NDA 213217 Supplement 11	BRUKINSA	ZANUBRUTINIB	BEIGENE USA INC	5/11/2023	3/7/2024	9.9	FOR THE TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY FOLLICULAR LYMPHOMA (FL), IN COMBINATION WITH OBINUTUZUMAB, AFTER TWO OR MORE LINES OF SYSTEMIC THERAPY	Not Yet Converted	
NDA 216059 Supplement 1	JAYPIRCA	PIRTOBRUTINIB	LOXO ONCOLOGY INC	6/2/2023	12/1/2023	6.0	FOR THE TREATMENT OF ADULT PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA OR SMALL LYMPHOCYTIC LYMPHOMA (CLL/SLL) WHO HAVE RECEIVED AT LEAST TWO PRIOR LINES OF THERAPY, INCLUDING A BTK INHIBITOR AND A BCL-2 INHIBITOR	Not Yet Converted	
BLA 125514 Supplement 148	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME LLC	8/4/2023	11/7/2023	3.1	IN COMBINATION WITH TRASTUZUMAB, FLUOROPYRIMIDINE AND PLATINUM-CONTAINING CHEMOTHERAPY, FOR THE FIRST-LINE TREATMENT OF PATIENTS WITH LOCALLY ADVANCED UNRESECTABLE OR METASTATIC HER2-POSITIVE GASTRIC OR GASTROESOPHAGEAL JUNCTION (GEJ) ADENOCARCINOMA	Converted	3/19/2025
NDA 214938 Supplement 2	VOXZOGO	VOSORITIDE	BIOMARIN PHARMACEUTICAL INC	12/21/2022	10/20/2023	10.0	INJECTION FOR THE TREATMENT OF ALL PEDIATRIC PATIENTS TO INCREASE LINEAR GROWTH IN PATIENTS WITH ACHONDROPLASIA WITH OPEN EPIPHYSES	Not Yet Converted	

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NDA 212725 Supplement 9	ROZLYTREK	ENTRECTINIB	GENENTECH INC	4/28/2023	10/20/2023	5.7	FOR TREATMENT OF ADULT AND PEDIATRIC PATIENTS OLDER THAN 1 MONTH OF AGE WITH SOLID TUMORS THAT HAVE A NEUROTROPHIC TYROSINE RECEPTOR KINASE (NTRK) GENE FUSION WITHOUT A KNOWN ACQUIRED RESISTANCE MUTATION AS DETECTED BY AN FDA-APPROVED TEST, ARE METASTATIC OR WHERE SURGICAL RESECTION IS LIKELY TO RESULT IN SEVERE MORBIDITY, AND HAVE PROGRESSED FOLLOWING TREATMENT OR HAVE NO SATISFACTORY ALTERNATIVE THERAPY, AND FOR A NEW ROUTE AND METHOD OF ADMINISTRATION FOR CAPSULES PREPARED AS AN ORAL SUSPENSION	Not Yet Converted	
NDA 218550	ROZLYTREK	ENTRECTINIB	GENENTECH INC	4/28/2023	10/20/2023	5.7	FOR THE TREATMENT OF ADULT AND PEDIATRIC PATIENTS OLDER THAN 1 MONTH OF AGE WITH SOLID TUMORS THAT HAVE A NEUROTROPHIC TYROSINE RECEPTOR KINASE (NTRK) GENE FUSION WITHOUT A KNOWN ACQUIRED RESISTANCE MUTATION AS DETECTED BY AN FDA-APPROVED TEST, ARE METASTATIC OR WHERE SURGICAL RESECTION IS LIKELY TO RESULT IN SEVERE MORBIDITY, AND HAVE PROGRESSED FOLLOWING TREATMENT OR HAVE NO SATISFACTORY ALTERNATIVE THERAPY	Not Yet Converted	
BLA 761345	ELREXFIO	ELRANATAMAB-BCMM	PFIZER INC	12/19/2022	8/14/2023	7.8	FOR THE TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY MULTIPLE MYELOMA WHO HAVE RECEIVED AT LEAST FOUR PRIOR LINES OF THERAPY, INCLUDING A PROTEASOME INHIBITOR, AN IMMUNOMODULATORY AGENT, AND AN ANTI-CD38 MONOCLONAL ANTIBODY	Not Yet Converted	
BLA 761342	TALVEY	TALQUETAMAB-TGVS	JANSSEN BIOTECH INC	12/9/2022	8/9/2023	8.0	FOR THE TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY MULTIPLE MYELOMA WHO HAVE RECEIVED AT LEAST FOUR PRIOR LINES OF THERAPY, INCLUDING A PROTEASOME INHIBITOR, AN IMMUNOMODULATORY AGENT AND AN ANTI-CD38 MONOCLONAL ANTIBODY	Not Yet Converted	
BLA 761309	COLUMVI	GLOFITAMAB-GXBM	GENENTECH, INC	11/1/2022	6/15/2023	7.4	FOR THE TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY DIFFUSE LARGE B-CELL LYMPHOMA, NOT OTHERWISE SPECIFIED (DLBCL, NOS) OR LARGE B-CELL LYMPHOMA (LBCL) ARISING FROM FOLLICULAR LYMPHOMA, AFTER TWO OR MORE LINES OF SYSTEMIC THERAPY	Not Yet Converted	
BLA 761324	EPKINLY	EPCORITAMAB-BYSP	GENMAB US INC	9/21/2022	5/19/2023	7.9	FOR THE TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY DIFFUSE LARGE B-CELL LYMPHOMA (DLBCL), NOT OTHERWISE SPECIFIED, INCLUDING DLBCL ARISING FROM INDOLENT LYMPHOMA, AND HIGH-GRADE B CELL LYMPHOMA AFTER TWO OR MORE LINES OF SYSTEMIC THERAPY	Not Yet Converted	
NDA 215887	QALSODY	TOFERSEN	BIOGEN INC	5/25/2022	4/25/2023	11.0	FOR THE TREATMENT OF AMYOTROPHIC LATERAL SCLEROSIS (ALS) IN ADULTS WHO HAVE A MUTATION IN THE SUPEROXIDE DISMUTASE 1 (SOD1) GENE	Not Yet Converted	
BLA 125514 Supplement 136	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME CORP	10/21/2022	4/3/2023	5.4	IN COMBINATION WITH ENFORTUMAB VEDOTIN FOR THE TREATMENT OF ADULT PATIENTS WITH LOCALLY ADVANCED OR METASTATIC UROTHELIAL CARCINOMA WHO ARE NOT ELIGIBLE FOR CISPLATIN-CONTAINING CHEMOTHERAPY	Converted	12/15/2023
BLA 761137 Supplement 18	PADCEV	ENFORTUMAB VEDOTIAN-EJFV	ASTELLAS PHARMA US INC	10/21/2022	4/3/2023	5.4	IN COMBINATION WITH PEMBROLIZUMAB FOR THE TREATMENT OF ADULT PATIENTS WITH LOCALLY ADVANCED OR METASTATIC UROTHELIAL CANCER (MUC) WHO ARE NOT ELIGIBLE FOR CISPLATIN-CONTAINING CHEMOTHERAPY	Converted	12/15/2023
BLA 761334	ZYNYZ	RETIFANLIMAB-DLWR	INCYTE CORP	8/8/2022	3/22/2023	7.4	FOR THE TREATMENT OF ADULT PATIENTS WITH METASTATIC OR RECURRENT LOCALLY ADVANCED MERKEL CELL CARCINOMA	Not Yet Converted	
NDA 216403	FILSPARI	SPARSENTAN	TRAVERE THERAPEUTICS INC	3/17/2022	2/17/2023	11.1	TO REDUCE PROTEINURIA IN ADULTS WITH PRIMARY IMMUNOGLOBULIN A NEPHROPATHY (IGAN) AT RISK OF RAPID DISEASE PROGRESSION, GENERALLY A URINE PROTEIN TO CREATININE RATIO (UPCR) ≥1.5 G/G	Converted	9/5/2024
NDA 216059	JAYPIRCA	PIRTOBRUTINIB	LOXO ONCOLOGY INC	5/27/2022	1/27/2023	8.0	FOR THE TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY MANTLE CELL LYMPHOMA AFTER AT LEAST TWO LINES OF SYSTEMIC THERAPY, INCLUDING A BTK INHIBITOR	Not Yet Converted	
NDA 213411 Supplement 4	TUKYSA	TUCATINIB	SEAGEN INC	7/19/2022	1/19/2023	6.0	IN COMBINATION WITH TRASTUZUMAB FOR THE TREATMENT OF ADULT PATIENTS WITH RAS WILD-TYPE, HER2-POSITIVE, UNRESECTABLE OR METASTATIC COLORECTAL CANCER THAT HAS PROGRESSED FOLLOWING TREATMENT WITH FLUOROPYRIMIDINE-, OXALIPLATIN-, AND IRINOTECAN-BASED CHEMOTHERAPY	Not Yet Converted	
BLA 761269	LEQEMBI	LECANEMAB-IRMB	EISAI INC	5/6/2022	1/6/2023	8.0	FOR THE TREATMENT OF ALZHEIMER'S DISEASE	Converted	7/6/2023
BLA 761263	LUNSUMIO	MOSUNETUZUMAB-AXGB	GENENTECH INC	4/29/2022	12/22/2022	7.8	FOR THE TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY FOLLICULAR LYMPHOMA AFTER TWO OR MORE LINES OF SYSTEMIC THERAPY	Not Yet Converted	

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NDA 216340	KRAZATI	ADAGRASIB	MIRATI THERAPEUTICS INC	12/14/2021	12/12/2022	11.9	FOR TREATMENT OF ADULT PATIENTS WITH KRAS G12C-MUTATED LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC), AS DETERMINED BY AN FDA APPROVED TEST, WHO HAVE RECEIVED AT LEAST ONE PRIOR SYSTEMIC THERAPY	Not Yet Converted	
BLA 761310	ELAHERE	MIRVETUXIMAB SORAVTANSINE-GYNX	IMMUNOGEN INC	3/28/2022	11/14/2022	7.6	FOR THE TREATMENT OF ADULT PATIENTS WITH FOLATE-α (FRα)-POSITIVE, PLATINUM-RESISTANT EPITHELIAL OVARIAN, FALLOPIAN TUBE, OR PRIMARY PERITONEAL CANCER, WHO HAVE RECEIVED ONE TO THREE PRIOR SYSTEMIC TREATMENT REGIMENS	Converted	3/22/2024
BLA 761291	TECVAYLI	TECLISTAMAB-CQYV	JANSSEN BIOTECH INC	12/28/2021	10/25/2022	9.9	FOR THE TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY MULTIPLE MYELOMA WHO HAVE RECEIVED AT LEAST FOUR PRIOR LINES OF THERAPY, INCLUDING A PROTEASOME INHIBITOR, AN IMMUNOMODULATORY AGENT, AND AN ANTI-CD38 MONOCLONAL ANTIBODY	Not Yet Converted	
NDA 214801	LYTGOBI	FUTIBATINIB	TAIHO ONCOLOGY INC	1/31/2022	9/30/2022	8.0	FOR THE TREATMENT OF ADULT PATIENTS WITH PREVIOUSLY TREATED, UNRESECTABLE, LOCALLY ADVANCED OR METASTATIC INTRAHEPATIC CHOLANGIOCARCINOMA HARBORING FIBROBLAST GROWTH FACTOR RECEPTOR 2 (FGFR2) GENE FUSIONS OR OTHER REARRANGEMENTS	Not Yet Converted	
NDA 213246 Supplement 8	RETEVMO	SELPERCATINIB	LOXO ONCOLOGY INC	5/31/2022	9/21/2022	3.7	FOR ADULT PATIENTS WITH LOCALLY ADVANCED OR METASTATIC SOLID TUMORS WITH A RET GENE FUSION THAT HAVE PROGRESSED ON OR FOLLOWING PRIOR SYSTEMIC TREATMENT OR WHO HAVE NO SATISFACTORY ALTERNATIVE TREATMENT OPTIONS	Not Yet Converted	
BLA 761139 Supplement 21	ENHERTU	FAM-TRASTUZUMAB DERUXTECAN-NXKI	DAIICHI SANKYO INC	2/16/2022	8/11/2022	5.8	FOR THE TREATMENT OF ADULT PATIENTS WITH UNRESECTABLE OR METASTATIC NON SMALL CELL LUNG CANCER (NSCLC) WHOSE TUMORS HAVE AN ACTIVATING HER2 (ERBB2) MUTATION, AS DETECTED BY AN FDA-APPROVED TEST, AND WHO HAVE RECEIVED A PRIOR SYSTEMIC THERAPY	Not Yet Converted	
NDA 216387 Original 2	CALQUENCE	ACALABRUTINIB	ASTRAZENECA UK LTD	10/4/2021	8/3/2022	10.0	FOR THE TREATMENT OF ADULT PATIENTS WITH MANTLE CELL LYMPHOMA (MCL) WHO HAVE RECEIVED AT LEAST ONE PRIOR THERAPY	Converted	1/16/2025
NDA 202806 Supplement 22	TAFINLAR	DABRAFENIB	NOVARTIS PHARMACEUTICALS CORP	9/22/2021	6/22/2022	9.0	IN COMBINATION WITH TRAMETINIB, FOR THE TREATMENT OF ADULT AND PEDIATRIC PATIENTS 6 YEARS OF AGE AND OLDER WITH UNRESECTABLE OR METASTATIC SOLID TUMORS WITH BRAF V600E MUTATION WHO HAVE PROGRESSED FOLLOWING PRIOR TREATMENT AND HAVE NO SATISFACTORY ALTERNATIVE TREATMENT OPTIONS	Not Yet Converted	
NDA 204114 Supplement 24	MEKINIST	TRAMETINIB	NOVARTIS PHARMACEUTICALS CORP	9/22/2021	6/22/2022	9.0	IN COMBINATION WITH DABRAFENIB FOR THE TREATMENT OF ADULT AND PEDIATRIC PATIENTS 6 YEARS OF AGE AND OLDER WITH UNRESECTABLE OR METASTATIC SOLID TUMORS WITH BRAF V600E MUTATION WHO HAVE PROGRESSED FOLLOWING PRIOR TREATMENT AND HAVE NO SATISFACTORY ALTERNATIVE TREATMENT OPTIONS	Not Yet Converted	
NDA 215039	VIJOICE	ALPELISIB	NOVARTIS PHARMACEUTICALS CORP	10/6/2021	4/5/2022	6.0	FOR THE TREATMENT OF ADULT AND PEDIATRIC PATIENTS 2 YEARS OF AGE AND OLDER WITH SEVERE MANIFESTATIONS OF PIK3CA-RELATED OVERGROWTH SPECTRUM (PROS) WHO REQUIRE SYSTEMIC THERAPY	Not Yet Converted	
NDA 208712	VONJO	PACRITINIB	CTI BIOPHARMA CORP	3/30/2021	2/28/2022	11.0	FOR THE TREATMENT OF ADULTS WITH INTERMEDIATE OR HIGH-RISK PRIMARY OR SECONDARY (POST-POLYCYTHEMIA VERA OR POST-ESSENTIAL THROMBOCYTHEMIA) MYELOFIBROSIS WITH A PLATELET COUNT BELOW 50 × 10^9/L	Not Yet Converted	
NDA 213137 Supplement 6	OXBRYTA (tablets)	VOXELOTOR	GLOBAL BLOOD THERAPEUTICS INC	6/25/2021	12/17/2021	5.8	FOR THE TREATMENT OF SICKLE CELL DISEASE IN ADULTS AND PEDIATRIC PATIENTS 4 YEARS OF AGE AND OLDER	Not Yet Converted	
NDA 216157	OXBRYTA (tablets for oral suspension)	VOXELOTOR	GLOBAL BLOOD THERAPEUTICS INC	6/25/2021	12/17/2021	5.8	FOR THE TREATMENT OF SICKLE CELL DISEASE IN ADULTS AND PEDIATRIC PATIENTS 4 YEARS OF AGE AND OLDER	Not Yet Converted	
NDA 215935	TARPEYO	BUDESONIDE	CALLIDITAS THERAPEUTICS AB	3/15/2021	12/15/2021	9.0	TO REDUCE PROTEINURIA IN ADULTS WITH PRIMARY IMMUNOGLOBULIN A NEPHROPATHY (IGAN) AT RISK OF RAPID DISEASE PROGRESSION, GENERALLY A URINE PROTEIN-TO-CREATININE RATIO (UPCR) ≥ 1.5 G/G	Converted	12/20/2023
NDA 214938	VOXZOGO	VOSORITIDE	BIOMARIN PHARMACEUTICAL INC	8/20/2020	11/19/2021	15.0	TO INCREASE LINEAR GROWTH IN PEDIATRIC PATIENTS WITH ACHONDROPLASIA WHO ARE 5 YEARS OF AGE AND OLDER WITH OPEN EPIPHYSES	Not Yet Converted	
NDA 215358 Original 1	SCEMBLIX	ASCIMINIB	NOVARTIS PHARMACEUTICALS CORP	6/24/2021	10/29/2021	4.2	FOR THE TREATMENT OF ADULT PATIENTS WITH PHILADELPHIA CHROMOSOME-POSITIVE CHRONIC MYELOID LEUKEMIA (PH+ CML) IN CHRONIC PHASE (CP), PREVIOUSLY TREATED WITH TWO OR MORE TYROSINE KINASE INHIBITORS (TKIS)	Converted	10/12/2022
BLA 761208	TIVDAK	TISOTUMAB VEDOTIN-TFTV	SEAGEN INC	2/10/2021	9/20/2021	7.3	FOR THE TREATMENT OF ADULT PATIENTS WITH RECURRENT OR METASTATIC CERVICAL CANCER WITH DISEASE PROGRESSION ON OR AFTER CHEMOTHERAPY	Converted	4/29/2024
NDA 215310	EXKIVITY	MOBOCERTINIB	TAKEDA PHARMACEUTICALS USA INC	2/26/2021	9/15/2021	6.6	FOR THE TREATMENT OF ADULT PATIENTS WITH LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WITH EGFR EXON 20 INSERTION MUTATIONS, AS DETECTED BY AN FDA-APPROVED TEST, WHOSE DISEASE HAS PROGRESSED ON OR AFTER PLATINUM-BASED CHEMOTHERAPY	Not Converted - Application Withdrawn	7/15/2024
NDA 213217 Supplement 5	BRUKINSA	ZANUBRUTINIB	BEIGENE USA INC	3/19/2021	9/14/2021	5.9	FOR THE TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY MARGINAL ZONE LYMPHOMA (MZL) WHO HAVE RECEIVED AT LEAST ONE ANTI-CD20-BASED REGIMEN	Not Yet Converted	

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BLA 761223	JEMPERLI	DOSTARLIMAB-GXLY	GLAXOSMITHKLINE LLC	12/18/2020	8/17/2021	8.0	FOR THE TREATMENT OF ADULT PATIENTS WITH MISMATCH REPAIR DEFICIENT (DMMR) RECURRENT OR ADVANCED SOLID TUMORS, AS DETERMINED BY AN FDAAPPROVED TEST, THAT HAVE PROGRESSED ON OR FOLLOWING PRIOR TREATMENT AND WHO HAVE NO SATISFACTORY ALTERNATIVE TREATMENT OPTIONS	Not Yet Converted	
BLA 761178	ADUHELM	ADUCANUMAB-AVWA	BIOGEN INC	7/7/2020	6/7/2021	11.0	FOR THE TREATMENT OF ALZHEIMER'S DISEASE	Not Converted - Application Withdrawn	11/1/2024
NDA 214622	TRUSELTIQ	INFIGRATINIB	QED THERAPEUTICS INC□	9/29/2020	5/28/2021	7.9	FOR THE TREATMENT OF ADULT PATIENTS WITH PREVIOUSLY TREATED, UNRESECTABLE LOCALLY ADVANCED OR METASTATIC CHOLANGIOCARCINOMA WITH FIBROBLAST GROWTH FACTOR RECEPTOR 2 (FGFR2) GENE FUSIONS OR OTHER REARRANGEMENT AS DETECTED BY AN FDA APPROVED TEST	Not Converted - Application Withdrawn	5/16/2024
NDA 214665	LUMAKRAS	SOTORASIB	AMGEN INC□	12/16/2020	5/28/2021	5.4	FOR TREATMENT OF ADULT PATIENTS WITH KRAS G12C-MUTATED LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC), AS DETERMINED BY AN FDA-APPROVED TEST, WHO HAVE RECEIVED AT LEAST ONE PRIOR SYSTEMIC THERAPY	Not Yet Converted	
BLA 761210	RYBREVANT	AMIVANTAMAB-VMJW	JANSSEN BIOTECH INC	11/24/2020	5/21/2021	5.9	FOR TREATMENT OF ADULT PATIENTS WITH LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WITH EPIDERMAL GROWTH FACTOR RECEPTOR (EGFR) EXON 20 INSERTION MUTATIONS, AS DETECTED BY AN FDA-APPROVED TEST, WHOSE DISEASE HAS PROGRESSED ON OR AFTER PLATINUM-BASED CHEMOTHERAPY	Converted	3/1/2024
BLA 125514 Supplement 97	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME CORP	11/6/2020	5/5/2021	5.9	IN COMBINATION WITH TRASTUZUMAB AND FLUOROPYRIMIDINE AND PLATINUM CONTAINING CHEMOTHERAPY, FOR THE FIRST-LINE TREATMENT OF PATIENTS WITH LOCALLY ADVANCED UNRESECTABLE OR METASTATIC HER2 POSITIVE GASTRIC OR GASTROESOPHAGEAL JUNCTION ADENOCARCINOMA	Converted	3/19/2025
BLA 761196	ZYNLONTA	LONCASTUXIMAB TESIRINE-LPYL	ADC THERAPEUTICS SA□	9/21/2020	4/23/2021	7.0	FOR THE TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY LARGE B-CELL LYMPHOMA AFTER TWO OR MORE LINES OF SYSTEMIC THERAPY, INCLUDING DIFFUSE LARGE B-CELL LYMPHOMA (DLBCL) NOT OTHERWISE SPECIFIED, DLBCL ARISING FROM LOW GRADE LYMPHOMA, AND HIGH-GRADE B-CELL LYMPHOMA	Not Yet Converted	
BLA 761174	JEMPERLI	DOSTARLIMAB-GXLY	GLAXOSMITHKLINE LLC	12/19/2019	4/22/2021	16.1	FOR THE TREATMENT OF ADULT PATIENTS WITH MISMATCH REPAIR DEFICIENT (DMMR) RECURRENT OR ADVANCED ENDOMETRIAL CANCER, AS DETERMINED BY AN FDA APPROVED TEST, THAT HAS PROGRESSED ON OR FOLLOWING PRIOR TREATMENT WITH A PLATINUM CONTAINING REGIMEN	Converted	2/9/2023
BLA 761115 Supplement 9	TRODELVY	SACITUZUMAB GOVITECAN-HZIY	IMMUNOMEDICS INC	11/24/2020	4/13/2021	4.6	FOR THE TREATMENT OF ADULT PATIENTS WITH LOCALLY ADVANCED OR METASTATIC UROTHELIAL CANCER (MUC) WHO HAVE PREVIOUSLY RECEIVED A PLATINUM-CONTAINING CHEMOTHERAPY AND EITHER PROGRAMMED DEATH RECEPTOR-1 (PD-1) OR PROGRAMMED DEATH LIGAND 1 (PD-L1) INHIBITOR	Not Converted - Indication Withdrawn	11/22/2024
BLA 125557 Supplement 18	BLINCYTO	BLINATUMOMAB	AMGEN INC	10/2/2020	3/11/2021	5.3	PROVIDES FOR A MODIFICATION TO THE B-CELL PRECURSOR ACUTE LYMPHOBLASTIC LEUKEMIA (ALL) IN FIRST OR SECOND COMPLETE REMISSION WITH MINIMAL RESIDUAL DISEASE INDICATION TO REVISE TO PATIENTS WITH CD19- POSITIVE ALL	Converted	6/20/2023
NDA 214383	PEPAXTO	MELPHALAN FLUFENAMIDE	ONCOPEPTIDES AB	6/30/2020	2/26/2021	7.9	IN COMBINATION WITH DEXAMETHASONE FOR THE TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY MULTIPLE MYELOMA WHO HAVE RECEIVED AT LEAST FOUR PRIOR LINES OF THERAPY AND WHOSE DISEASE IS REFRACTORY TO AT LEAST ONE PROTEASOME INHIBITOR, ONE IMMUNOMODULATORY AGENT, AND ONE CD-38 DIRECTED MONOCLONAL ANTIBODY	Not Converted - Application Withdrawn	2/23/2024
NDA 213026	AMONDYS 45	CASIMERSEN	SAREPTA THERAPEUTICS INC	6/25/2020	2/25/2021	8.1	FOR THE TREATMENT OF DUCHENNE MUSCULAR DYSTROPHY (DMD) IN PATIENTS WHO HAVE A CONFIRMED MUTATION OF THE DMD GENE THAT IS AMENABLE TO EXON 45 SKIPPING	Not Yet Converted	
BLA 761097 Supplement 9	LIBTAYO	CEMIPLIMAB-RWLC	REGENERON PHARMACEUTICALS INC	9/3/2020	2/9/2021	5.2	FOR THE TREATMENT OF PATIENTS WITH METASTATIC BASAL CELL CARCINOMA (BCC) PREVIOUSLY TREATED WITH A HEDGEHOG PATHWAY INHIBITOR	Converted	4/28/2023
NDA 213176 Original 1	UKONIQ	UMBRALISIB	TG THERAPEUTICS INC	6/15/2020	2/5/2021	7.7	FOR THE TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY MARGINAL ZONE LYMPHOMA (MZL) WHO HAVE RECEIVED AT LEAST ONE PRIOR ANTI-CD20-BASED REGIMEN	Not Converted - Application Withdrawn	5/31/2022
NDA 213176 Original 2	UKONIQ	UMBRALISIB	TG THERAPEUTICS INC	6/15/2020	2/5/2021	7.7	FOR THE TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY FOLLICULAR LYMPHOMA (FL) WHO HAVE RECEIVED AT LEAST THREE PRIOR LINES OF SYSTEMIC THERAPY	Not Converted - Application Withdrawn	5/31/2022
NDA 214096	TEPMETKO	TEPOTINIB	EMD SERONO INC	6/29/2020	2/3/2021	7.2	FOR THE TREATMENT OF ADULT PATIENTS WITH METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) HARBORING MESENCHYMAL-EPITHELIAL TRANSITION (MET) EXON 14 SKIPPING ALTERATIONS	Converted	2/15/2024
BLA 761145 Supplement 2	DARZALEX FASPRO	DARATUMUMAB AND HYALURONIDASE-FIHJ	JANSSEN BIOTECH INC	9/9/2020	1/15/2021	4.2	FOR THE TREATMENT OF PATIENTS WITH LIGHT CHAIN (AL) AMYLOIDOSIS IN COMBINATION WITH BORTEZOMIB, CYCLOPHOSPHAMIDE AND DEXAMETHASONE IN NEWLY DIAGNOSED PATIENTS	Not Yet Converted	
NDA 214701	GAVRETO	PRALSETINIB	BLUEPRINT MEDICINES CORP	6/30/2020	12/1/2020	5.1	FOR THE TREAMENT OF ADULT AND PEDIATRIC PATIENTS 12 YEARS OF AGE AND OLDER WITH ADVANCED OR METASTATIC RET-MUTANT MEDULLARY THYROID CANCER (MTC) WHO REQUIRE SYSTEMIC THERAPY	Not Converted - Indication Withdrawn	7/20/2023

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NDA 214701	GAVRETO	PRALSETINIB	BLUEPRINT MEDICINES CORP	6/30/2020	12/1/2020	5.1	FOR THE TREATMENT OF ADULT AND PEDIATRIC PATIENTS 12 YEARS OF AGE AND OLDER WITH ADVANCED OR METASTATIC RET FUSION-POSITIVE THYROID CANCER WHO REQUIRE SYSTEMIC THERAPY AND WHO ARE RADIOACTIVE IODINE-REFRACTORY (IF RADIOACTIVE IODINE IS APPROPRIATE)	Not Yet Converted	
BLA 761171	DANYELZA	NAXITAMAB-GQGK	Y-MABS THERAPEUTICS INC	3/31/2020	11/25/2020	7.9	IN COMBINATION WITH GRANULOCYTE-MACROPHAGE COLONY-STIMULATING FACTOR (GM-CSF), FOR THE TREATMENT OF PEDIATRIC PATIENTS 1 YEAR OF AGE AND OLDER AND ADULT PATIENTS WITH RELAPSED OR REFRACTORY HIGH-RISK NEUROBLASTOMA IN THE BONE OR BONE MARROW WHO HAVE DEMONSTRATED A PARTIAL RESPONSE, MINOR RESPONSE, OR STABLE DISEASE TO PRIOR THERAPY	Not Yet Converted	
BLA 125514 Supplement 88	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME CORP	5/28/2020	11/13/2020	5.6	IN COMBINATION WITH CHEMOTHERAPY, FOR THE TREATMENT OF PATIENTS WITH LOCALLY RECURRENT UNRESECTABLE OR METASTATIC TRIPLE NEGATIVE BREAST CANCER WHOSE TUMORS EXPRESS PD-L1 [COMBINED POSITIVE SCORE (CPS) ≥10] AS DETERMINED BY AN FDA APPROVED TEST	Converted	7/26/2021
NDA 213721	GAVRETO	PRALSETINIB	BLUEPRINT MEDICINES CORP	3/23/2020	9/4/2020	5.4	FOR THE TREATMENT OF ADULT PATIENTS WITH METASTATIC RET FUSION-POSITIVE NON-SMALL CELL LUNG CANCER (NSCLC) AS DETECTED BY AN FDA APPROVED TEST	Converted	8/9/2023
NDA 212154	VILTEPSO	VILTOLARSEN	NIPPON SHINYAKU CO LTD□	12/12/2019	8/12/2020	8.0	FOR THE TREATMENT OF DUCHENNE MUSCULAR DYSTROPHY (DMD) IN PATIENTS WHO HAVE A CONFIRMED MUTATION OF THE DMD GENE THAT IS AMENABLE TO EXON 53 SKIPPING	Not Yet Converted	
NDA 213464	LAMPIT	NIFURTIMOX	BAYER HEALTHCARE PHARMACEUTICALS	12/6/2019	8/6/2020	8.0	FOR THE TREATMENT OF CHAGAS DISEASE IN PEDIATRIC PATIENTS BIRTH TO LESS THAN 18 YEARS OF AGE AND WEIGHING AT LEAST 2.5 KG	Converted	6/2/2023
BLA 761158	BLENREP	BELANTAMAB MAFODOTIN-BLMF	GLAXOSMITHKLINE INTELLECTUAL PROPERTY DEVELOPMENT LTD ENGLAND	12/5/2019	8/5/2020	8.0	FOR THE TREATMENT OF ADULTS WITH RELAPSED OR REFRACTORY MULTIPLE MYELOMA WHO HAVE RECEIVED AT LEAST FOUR PRIOR THERAPIES INCLUDING AN ANTI-CD38 MONOCLONAL ANTIBODY, A PROTEASOME INHIBITOR, AND AN IMMUNOMODULATORY AGENT	Not Converted - Application Withdrawn	2/6/2023
BLA 761163	MONJUVI	TAFASITAMAB-CXIX	MORPHOSYS US INC	12/30/2019	7/31/2020	7.0	IN COMBINATION WITH LENALIDOMIDE FOR THE TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY DIFFUSE LARGE B-CELL LYMPHOMA (DLBCL) NOT OTHERWISE SPECIFIED, INCLUDING DLBCL ARISING FROM LOW GRADE LYMPHOMA, AND WHO ARE NOT ELIGIBLE FOR AUTOLOGOUS STEM CELL TRANSPLANT (ASCT)	Not Yet Converted	
BLA 125514 Supplement 92 [4]	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME	6/12/2020	6/24/2020	0.4	PROVIDES FOR AN ALTERNATE DOSAGE REGIMEN OF 400 MG EVERY 6 WEEKS FOR ADULT PATIENTS WITH RECURRENT OR METASTATIC CUTANEOUS SQUAMOUS CELL CARCINOMA (CSCC) THAT IS NOT CURABLE BY SURGERY OR RADIATION	Converted	12/16/2022
NDA 212306 Supplement 1	XPOVIO	SELINEXOR	KARYOPHARM THERAPEUTICS INC	12/23/2019	6/22/2020	6.0	FOR THE TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY DIFFUSE LARGE B-CELL LYMPHOMA (DLBCL), NOT OTHERWISE SPECIFIED, INCLUDING DLBCL ARISING FROM FOLLICULAR LYMPHOMA, AFTER AT LEAST 2 LINES OF SYSTEMIC THERAPY	Not Yet Converted	
NDA 213400	TAZVERIK	TAZEMETOSTAT	EPIZYME INC	12/18/2019	6/18/2020	6.0	FOR THE TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY (R/R) FOLLICULAR LYMPHOMA (FL) WHOSE TUMORS ARE POSITIVE FOR AN EZH2 MUTATION AS DETECTED BY AN FDA-APPROVED TEST AND WHO HAVE RECEIVED AT LEAST 2 PRIOR SYSTEMIC THERAPIES; and THE TREATMENT OF ADULT PATIENTS WITH R/R FL WHO HAVE NO SATISFACTORY ALTERNATIVE TREATMENT OPTIONS	Not Yet Converted	
BLA 125514 Supplement 71	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME	12/16/2019	6/16/2020	6.0	FOR THE TREATMENT OF ADULT AND PEDIATRIC PATIENTS WITH UNRESECTABLE OR METASTATIC TUMOR MUTATIONAL BURDEN-HIGH (TMB-H) [≥10 MUTATIONS/MEGABASE (MUT/MB)] SOLID TUMORS, AS DETERMINED BY AN FDA-APPROVED TEST, THAT HAVE PROGRESSED FOLLOWING PRIOR TREATMENT AND WHO HAVE NO SATISFACTORY ALTERNATIVE TREATMENT OPTIONS	Not Yet Converted	
BLA 125514 Supplement 90 [4]	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME	6/2/2020	6/16/2020	0.5	PROVIDES FOR AN ALTERNATE DOSE/SCHEDULE OF 400 MG EVERY 6 WEEKS FOR ADULT PATIENTS WITH UNRESECTABLE OR METASTATIC TMB-H [≥10 MUTATIONS/MEGABASE (MUT/MB)] SOLID TUMORS, AS DETERMINED BY AN FDA-APPROVED TEST, THAT HAVE PROGRESSED FOLLOWING PRIOR TREATMENT AND WHO HAVE NO SATISFACTORY ALTERNATIVE TREATMENT OPTIONS	Converted	12/16/2022
NDA 213702	ZEPZELCA	LURBINECTEDIN	JAZZ PHARMACEUTICALS IRELAND LTD	12/16/2019	6/15/2020	6.0	FOR THE TREATMENT OF ADULT PATIENTS WITH METASTATIC SMALL CELL LUNG CANCER (SCLC) WITH DISEASE PROGRESSION ON OR AFTER PRIOR PLATINUM-BASED CHEMOTHERAPY	Not Yet Converted	
NDA 204384 Supplement 13	SIRTURO	BEDAQUILINE	JANSSEN RESEARCH AND DEVELOPMENT	11/27/2019	5/27/2020	6.0	FOR THE TREATMENT OF PULMONARY MULTI-DRUG RESISTANT TUBERCULOSIS AS PART OF COMBINATION THERAPY, IN ADULT AND PEDIATRIC PATIENTS (12 TO LESS THAN 18 YEARS OF AGE AND WEIGHING AT LEAST 30 KG) TO INCLUDE PATIENTS ≥ 5 TO <12 YEARS OF AGE AND WEIGHING AT LEAST 15 KG	Converted	6/21/2024
NDA 212269	FERRIPROX	DEFERIPRONE	CHIESI USA INC	7/19/2019	5/19/2020	10.0	FOR THE TREATMENT OF PATIENTS WITH TRANSFUSIONAL IRON OVERLOAD DUE TO THALASSEMIA SYNDROMES WHEN CURRENT CHELATION THERAPY IS INADEQUATE	Converted	4/30/2021

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NDA 209115 Supplement 4	RUBRACA	RUCAPARIB	CLOVIS ONCOLOGY	11/15/2019	5/15/2020	6.0	FOR THE TREATMENT OF ADULT PATIENTS WITH A DELETERIOUS BRCA MUTATION (GERMLINE AND/OR SOMATIC)-ASSOCIATED METASTATIC CASTRATION-RESISTANT PROSTATE CANCER WHO HAVE BEEN TREATED WITH ANDROGEN RECEPTOR-DIRECTED THERAPY AND A TAXANE-BASED CHEMOTHERAPY	Not Yet Converted	
NDA 204026 Supplement 23	POMALYST	POMALIDOMIDE	CELGENE	11/14/2019	5/14/2020	6.0	FOR THE TREATMENT OF ADULT PATIENTS WITH AIDS-RELATED KAPOSI SARCOMA (KS) AFTER FAILURE OF HIGHLY ACTIVE ANTIRETROVIRAL THERAPY (HAART)	Not Yet Converted	
NDA 204026 Supplement 24	POMALYST	POMALIDOMIDE	CELGENE	11/19/2019	5/14/2020	5.8	FOR THE TREATMENT OF KAPOSI'S SARCOMA IN PATIENTS WHO ARE HIV-NEGATIVE	Not Yet Converted	
NDA 213246	RETEVMO	SELPERCATINIB	LOXO ONCOLOGY INC	12/4/2019	5/8/2020	5.1	FOR THE TREATMENT OF ADULT AND PEDIATRIC PATIENTS 12 YEARS OF AGE AND OLDER WITH ADVANCED OR METASTATIC RET FUSION-POSITIVE THYROID CANCER WHO REQUIRE SYSTEMIC THERAPY AND WHO ARE RADIOACTIVE IODINE-REFRACTORY (IF RADIOACTIVE IODINE IS APPROPRIATE)	Converted	6/12/2024
NDA 213246	RETEVMO	SELPERCATINIB	LOXO ONCOLOGY INC	12/4/2019	5/8/2020	5.1	FOR THE TREATMENT OF ADULT PATIENTS WITH METASTATIC RET FUSION-POSITIVE NON-SMALL CELL LUNG CANCER (NSCLC)	Converted	9/21/2022
NDA 213246	RETEVMO	SELPERCATINIB	LOXO ONCOLOGY INC	12/4/2019	5/8/2020	5.1	FOR THE TREATMENT OF ADULT AND PEDIATRIC PATIENTS 12 YEARS OF AGE AND OLDER WITH ADVANCED OR METASTATIC RET-MUTANT MEDULLARY THYROID CANCER (MTC) WHO REQUIRE SYSTEMIC THERAPY	Converted	9/27/2024
NDA 213591	TABRECTA	CAPMATINIB	NOVARTIS PHARMACEUTICAL CORP	12/10/2019	5/6/2020	4.8	FOR THE TREATMENT OF ADULT PATIENTS WITH METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WHOSE TUMORS HAVE A MUTATION THAT LEADS TO MESENCHYMAL-EPITHELIAL TRANSITION (MET) EXON 14 SKIPPING AS DETECTED BY AN FDA-APPROVED TEST	Converted	8/10/2022
BLA 125514 Supplement 59 [4]	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME	4/18/2019	4/28/2020	12.4	PROVIDES FOR AN ALTERNATE DOSE/SCHEDULE OF 400MG EVERY 6 WEEKS FOR ADULT PATIENTS WITH UNRESECTABLE OR METASTATIC MELANOMA	Converted	12/16/2022
BLA 125514 Supplement 60 [4]	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME	4/23/2019	4/28/2020	12.2	PROVIDES FOR AN ALTERNATE DOSE/SCHEDULE OF 400MG EVERY 6 WEEKS FOR ADULT PATIENTS WITH HEMATOLOGICAL MALIGNANCIES: HODGKIN LYMPHOMA	Not Yet Converted	
BLA 125514 Supplement 61 [4]	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME	4/23/2019	4/28/2020	12.2	PROVIDES FOR AN ALTERNATE DOSE/SCHEDULE OF 400MG EVERY 6 WEEKS FOR ADULT PATIENTS WITH HEMATOLOGICAL MALIGNANCIES: PRIMARY MEDIASTINAL B-CELL LYMPHOMA	Not Yet Converted	
BLA 125514 Supplement 62 [4]	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME	4/23/2019	4/28/2020	12.2	PROVIDES FOR AN ALTERNATE DOSE/SCHEDULE OF 400MG EVERY 6 WEEKS FOR ADULT PATIENTS WITH HEPATOCELLULAR CARCINOMA (HCC) WHO HAVE BEEN PREVIOUSLY TREATED WITH AN ANTI-ANGIOGENIC TYROSINE KINASE INHIBITOR (TKI)	Converted	12/16/2022
BLA 125514 Supplement 64 [4]	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME	4/23/2019	4/28/2020	12.2	PROVIDES FOR AN ALTERNATE DOSE/SCHEDULE OF 400MG EVERY 6 WEEKS FOR ADULT PATIENTS WITH ADVANCED OR METASTATIC GASTRIC OR GASTROESOPHAGEAL JUNCTION ADENOCARCINOMA	Converted	12/16/2022
BLA 125514 Supplement 69 [4]	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME	9/23/2019	4/28/2020	7.2	PROVIDES FOR AN ALTERNATE DOSE/SCHEDULE OF 400MG EVERY 6 WEEKS FOR ADULT PATIENTS WITH NON-SMALL CELL LUNG CANCER (NSCLC)	Converted	12/16/2022
BLA 125514 Supplement 76 [4]	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME	4/14/2020	4/28/2020	0.5	PROVIDES FOR AN ALTERNATE DOSE/SCHEDULE OF 400MG EVERY 6 WEEKS FOR ADULT PATIENTS WITH RENAL CELL CANCER (RCC)	Converted	12/16/2022
BLA 125514 Supplement 77 [4]	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME	4/14/2020	4/28/2020	0.5	PROVIDES FOR AN ALTERNATE DOSE/SCHEDULE OF 400MG EVERY 6 WEEKS FOR ADULT PATIENTS WITH ENDOMETRIAL CANCER	Converted	12/16/2022
BLA 125514 Supplement 78 [4]	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME	4/14/2020	4/28/2020	0.5	PROVIDES FOR AN ALTERNATE DOSE/SCHEDULE OF 400MG EVERY 6 WEEKS FOR ADULT PATIENTS WITH ADVANCED CERVICAL CANCER WITH DISEASE PROGRESSION DURING OR FOLLOWING CHEMOTHERAPY	Converted	12/16/2022
BLA 125514 Supplement 82 [4]	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME	4/15/2020	4/28/2020	0.4	PROVIDES FOR AN ALTERNATE DOSE/SCHEDULE OF 400MG EVERY 6 WEEKS FOR ADULT PATIENTS WITH RECURRENT LOCALLY ADVANCED OR METASTATIC ESOPHAGEAL CANCER WITH DISEASE PROGRESSION ON OR AFTER 2 OR MORE PRIOR LINES OF SYSTEMIC THERAPY	Converted	12/16/2022
BLA 125514 Supplement 83 [4]	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME	4/20/2020	4/28/2020	0.3	PROVIDES FOR AN ALTERNATE DOSE/SCHEDULE OF 400MG EVERY 6 WEEKS FOR ADULT PATIENTS WITH UNRESECTABLE OR METASTATIC MICROSATELLITE INSTABILITY-HIGH (MSI-H) OR MISMATCH REPAIR DEFICIENT (DMMR) SOLID TUMORS THAT HAVE PROGRESSED FOLLOWING PRIOR TX AND WHO HAVE NO SATISFACTORY ALTERNATIVE TX OPTIONS	Converted	12/16/2022
BLA 125514 Supplement 63 [4]	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME	4/23/2019	4/28/2020	12.2	PROVIDES FOR AN ALTERNATE DOSE/SCHEDULE OF 400MG EVERY 6 WEEKS FOR ADULT PATIENTS WITH MERKEL CELL CARCINOMA	Converted	12/16/2022
BLA 125514 Supplement 79 [4]	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME	4/14/2020	4/28/2020	0.5	PROVIDES FOR AN ALTERNATE DOSE/SCHEDULE OF 400MG EVERY 6 WEEKS FOR ADULT PATIENTS WITH BCG-UNRESPONSIVE, HIGH RISK, NON-MUSCLE INVASIVE BLADDER CANCER (NMIBC) WITH CARCINOMA IN-SITU (CIS) WITH OR WITHOUT PAPILLARY TUMORS WHO ARE INELIGIBLE FOR OR HAVE ELECTED NOT TO UNDERGO CYSTECTOMY	Converted	12/16/2022
BLA 125514 Supplement 80 [4]	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME	4/14/2020	4/28/2020	0.5	PROVIDES FOR AN ALTERNATE DOSE/SCHEDULE OF 400MG EVERY 6 WEEKS FOR ADULT PATIENTS WITH RECURRENT OR METASTATIC HEAD AND NECK SQUAMOUS CELL CARCINOMA (HNSCC) WITH DISEASE PROGRESSION ON OR AFTER PLATINUM-CONTAINING CHEMOTHERAPY	Converted	12/16/2022

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BLA 125514 Supplement 81 [4]	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME	4/15/2020	4/28/2020	0.4	PROVIDES FOR AN ALTERNATE DOSE/SCHEDULE OF 400MG EVERY 6 WEEKS FOR ADULT PATIENTS WITH METASTATIC SCLC WITH DISEASE PROGRESSION ON OR AFTER PLATINUM-BASED CHEMOTHERAPY AND AT LEAST ONE OTHER LINE OF THERAPY	Converted	12/16/2022
BLA 761115	TRODELVY	SACITUZUMAB GOVITECAN-HZIY	IMMUNOMEDICS INC	5/18/2018	4/22/2020	23.2	FOR THE TREATMENT OF ADULT PATIENTS WITH METASTATIC TRIPLE-NEGATIVE BREAST CANCER (MTNBC) WHO HAVE RECEIVED AT LEAST TWO PRIOR THERAPIES FOR METASTATIC DISEASE	Converted	4/7/2021
NDA 213736	PEMAZYRE	PEMIGATINIB	INCYTE CORP	9/30/2019	4/17/2020	6.6	FOR THE TREATMENT OF ADULTS WITH PREVIOUSLY TREATED, UNRESECTABLE LOCALLY ADVANCED OR METASTATIC CHOLANGIOCARCINOMA WITH A FIBROBLAST GROWTH FACTOR RECEPTOR 2 (FGFR2) FUSION OR OTHER REARRANGEMENT AS DETECTED BY AN FDA-APPROVED TEST	Not Yet Converted	
NDA 208574 Original 2		ROMIDEPSIN	TEVA PHARMACEUTICALS USA INC	8/18/2015	3/13/2020	54.9	FOR THE TREATMENT OF PERIPHERAL T-CELL LYMPHOMA (PTCL) IN ADULT PATIENTS WHO HAVE RECEIVED AT LEAST ONE PRIOR THERAPY	Not Converted - Indication Withdrawn	12/8/2021
BLA 125377 Supplement 108	YERVOY	IPILIMUMAB	BRISTOL MYERS SQUIBB	9/10/2019	3/10/2020	6.0	IN COMBINATION WITH NIVOLUMAB, FOR THE TREATMENT OF PATIENTS WITH HEPATOCELLULAR CARCINOMA (HCC) WHO HAVE BEEN PREVIOUSLY TREATED WITH SORAFENIB	Converted	4/11/2025
BLA 125554 Supplement 78	OPDIVO	NIVOLUMAB	BRISTOL MYERS SQUIBB	9/10/2019	3/10/2020	6.0	IN COMBINATION WITH IPILIMUMAB, FOR THE TREATMENT OF PATIENTS WITH HEPATOCELLULAR CARCINOMA (HCC) WHO HAVE BEEN PREVIOUSLY TREATED WITH SORAFENIB	Converted	4/11/2025
NDA 211723	TAZVERIK	TAZEMETOSTAT	EPIZYME INC	5/23/2019	1/23/2020	8.1	FOR THE TREATMENT OF ADULTS AND PEDIATRIC PATIENTS AGED 16 YEARS AND OLDER WITH METASTATIC OR LOCALLY ADVANCED EPITHELIOID SARCOMA NOT ELIGIBLE FOR COMPLETE RESECTION	Not Yet Converted	
BLA 761139	ENHERTU	FAM-TRASTUZUMAB DERUXTECAN-NXKI	DAIICHI SANKYO INC	8/29/2019	12/20/2019	3.7	FOR THE TREATMENT OF ADULT PATIENTS WITH UNRESECTABLE OR METASTATIC HER2-POSITIVE BREAST CANCER WHO HAVE RECEIVED TWO OR MORE PRIOR ANTI-HER2-BASED REGIMENS IN THE METASTATIC SETTING	Converted	5/4/2022
BLA 761137	PADCEV	ENFORTUMAB VEDOTIAN-EJFV	ASTELLAS PHARMA US INC	7/15/2019	12/18/2019	5.1	FOR THE TREATMENT OF ADULT PATIENTS WITH LOCALLY ADVANCED OR METASTATIC UROTHELIAL CANCER (MUC) WHO HAVE PREVIOUSLY RECEIVED A PROGRAMMED DEATH RECEPTOR-1 (PD-1) OR PROGRAMMED DEATH-LIGAND 1 (PD-L1) INHIBITOR, AND A PLATINUM-CONTAINING CHEMOTHERAPY IN THE NEOADJUVANT/ADJUVANT, LOCALLY ADVANCED OR METASTATIC SETTING	Converted	7/9/2021
NDA 211970	VYONDYS 53	GOLODIRSEN	SAREPTA THERAPEUTICS INC	12/19/2018	12/12/2019	11.8	FOR THE TREATMENT OF DUCHENNE MUSCULAR DYSTROPHY (DMD) IN PATIENTS WHO HAVE A CONFIRMED MUTATION OF THE DMD GENE THAT IS AMENABLE TO EXON 53 SKIPPING	Not Yet Converted	
NDA 213137	OXBRYTA	VOXELOTOR	GLOBAL BLOOD THERAPEUTICS INC	6/26/2019	11/25/2019	5.0	FOR THE TREATMENT OF SICKLE CELL DISEASE IN ADULTS AND PEDIATRIC PATIENTS 12 YEARS OF AGE AND OLDER	Not Yet Converted	
NDA 213217	BRUKINSA	ZANUBRUTINIB	BEIGENE USA INC	6/27/2019	11/14/2019	4.6	FOR THE TREATMENT OF ADULT PATIENTS WITH MANTLE CELL LYMPHOMA (MCL) WHO HAVE RECEIVED AT LEAST ONE PRIOR THERAPY	Not Yet Converted	
NDA 206947 Supplement 11	LENVIMA	LENVATINIB	EISAI INC	6/17/2019	9/17/2019	3.0	IN COMBINATION WITH PEMBROLIZUMAB, FOR THE TREATMENT OF PATIENTS WITH ADVANCED ENDOMETRIAL CARCINOMA THAT IS NOT MICROSATELLITE INSTABILITY-HIGH (MSI-H) OR MISMATCH REPAIR DEFICIENT (DMMR), WHO HAVE DISEASE PROGRESSION FOLLOWING PRIOR SYSTEMIC THERAPY AND ARE NOT CANDIDATES FOR CURATIVE SURGERY OR RADIATION	Converted	7/21/2021
BLA 125514 Supplement 65	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME	6/17/2019	9/17/2019	3.0	IN COMBINATION WITH LENVATINIB, FOR THE TREATMENT OF PATIENTS WITH ADVANCED ENDOMETRIAL CARCINOMA THAT IS NOT MICROSATELLITE INSTABILITY-HIGH (MSI-H) OR MISMATCH REPAIR DEFICIENT (DMMR), WHO HAVE DISEASE PROGRESSION FOLLOWING PRIOR SYSTEMIC THERAPY AND ARE NOT CANDIDATES FOR CURATIVE SURGERY OR RADIATION	Converted	7/21/2021
NDA 212726 Original 1	ROZLYTREK	ENTRECTINIB	GENENTECH INC	12/18/2018	8/15/2019	7.9	FOR THE TREATMENT OF ADULT AND PEDIATRIC PATIENTS 12 YEARS OF AGE AND OLDER WITH SOLID TUMORS THAT HAVE A NEUROTROPHIC TYROSINE RECEPTOR KINASE (NTRK) GENE FUSION WITHOUT A KNOWN ACQUIRED RESISTANCE MUTATION, ARE METASTATIC OR WHERE SURGICAL RESECTION IS LIKELY TO RESULT IN SEVERE MORBIDITY, AND HAVE PROGRESSED FOLLOWING TREATMENT OR HAVE SATISFACTORY ALTERNATIVE THERAPY	Not Yet Converted	
NDA 204384 Supplement 10	SIRTURO	BEDAQUILINE	JANSSEN RESEARCH AND DEVELOPMENT LLC	10/11/2018	8/9/2019	9.9	AS PART OF COMBINATION THERAPY FOR THE TREATMENT OF ADULT AND PEDIATRIC PATIENTS (12 TO LESS THAN 18 YEARS OF AGE AND WEIGHING AT LEAST 30KG) WITH PULMONARY MULTI-DRUG RESISTANT TUBERCULOSIS (MDR-TB)	Converted	6/21/2024
NDA 212306	XPOVIO	SELINEXOR	KARYOPHARM THERAPEUTICS INC	8/6/2018	7/3/2019	10.9	IN COMBINATION WITH DEXAMETHASONE FOR THE TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY MULTIPLE MYELOMA (RRMM) WHO HAVE RECEIVED AT LEAST FOUR PRIOR THERAPIES AND WHOSE DISEASE IS REFRACTORY TO AT LEAST TWO PROTEASOME INHIBITORS, AT LEAST TWO IMMUNOMODULATORY AGENTS, AND AN ANTI-CD38 MONOCLONAL ANTIBODY	Converted	12/18/2020
BLA 125514 Supplement 53	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME	12/17/2018	6/17/2019	6.0	FOR THE TREATMENT OF PATIENTS WITH METASTATIC SMALL CELL LUNG CANCER WITH DISEASE PROGRESSION ON OR AFTER PLATINUM-BASED CHEMOTHERAPY AND AT LEAST ONE OTHER PRIOR LINE OF THERAPY	Not Converted - Indication Withdrawn	3/30/2021

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BLA 761121	POLIVY	POLATUZUMAB VEDOTIN-PIIQ	GENENTECH	12/19/2018	6/10/2019	5.7	IN COMBINATION WITH BENDAMUSTINE AND RITUXIMAB PRODUCT, FOR THE TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY DIFFUSE LARGE B-CELL LYMPHOMA, NOT OTHERWISE SPECIFIED, AFTER AT LEAST TWO PRIOR THERAPIES	Converted	4/19/2023
NDA 212018	BALVERSA	ERDAFITINIB	JANSSEN BIOTECH	9/18/2018	4/12/2019	6.8	FOR THE TREATMENT OF ADULT PATIENTS WITH LOCALLY ADVANCED OR METASTATIC UROTHELIAL CARCINOMA (MUC), THAT HAS: SUSCEPTIBLE FGFR3 OR FGFR2 GENETIC ALTERATIONS AND PROGRESSED DURING OR FOLLOWING AT LEAST ONE LINE OF PRIOR PLATINUM CONTAINING CHEMOTHERAPY, INCLUDING WITHIN 12 MONTHS OF NEOADJUVANT OR ADJUVANT PLATINUM CONTAINING CHEMOTHERAPY	Converted	1/19/2024
BLA 761034 Supplement 18	TECENTRIQ	ATEZOLIZUMAB	GENENTECH	9/12/2018	3/8/2019	5.8	IN COMBINATION WITH PACLITAXEL PROTEIN-BOUND FOR THE TREATMENT OF ADULT PATIENTS WITH UNRESECTABLE LOCALLY ADVANCED OR METASTATIC TRIPLE-NEGATIVE BREAST CANCER (TNBC) WHOSE TUMORS EXPRESS PD-L1 (PD-L1 STAINED TUMOR-INFILTRATING IMMUNE CELLS [IC] OF ANY INTENSITY COVERING ≥ 1% OF THE TUMOR AREA), AS DETERMINED BY AN FDA-APPROVED TEST	Not Converted - Indication Withdrawn	10/6/2021
BLA 125514 Supplement 45	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME	6/29/2018	12/19/2018	5.7	FOR THE TREATMENT OF ADULT AND PEDIATRIC PATIENTS WITH RECURRENT LOCALLY ADVANCED OR METASTATIC MERKEL CELL CARCINOMA	Converted	10/12/2023
NDA 210861	VITRAKVI (CAPSULES)	LAROTRECTINIB	LOXO ONCOLOGY	3/26/2018	11/26/2018	8.1	FOR THE TREATMENT OF ADULT AND PEDIATRIC PATIENTS WITH SOLID TUMORS THAT HAVE A NEUROTROPHIC RECEPTOR TYROSINE KINASE (NTRK) GENE FUSION WITHOUT A KNOWN ACQUIRED RESISTANCE MUTATION; ARE METASTATIC OR WHERE SURGICAL RESECTION IS LIKELY TO RESULT IN SEVERE MORBIDITY; AND HAVE NO SATISFACTORY ALTERNATIVE TREATMENTS OR THAT HAVE PROGRESSED FOLLOWING TREATMENT	Converted	4/9/2025
NDA 211710	VITRAKVI (ORAL SOLUTION)	LAROTRECTINIB	LOXO ONCOLOGY	3/26/2018	11/26/2018	8.1	FOR THE TREATMENT OF ADULT AND PEDIATRIC PATIENTS WITH SOLID TUMORS THAT HAVE A NEUROTROPHIC RECEPTOR TYROSINE KINASE (NTRK) GENE FUSION WITHOUT A KNOWN ACQUIRED RESISTANCE MUTATION; ARE METASTATIC OR WHERE SURGICAL RESECTION IS LIKELY TO RESULT IN SEVERE MORBIDITY; AND HAVE NO SATISFACTORY ALTERNATIVE TREATMENTS OR THAT HAVE PROGRESSED FOLLOWING TREATMENT	Converted	4/9/2025
NDA 208573 Supplement 9	VENCLEXTA	VENETOCLAX	ABBVIE	6/25/2018	11/21/2018	4.9	IN COMBINATION WITH AZACITIDINE OR DECITABINE OR LOW-DOSE CYTARABINE FOR THE TREATMENT OF NEWLY-DIAGNOSED ACUTE MYELOID LEUKEMIA (AML) IN ADULTS AGE 75 YEARS OR OLDER, OR WHO HAVE COMORBIDITIES THAT PRECLUDE USE OF INTENSIVE INDUCTION CHEMOTHERAPY	Converted	10/16/2020
BLA 125514 Supplement 42	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME	5/9/2018	11/9/2018	6.0	FOR THE TREATMENT OF PATIENTS WITH HEPATOCELLULAR CARCINOMA WHO HAVE BEEN PREVIOUSLY TREATED WITH SORAFENIB	Converted	1/25/2024
NDA 210868	LORBRENA	LORLATINIB	PFIZER	12/5/2017	11/2/2018	10.9	FOR THE TREATMENT OF PATIENTS WITH ANAPLASTIC LYMPHOMA KINASE (ALK)-POSITIVE METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WHOSE DISEASE HAS PROGRESSED ON: • CRIZOTINIB AND AT LEAST ONE OTHER ALK INHIBITOR FOR METASTATIC DISEASE; OR • ALECTINIB AS THE FIRST ALK INHIBITOR THERAPY FOR METASTATIC DISEASE; OR • CERITINIB AS THE FIRST ALK INHIBITOR THERAPY FOR METASTATIC DISEASE	Converted	3/3/2021
NDA 207356	ARIKAYCE	AMIKACIN LIPOSOME INHALATION SUSPENSION	INSMED	3/28/2018	9/28/2018	6.0	FOR THE TREATMENT OF MYCOBACTERIUM AVIUM COMPLEX (MAC) LUNG DISEASE AS PART OF A COMBINATION ANTIBACTERIAL DRUG REGIMEN IN PATIENTS WHO DO NOT ACHIEVE NEGATIVE SPUTUM CULTURES AFTER A MINIMUM OF 6 CONSECUTIVE MONTHS OF A MULTIDRUG BACKGROUND REGIMEN THERAPY. AS ONLY LIMITED CLINICAL SAFETY AND EFFECTIVENESS DATA FOR ARIKAYCE ARE CURRENTLY AVAILABLE, RESERVE ARIKAYCE FOR USE IN ADULTS WHO HAVE LIMITED OR NO ALTERNATIVE TREATMENT OPTIONS. THIS DRUG IS INDICATED FOR USE IN A LIMITED AND SPECIFIC POPULATION OF PATIENTS. THIS INDICATION IS APPROVED UNDER ACCELERATED APPROVAL BASED ON ACHIEVING SPUTUM CULTURE CONVERSION (DEFINED AS 3 CONSECUTIVE NEGATIVE MONTHLY SPUTUM CULTURES) BY MONTH 6. CLINICAL BENEFIT HAS NOT YET BEEN ESTABLISHED	Not Yet Converted	
NDA 211155	COPIKTRA	DUVELISIB	VERASTEM	2/5/2018	9/24/2018	7.6	FOR THE TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY FOLLICULAR LYMPHOMA (FL) AFTER AT LEAST TWO PRIOR SYSTEMIC THERAPIES	Not Converted - Indication Withdrawn	12/17/2021
BLA 125554 Supplement 67	OPDIVO	NIVOLUMAB	BRISTOL MYERS SQUIBB	2/16/2018	8/16/2018	6.0	FOR THE TREATMENT OF PATIENTS WITH METASTATIC SMALL CELL LUNG CANCER (SCLC) WITH PROGRESSION AFTER PLATINUM-BASED CHEMOTHERAPY AND AT LEAST ONE OTHER LINE OF THERAPY	Not Converted - Indication Withdrawn	12/29/2020
NDA 208623	GALAFOLD	MIGALASTAT	AMICUS THERAPEUTICS	12/13/2017	8/10/2018	7.9	FOR THE TREATMENT OF ADULTS WITH A CONFIRMED DIAGNOSIS OF FABRY DISEASE AND AN AMENABLE GALACTOSIDASE ALPHA GENE (GLA) VARIANT BASED ON IN VITRO ASSAY DATA	Not Yet Converted	

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BLA 125377 Supplement 96	YERVOY	IPILIMUMAB	BRISTOL MYERS SQUIBB	1/10/2018	7/10/2018	6.0	IN COMBINATION WITH NIVOLUMAB FOR THE TREATMENT OF ADULTS AND PEDIATRIC PATIENTS 12 YEARS AND OLDER WITH MICROSATELLITE INSTABILITY-HIGH (MSI H) OR DNA MISMATCH REPAIR DEFICIENT (DMMR), METASTATIC COLORECTAL CANCER THAT HAS PROGRESSED FOLLOWING TREATMENT WITH A FLUOROPYRIMIDINE, OXALIPLATIN, AND IRINOTECAN	Converted	4/8/2025
BLA 125554 Supplement 63	OPDIVO	NIVOLUMAB	BRISTOL MYERS SQUIBB	1/10/2018	7/10/2018	6.0	IN COMBINATION WITH IPILIMUMAB FOR THE TREATMENT OF ADULTS AND PEDIATRIC PATIENTS 12 YEARS AND OLDER WITH MICROSATELLITE INSTABILITY-HIGH (MSI H) OR DNA MISMATCH REPAIR DEFICIENT (DMMR), METASTATIC COLORECTAL CANCER THAT HAS PROGRESSED FOLLOWING TREATMENT WITH A FLUOROPYRIMIDINE, OXALIPLATIN, AND IRINOTECAN	Converted	4/8/2025
BLA 125514 Supplement 30	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME	10/3/2017	6/13/2018	8.3	FOR THE TREAMENT OF ADULT AND PEDIATRIC PATIENTS WITH REFRACTORY PRIMARY MEDIASTINAL LARGE B-CELL LYMPHOMA (PMBCL), OR WHO HAVE RELAPSED AFTER 2 OR MORE PRIOR LINES OF THERAPY	Converted	10/14/2020
BLA 125514 Supplement 34	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME	12/28/2017	6/12/2018	5.5	FOR THE TREATMENT OF PATIENTS WITH RECURRENT OR METASTATIC CERVICAL CANCER WITH DISEASE PROGRESSION ON OR AFTER CHEMOTHERPAY WHOSE TUMORS EXPRESS PD-L1 (CPS > 1) AS DETERMINED BY AN FDA-APPROVED TEST	Converted	10/13/2021
NDA 021462 Supplement 51	ALIMTA	PEMETREXED DISODIUM	ELI LILLY AND COMPANY	8/3/2017	6/4/2018	10.0	IN COMBINATION WITH PEMBROLIZUMAB AND CARBOPLATIN, FOR THE FIRST-LINE TREATMENT OF METASTATIC, NON-SQUAMOUS, NON-SMALL CELL LUNG CANCER	Converted	1/30/2019
BLA 125557 Supplement 13	BLINCYTO	BLINATUMOMAB	AMGEN	9/29/2017	3/29/2018	6.0	FOR THE TREAMENT OF B-CELL PRECURSOR ACUTE LYMPHOBLASTIC LEUKEMIA (ALL) IN FIRST OR SECOND COMPLETED REMISSION WITH MINIMAL RESIDUAL DISEASE (MRD) GREATER OR EQUAL TO 0.1% IN ADULTS AND CHILDREN	Converted	6/20/2023
NDA 210563 Original 2	IMBRUVICA	IBRUTINIB	PHARMACYCLICS	8/31/2017	2/16/2018	5.6	FOR THE TREATMENT OF ADULT PATIENTS WITH MANTLE CELL LYMPHOMA (MCL) WHO HAVE RECEIVED AT LEAST ONE PRIOR THERAPY	Not Converted - Indication Withdrawn	5/18/2023
NDA 210563 Original 2	IMBRUVICA	IBRUTINIB	PHARMACYCLICS	8/31/2017	2/16/2018	5.6	FOR THE TREATMENT OF ADULT PATIENTS WITH MARGINAL ZONE LYMPHOMA (MZL) WHO REQUIRE SYSTEMIC THERAPY AND HAVE RECEIVED AT LEAST ONE PRIOR ANTI- CD20 BASED THERAPY	Not Converted - Indication Withdrawn	5/18/2023
NDA 203341 Supplement 9	BOSULIF	BOSUTINIB	PF PRISM CV	6/26/2017	12/19/2017	5.8	FOR THE TREATMENT OF ADULT PATIENTS WITH NEWLY DIAGNOSED CHRONIC PHASE (CP) PHILADELPHIA CHROMOSOME POSITIVE CHRONIC MYELOGENOUS LEUKEMIA (PH+CML)	Converted	5/14/2021
NDA 210259	CALQUENCE	ACALABRUTINIB	ASTRAZENECA PHARMACEUTICALS	6/13/2017	10/31/2017	4.6	FOR THE TREATMENT OF ADULT PATIENTS WITH MANTLE CELL LYMPHOMA (MCL) WHO HAVE RECEIVED AT LEAST ONE PRIOR THERAPY	Converted	1/16/2025
BLA 125554 Supplement 41	OPDIVO	NIVOLUMAB	BRISTOL MYERS SQUIBB	3/24/2017	9/22/2017	6.0	FOR THE TREATMENT OF PATIENTS WITH HEPATOCELLULAR CARCINOMA WHO HAVE BEEN PREVIOUSLY TREATED WITH SORAFENIB	Not Converted - Indication Withdrawn	7/23/2021
BLA 125514 Supplement 24	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME	3/22/2017	9/22/2017	6.0	FOR THE TREATMENT OF PATIENTS WITH RECURRENT LOCALLY ADVANCED OR METASTATIC GASTRIC OR GASTROESOPHAGEAL JUNCTION ADENOCARCINOMA WHOSE TUMORS EXPRESS PD-L1 [COMBINED POSITIVE SCORE (CPS) ≥1] AS DETERMINED BY AN FDA-APPROVED TEST, WITH DISEASE PROGRESSION ON OR AFTER TWO OR MORE PRIOR LINES OF THERAPY INCLUDING FLUOROPYRIMIDINE- AND PLATINUM-CONTAINING CHEMOTHERAPY AND IF APPROPRIATE, HER2/NEU TARGETED THERAPY	Not Converted - Indication Withdrawn	2/4/2022
NDA 209936	ALIQOPA	COPANLISIB	BAYER HEALTHCARE PHARMACEUTICALS	3/16/2017	9/14/2017	6.0	FOR THE TREATMENT OF ADULT PATIENTS WITH RELAPSED FOLLICULAR LYMPHOMA (FL) WHO HAVE RECEIVED AT LEAST TWO PRIOR SYSTEMIC THERAPIES	Not Converted - Application Withdrawn	3/18/2024
NDA 209570	N/A [1]	BENZNIDAZOLE	CHEMO RESEARCH AL C/O EXCELTIS USA	12/29/2016	8/29/2017	8.0	FOR THE TREATMENT OF CHAGAS DISEASE (AMERICAN TRYPANOSOMIASIS), CAUSED BY TRYPANOSOMA CRUZI, IN PEDIATRIC PATIENTS 2 TO 12 YEARS OF AGE	Not Yet Converted	
BLA 125554 Supplement 34	OPDIVO	NIVOLUMAB	BRISTOL MYERS SQUIBB	2/2/2017	7/31/2017	5.9	FOR THE TREATMENT OF ADULT AND PEDIATRIC PATIENTS 12 YEARS AND OLDER WITH MICROSATELLITE INSTABILITY-HIGH (MSI-H) OR MISMATCH REPAIR DEFICIENT (DMMR) METASTATIC COLORECTAL CANCER (CRC) THAT HAS PROGRESSED FOLLOWING TREATMENT WITH A FLUOROPYRIMIDINE, OXALIPLATIN, AND IRINOTECAN	Converted	4/8/2025
BLA 125514 Supplement 14	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME	9/8/2016	5/23/2017	5.4	FOR THE 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	Converted	3/28/2023
NDA 207968	JADENU SPRINKLE	DEFERASIROX	NOVARTIS PHARMACEUTICALS	7/21/2016	5/18/2017	9.9	FOR THE TREATMENT OF CHRONIC IRON OVERLOAD DUE TO BLOOD TRANSFUSIONS (TRANSFUSIONAL HEMOSIDEROSIS) IN PATIENTS 2 YEARS OF AGE AND OLDER	Converted	5/11/2018

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NDA 207968	JADENU SPRINKLE	DEFERASIROX	NOVARTIS PHARMACEUTICALS	7/21/2016	5/18/2017	9.9	FOR THE TREATMENT OF CHRONIC IRON OVERLOAD IN PATIENTS 10 YEARS OF AGE AND OLDER WITH NON-TRANSFUSION-DEPENDENT THALASSEMIA (NTDT) SYNDROMES AND WITH A LIVER IRON CONCENTRATION (LIC) OF AT LEAST 5 MILLIGRAMS OF IRON PER GRAM OF LIVER DRY WEIGHT (MG FE/G DW) AND A SERUM FERRITIN GREATER THAN 300 MCG/L	Converted	7/23/2020
BLA 125514 Supplement 17	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME	12/14/2016	5/18/2017	5.1	FOR THE TREATMENT OF PATIENTS WITH LOCALLY ADVANCED OR METASTATIC UROTHELIAL CARCINOMA WHO ARE NOT ELIGIBLE FOR CISPLATIN-CONTAINING CHEMOTHERAPY	Converted	8/31/2021
BLA 125514 Supplement 16	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME	11/10/2016	5/10/2017	6.0	IN COMBINATION WITH PEMETREXED AND CARBOPLATIN, FOR THE FIRST-LINE TREATMENT OF PATIENTS WITH METASTATIC NON-SQUAMOUS, NON-SMALL CELL LUNG CANCER	Converted	8/20/2018
BLA 761078	BAVENCIO	AVELUMAB	EMD SERONO	12/27/2016	5/9/2017	4.4	FOR THE TREATMENT OF PATIENTS WITH LOCALLY ADVANCED OR METASTATIC UROTHELIAL CARCINOMA (UC) WHO: HAVE DISEASE PROGRESSION DURING OR FOLLOWING PLATINUM-CONTAINING CHEMOTHERAPY OR WHO HAVE DISEASE PROGRESSION WITHIN 12 MONTHS OF NEOADJUVANT OR ADJUVANT TREATMENT WITH PLATINUM-CONTAINING CHEMOTHERAPY	Converted	6/30/2020
BLA 761069	IMFINZI	DURVALUMAB	ASTRAZENECA PHARMACEUTICALS	10/13/2016	5/1/2017	6.6	FOR THE 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	Not Converted - Indication Withdrawn	2/19/2021
NDA 208772	ALUNBRIG	BRIGATINIB	ARIAD PHARMACEUTICALS	8/29/2016	4/28/2017	8.0	FOR 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	Converted	5/22/2020
BLA 125554 Supplement 31	OPDIVO	NIVOLUMAB	BRISTOL MYERS SQUIBB	12/9/2016	4/25/2017	4.5	FOR THE TREATMENT OF ADULT PATIENTS WITH CLASSICAL HODGKIN LYMPHOMA THAT HAS RELAPSED OR PROGRESSED AFTER: • AUTOLOGOUS HEMATOPOIETIC STEM CELL TRANSPLANTATION (HSCT) AND BRENTUXIMAB VEDOTIN, OR • 3 OR MORE LINES OF SYSTEMIC THERAPY THAT INCLUDES AUTOLOGOUS HSCT	Not Yet Converted	
BLA 761034 Supplement 1	TECENTRIQ	ATEZOLIZUMAB	GENENTECH	10/31/2016	4/17/2017	5.5	FOR THE TREATMENT OF PATIENTS WITH LOCALLY ADVANCED OR METASTATIC UROTHELIAL CARCINOMA WHO ARE NOT ELIGIBLE FOR CISPLATIN-CONTAINING CHEMOTHERAPY, OR HAVE DISEASE PROGRESSION DURING OR FOLLOWING ANY PLATINUM-CONTAINING CHEMOTHERAPY, OR WITHIN 12 MONTHS OF NEOADJUVANT OR ADJUVANT CHEMOTHERAPY	Not Converted - Indication Withdrawn	12/2/2022
BLA 761049	BAVENCIO	AVELUMAB	EMD SERONO	9/23/2016	3/23/2017	6.0	FOR THE TREATMENT OF ADULTS AND PEDIATRIC PATIENTS 12 YEARS AND OLDER WITH METASTATIC MERKEL CELL CARCINOMA	Converted	9/6/2023
BLA 125514 Supplement 15	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME	9/15/2016	3/14/2017	5.9	FOR THE TREATMENT OF ADULT AND PEDIATRIC PATIENTS WITH REFRACTORY CLASSICAL HODGKIN LYMPHOMA, OR WHO HAVE RELAPSED AFTER 3 OR MORE PRIOR LINES OF THERAPY	Converted	10/14/2020
BLA 125554 Supplement 24	OPDIVO	NIVOLUMAB	BRISTOL MYERS SQUIBB	9/2/2016	2/2/2017	5.0	FOR THE TREATMENT OF LOCALLY ADVANCED OR METASTATIC UROTHELIAL CARCINOMA 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	Converted	8/19/2021
NDA 205552 Supplement 16	IMBRUVICA	IBRUTINIB	PHARMACYCLICS	9/23/2016	1/18/2017	3.8	FOR THE TREATMENT OF PATIENTS WITH MARGINAL ZONE LYMPHOMA (MZL) WHO REQUIRE SYSTEMIC THERAPY AND HAVE RECEIVED AT LEAST ONE PRIOR ANTI-CD20-BASED THERAPY	Not Converted - Indication Withdrawn	5/18/2023
NDA 209115 [5] Supplement 4	RUBRACA	RUCAPARIB	CLOVIS ONCOLOGY	6/23/2016	12/19/2016	5.9	FOR THE TREATMENT OF PATIENTS WITH DELETERIOUS BRCA MUTATION (GERMLINE AND/OR SOMATIC) ASSOCIATED ADVANCED OVARIAN CANCER WHO HAVE BEEN TREATED WITH TWO OR MORE CHEMOTHERAPIES	Converted	4/6/2018
BLA 761038	LARTRUVO	OLARATUMAB	ELI LILLY AND COMPANY	2/24/2016	10/19/2016	7.8	IN COMBINATION WITH DOXORUBICIN FOR THE TREATMENT OF ADULT PATIENTS WITH SOFT TISSUE SARCOMA (STS) WITH A HISTOLOGIC SUBTYPE FOR WHICH AN ANTHRACYCLINE-CONTAINING REGIMEN IS APPROPRIATE AND WHICH IS NOT AMENABLE TO CURATIVE TREATMENT WITH RADIOTHERAPY OR SURGERY	Not Converted - Application Withdrawn	2/25/2020
NDA 206488	EXONDYS 51	ETEPLIRSEN	SAREPTA THERAPEUTICS	6/26/2015	9/19/2016	14.8	FOR THE TREATMENT OF DUCHENNE MUSCULAR DYSTROPHY (DMD) IN PATIENTS WHO HAVE A CONFIRMED MUTATION OF THE DMD GENE THAT IS AMENABLE TO EXON 51 SKIPPING	Not Yet Converted	
BLA 125514 Supplement 9	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME	2/9/2016	8/5/2016	5.9	FOR THE TREATMENT OF PATIENTS WITH RECURRENT OR METASTATIC SQUAMOUS CELL CARCINOMA OF THE HEAD AND NECK WITH DISEASE PROGRESSION ON OR AFTER PLATINUM-CONTAINING CHEMOTHERAPY	Converted	6/10/2019
NDA 207999	OCALIVA	OBETICHOLIC ACID	INTERCEPT PHARMACEUTICALS	6/29/2015	5/27/2016	10.9	FOR THE TREATMENT OF PRIMARY BILIARY CHOLANGITIS (PBC) IN COMBINATION WITHURSODEOXYCHOLIC ACID (UDCA) IN ADULTS WITH AN INADEQUATE RESPONSE TO UDCA, OR AS MONOTHERAPY IN ADULTS UNABLE TO TOLERATE UDCA	Not Yet Converted	

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BLA 761034	TECENTRIQ	ATEZOLIZUMAB	GENENTECH	1/12/2016	5/18/2016	4.2	FOR THE 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	Not Converted - Indication Withdrawn	4/13/2021
BLA 125554 Supplement 19	OPDIVO	NIVOLUMAB	BRISTOL MYERS SQUIBB	3/1/2016	5/17/2016	2.5	FOR THE TREATMENT OF CLASSICAL HODGKIN LYMPHOMA THAT HAS RELAPSED OR PROGRESSED AFTER AUTOLOGOUS HEMATOPOIETIC STEM CELL TRANSPLANTATION (HSCT) AND POST-TRANSPLANTATION BRENTUXIMAB VEDOTIN	Not Yet Converted	
NDA 208573	VENCLEXTA	VENETOCLAX	ABBVIE	10/29/2015	4/11/2016	5.4	FOR THE TREATMENT OF PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) WITH 17P DELETION, AS DETECTED BY AN FDA APPROVED TEST, WHO HAVE RECEIVED AT LEAST ONE PRIOR THERAPY	Converted	6/8/2018
NDA 204630	PROVAYBLUE	METHYLENE BLUE	PROVEPHARM SAS	10/9/2015	4/8/2016	6.0	FOR THE TREATMENT OF PEDIATRIC AND ADULT PATIENTS WITH ACQUIRED METHEMOGLOBINEMIA	Converted	1/8/2024
BLA 125554 Supplement 7	OPDIVO	NIVOLUMAB	BRISTOL MYERS SQUIBB	7/23/2015	1/23/2016	6.0	1) IN COMBINATION WITH IPILIMUMAB FOR THE TREATMENT OF PATEINTS WITH UNRESECTABLE OR METASTATIC MELANOMA TO REMOVE THE RESTRICTION FOR THE TREATMENT OF ONLY PATIENTS WIHT BRAF WILD-TYPE MELANOMA, 2) AS A SINGLE AGENT FOR THE TREATMENT OF PATIENTS WITH BRAF V600 MUTATION POSITIVE, UNRESECTABLE OR METASTATIC MELANOMA TO REMOVE THE RESTRICTION THAT SUCH PATIENTS SHOULD HAVE DISEASE PROGRESSION FOLLOWING IPILIMUMAB AND A BRAF INHIBITOR	Converted	3/7/2019
NDA 208434	ALECENSA	ALECTINIB	HOFFMAN LA ROCHE	7/6/2015	12/11/2015	5.2	FOR THE 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	Converted	11/6/2017
BLA 761036	DARZALEX	DARATUMUMAB	JANSSEN BIOTECH	7/9/2015	11/16/2015	4.3	FOR 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	Converted	11/21/2016
NDA 208065	TAGRISSO	OSIMERTINIB	ASTRAZENECA PHARMACEUTICALS	6/5/2015	11/13/2015	5.3	FOR THE TREATMENT OF PATIENTS WITH METASTATIC EPIDERMAL GROWTH FACTOR RECEPTOR (EGFR) T790M MUTATION-POSITIVE-NON-SMALL-CELL LUNG CANCER (NSCLC), AS DETECTED BY AN FDAAPPROVED TEST, WHO HAVE PROGRESSED ON OR AFTER EGFR TKI THERAPY	Converted	3/30/2017
BLA 761025	PRAXBIND	IDARUCIZUMAB	BOEHRINGER INGELHEIM PHARMACEUTICALS	2/19/2015	10/16/2015	7.9	FOR THE 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	Converted	4/12/2018
BLA 125514 Supplement 5	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME	4/2/2015	10/2/2015	6.0	FOR THE 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	Converted	10/24/2016
BLA 125554 Supplement 2	OPDIVO	NIVOLUMAB	BRISTOL MYERS SQUIBB	3/30/2015	9/30/2015	6.0	IN COMBINATION WITH IPILIMUMAB, FOR THE TREATMENT OF PATIENTS WITH BRAF V600 WILD-TYPE, UNRESECTABLE OR METASTATIC MELANOMA	Converted	3/7/2019
NDA 208030	FERRIPROX	DEFERIPRONE	APOPHARMA	11/17/2014	9/9/2015	9.7	FOR THE TREATMENT OF PATIENTS WITH TRANSFUSIONAL IRON OVERLOAD DUE TO THALASSEMIA SYNDROMES WHEN CURRENT CHELATION THERAPY IS INADEQUATE	Converted	4/30/2021
NDA 206910	JADENU	DEFERASIROX	NOVARTIS PHARMACEUTICALS	5/30/2014	3/30/2015	10.0	FOR THE TREATMENT OF CHRONIC IRON OVERLOAD DUE TO BLOOD TRANSFUSIONS (TRANSFUSIONAL HEMOSIDEROSIS) IN PATIENTS 2 YEARS OF AGE AND OLDER	Converted	5/11/2018
NDA 206910	JADENU	DEFERASIROX	NOVARTIS PHARMACEUTICALS	5/30/2014	3/30/2015	10.0	FOR THE TREATMENT OF CHRONIC IRON OVERLOAD IN PATIENTS 10 YEARS OF AGE AND OLDER WITH NON-TRANSFUSION-DEPENDENT THALASSEMIA (NTDT) SYNDROMES AND WITH A LIVER IRON CONCENTRATION (LIC) OF AT LEAST 5 MILLIGRAMS OF IRON PER GRAM OF LIVER DRY WEIGHT (MG FE/G DW) AND A SERUM FERRITIN GREATER THAN 300 MCG/L	Converted	7/23/2020
NDA 205353	FARYDAK	PANOBINOSTAT	NOVARTIS PHARMACEUTICALS	3/24/2014	2/23/2015	11.0	IN COMBINATION WITH BORTEZOMIB (BTZ) AND DEXAMETHASONE(DEX) FOR THE TREATMENT OF PATIENTS WITH MULTIPLE MYELOMA (MM) WHO HAVE RECEIVED AT LEAST 2 PRIOR REGIMENS, INCLUDING BORTEZOMIB AND AN IMMUNOMODULATORY AGENT	Not Converted - Application Withdrawn	3/24/2022

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NDA 207103	IBRANCE	PALBOCICLIB	PFIZER	8/13/2014	2/3/2015	5.7	IN COMBINATION WITH LETROZOLE FOR THE 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	Converted	3/31/2017
BLA 125554	OPDIVO	NIVOLUMAB	BRISTOL MYERS SQUIBB	7/30/2014	12/22/2014	4.8	FOR THE TREATMENT OF UNRESECTABLE OR METASTATIC MELANOMA AND DISEASE PROGRESSION FOLLOWING IPILIMUMAB AND, IF BRAF V600 MUTATION POSITIVE, A BRAF INHIBITOR	Converted	3/7/2019
NDA 206162	LYNPARZA	OLAPARIB	ASTRAZENECA PHARMACEUTICALS	2/3/2014	12/19/2014	10.5	FOR PATIENTS WITH DELETERIOUS OR SUSPECTED DELETERIOUS GERMLINE BRCA MUTATED ADVANCED OVARIAN CANCER WHO HAVE BEEN TREATED WITH THREE OR MORE PRIOR LINES OF CHEMOTHERAPY	Not Converted - Application Withdrawn	3/26/2024
BLA 125557	BLINCYTO	BLINATUMOMAB	AMGEN	9/19/2014	12/3/2014	2.5	FOR THE TREATMENT OF PHILADELPHIA CHROMOSOME NEGATIVE RELAPSED OR REFRACTORY B-CELL PRECURSOR ACUTE LYMPHOBLASTIC LEUKEMIA (ALL)	Converted	7/11/2017
BLA 125514	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME	2/27/2014	9/4/2014	6.2	FOR THE TREATMENT OF PATIENTS WITH UNRESECTABLE OR METASTATIC MELANOMA AND DISEASE PROGRESSION FOLLOWING IPILIMUMAB AND, IF BRAF V600 MUTATION POSITIVE, A BRAF INHIBITOR	Converted	12/18/2015
NDA 205858	ZYDELIG	IDELALISIB	GILEAD SCIENCES	9/11/2013	7/23/2014	10.4	FOR THE TREATMENT OF RELAPSED FOLLICULAR B-CELL NON-HODGKIN LYMPHOMA (FL) IN PATIENTS WHO HAVE RECEIVED AT LEAST TWO PRIOR SYSTEMIC THERAPIES AND RELAPSED SMALL LYMPHOCYTIC LYMPHOMA (SLL) IN PATIENTS WHO HAVE RECEIVED AT LEAST TWO PRIOR SYSTEMIC THERAPIES	Not Converted - Indication Withdrawn	2/18/2022
NDA 206256	BELEODAQ	BELINOSTAT	SPECTRUM PHARMACEUTICALS	12/9/2013	7/3/2014	6.8	FOR THE TREATMENT OF PATIENTS WITH RELAPSED OR REFRACTORY PERIPHERAL T-CELL LYMPHOMA	Not Yet Converted	
NDA 205755	ZYKADIA	CERITINIB	NOVARTIS PHARMACEUTICALS	12/24/2013	4/29/2014	4.1	FOR THE TREATMENTOF PATIENTS WITH ANAPLASTIC LYMPHOMA KINASE (ALK)-POSITIVE METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WHO HAVE PROGRESSED ON OR ARE INTOLERANT TO CRIZOTINIB	Converted	5/26/2017
NDA 203202	NORTHERA	DROXIDOPA	LUNDBECK NA LTD	9/28/2011	2/18/2014	28.7	FOR THE 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	Not Yet Converted	
NDA 205552 Original 2	IMBRUVICA	IBRUTINIB	PHARMACYCLICS	6/28/2013	2/12/2014	7.5	FOR THE TREATMENT OF PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) WHO HAVE RECEIVED AT LEAST ONE PRIOR THERAPY	Converted	7/28/2014
NDA 202806 Supplement 2	TAFINLAR	DABRAFENIB	NOVARTIS PHARMACEUTICALS	7/9/2013	1/9/2014	6.0	IN COMBINATION WITH TRAMETINIB, FOR THE TREATMENT OF PATIENTS WITH UNRESECTABLE OR METASTATIC MELANOMA WITH BRAF V600E OR V600K MUTATIONS, AS DETECTED BY AN FDA-APPROVED TEST	Converted	11/20/2015
NDA 204114 Supplement 1	MEKINIST	TRAMETINIB	NOVARTIS PHARMACEUTICALS	7/8/2013	1/8/2014	6.0	IN COMBINATION WITH DABRAFENIB, FOR THE TREATMENT OF PATIENTS WITH UNRESECTABLE OR METASTATIC MELANOMA WITH BRAF V600E OR V600K MUTATIONS, AS DETECTED BY AN FDA-APPROVED TEST	Converted	11/20/2015
NDA 205552 Original 1	IMBRUVICA	IBRUTINIB	PHARMACYCLICS	6/28/2013	11/13/2013	4.5	FOR THE TREATMENT OF PATIENTS WITH MANTLE CELL LYMPHOMA (MCL)	Not Converted - Indication Withdrawn	5/18/2023
BLA 125409 Supplement 51	PERJETA	PERTUZUMAB	GENENTECH	5/1/2013	9/30/2013	5.0	IN COMBINATION WITH TRASTUZUMAB AND DOCETAXEL FOR THE NEOADJUVANT TREATMENT OF PATIENTS WITH HER2-POSITIVE, LOCALLY ADVANCED, INFLAMMATORY, OR EARLY STAGE BREAST CANCER (EITHER GREATER THAN 2 CM IN DIAMETER OR NODE POSITIVE) AS PART OF A COMPLETE TREATMENT REGIMEN FOR EARLY BREAST CANCER	Converted	12/20/2017
BLA 125151 Supplement 184	ELAPRASE	IDURSULFASE	SHIRE HUMAN GENETIC THERAPIES	9/24/2012	6/24/2013	9.0	PROVIDES FOR ADDITIONAL SAFETY AND EFFICACY INFORMATION FOR THE TREATMENT OF PATIENTS WITH HUNTER SYNDROME 5 YEARS OF AGE AND YOUNGER	Not Yet Converted	
NDA 204026	POMALYST	POMALIDOMIDE	CELGENE	4/10/2012	2/8/2013	10.0	FOR THE TREATMENT OF PATIENTS WITH MULTIPLE MYELOMA WHO HAVE RECEIVED AT LEAST TWO PRIOR THERAPIES INCLUDING LENALIDOMIDE AND BORTEZOMIB AND HAVE DEMONSTRATED DISEASE PROGRESSION ON OR WITHIN 60 DAYS OF COMPLETION OF THE LAST THERAPY	Converted	4/23/2015
NDA 021882 Supplement 15	EXJADE	DEFERASIROX	NOVARTIS PHARMACEUTICALS	12/23/2011	1/23/2013	13.1	FOR THE TREATMENT OF CHRONIC IRON OVERLOAD IN PATIENTS 10 YEARS OF AGE AND OLDER WITH NON-TRANSFUSION DEPENDENT THALASSEMIA (NTDT) SYNDROMES AND WITH A LIVER IRON CONCENTRATION (LIC) OF AT LEAST5 MILLIGRAMS OF IRON PER GRAM OF LIVER DRY WEIGHT (MG FE/G DW) AND A SERUM FERRITIN GREATER THAN 300 MCG/L	Converted	7/23/2020

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NDA 204384	SIRTURO	BEDAQUILINE	JANSSEN RESEARCH AND DEVELOPMENT	6/29/2012	12/28/2012	6.0	FOR THE TREATMENT OF, AS COMBINATION THERAPY, ADULTS (≥ 18 YEARS) WITH PULMONARY MULTI-DRUG RESISTANT TUBERCULOSIS (MDR-TB)	Converted	6/21/2024
NDA 203469	ICLUSIG	PONATINIB	ARIAD PHARMACEUTICALS	9/27/2012	12/14/2012	2.6	FOR THE TREATMENT OF ADULT PATIENTS WITH CHRONIC PHASE, ACCELERATED PHASE, OR BLAST PHASE CHRONIC MYELOID LEUKEMIA (CML) THAT IS RESISTANT OR INTOLERANT TO PRIOR TYROSINE KINASE INHIBITOR THERAPY OR PHILADELPHIA CHROMOSOME POSITIVE ACUTE LYMPHOBLASTIC LEUKEMIA (PH+ALL) THAT IS RESISTANT OR INTOLERANT TO PRIOR TYROSINE KINASE INHIBITOR THERAPY	Converted	11/28/2016
NDA 203585	SYNRIBO	OMACETAXINE MEPESUCCINATE	TEVA PHARMACEUTICALS INTERNATIONAL	3/30/2012	10/26/2012	6.9	FOR THE TREATMENT OF ADULT PATIENTS WITH CHRONIC OR ACCELERATED PHASE CHRONIC MYELOID LEUKEMIA (CML) WITH RESISTANCE AND/OR INTOLERANCE TO TWO OR MORE TYROSINE KINASE INHIBITORS (TKI)	Converted	2/10/2014
NDA 203985	AFINITOR DISPERZ	EVEROLIMUS	NOVARTIS PHARMACEUTICALS	2/29/2012	8/29/2012	6.0	FOR THE TREATMENT OF PEDIATRIC AND ADULT PATIENTS WITH TUBEROUS SCLEROSIS COMPLEX (TSC) FOR THE TREATMENT OF SUBEPENDYMAL GIANT CELL ASTROCYTOMA (SEGA) THAT REQUIRES THERAPEUTIC INTERVENTION BUT CANNOT BE CURATIVELY RESECTED	Converted	1/29/2016
NDA 202497	MARQIBO	VINCRISTINE SULFATE (LIPOSOMAL)	TALON THERAPEUTICS	7/12/2011	8/9/2012	13.0	FOR THE TREATMENT OF ADULTS WITH PHILADELPHIA (PH) CHROMOSOME NEGATIVE (-) ACUTE LYMPHOBLASTIC LEUKEMIA (ALL) IN SECOND RELAPSE OR GREATER RELAPSE OR WHOSE DISEASE HAS PROGRESSED FOLLOWING TWO OR GREATHER TREATMENT LINES OF ANTI-LEUKEMIA THERAPIES	Not Converted - Application Withdrawn	5/2/2022
NDA 202714	KYPROLIS	CARFILZOMIB	ONYX THERAPEUTICS	9/27/2011	7/20/2012	9.8	FOR THE TREATMENT OF PATIENTS WITH MULTIPLE MYELOMA WHO HAVE RECEIVED AT LEAST TWO PRIOR THERAPIES INCLUDING BORTEZOMIB AND AN IMMUNOMODULATORY AGENT AND HAVE DEMONSTRATED DISEASE PROGRESSION ON OR WITHIN 60 DAYS OF COMPLETION OF THE LAST THERAPY	Converted	1/21/2016
NDA 022334 Supplement 17	AFINITOR	EVEROLIMUS	NOVARTIS PHARMACEUTICALS	12/19/2011	4/26/2012	4.2	TREATMENT OF ADULTS WITH RENAL ANGIOMYOLIPOMA AND TUBEROUS SCLEROSIS COMPLEX (TSC) NOT REQUIRING IMMEDIATE SURGERY	Converted	2/18/2016
NDA 021825	FERRIPROX	DEFERIPRONE	APOPHARMA	1/30/2009	10/14/2011	32.4	FOR THE TREATMENT OF TRANSFUSIONAL IRON OVERLOAD DUE TO THALASSEMIA SYNDROMES WHEN CURRENT CHELATION THERAPY IS INADEQUATE	Converted	4/30/2021
NDA 202570	XALKORI	CRIZOTINIB	PF PRISM CV	3/30/2011	8/26/2011	4.9	FOR THE TREATMENT OF PATIENTS WITH LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) THAT IS ANAPLASTIC LYMPHOMA KINASE (ALK)-POSITIVE AS DETECTED BY AN FDA APPROVED TEST	Converted	11/20/2013
BLA 125388	ADCETRIS	BRENTUXIMAB VEDOTIN	SEATTLE GENETICS	2/28/2011	8/19/2011	5.7	FOR THE TREATMENT OF PATIENTS WITH HODGKIN LYMPHOMA AFTER FAILURE OF AUTOLOGOUS STEM CELL TRANSPLANT (ASCT) OR AFTER FAILURE OF AT LEAST TWO PRIOR MULTI-AGENT CHEMOTHERAPY REGIMENS IN PATIENTS WHO ARE NOT ASCT CANDIDATES	Converted	8/17/2015
BLA 125388 Supplement 6	ADCETRIS	BRENTUXIMAB VEDOTIN	SEATTLE GENETICS	2/28/2011	8/19/2011	5.7	FOR THE TREATMENT OF PATIENTS WITH SYSTEMIC ANAPLASTIC LARGE CELL LYMPHOMA (sALCL) AFTER FAILURE OF AT LEAST ONE PRIOR MULIT-AGENT CHEMOTHERPAY REGIMEN	Converted	3/20/2018
NDA 022393 Supplement 4	ISTODAX	ROMIDEPSIN	CELGENE	12/17/2010	6/16/2011	6.0	THE TREATMENT OF PERIPHERAL T-CELL LYMPHOMA (PTCL) IN PATIENTS WHO HAVE RECEIVED AT LEAST ONE PRIOR THERAPY	Not Converted - Indication Withdrawn	7/30/2021
NDA 021945	MAKENA	HYDROXYPROGESTERONE CAPROATE	AMAG PHARMA USA	4/20/2006	2/3/2011	57.5	TO REDUCE THE RISK OF PRETERM BIRTH IN WOMEN WITH A SINGLETON PREGNANCY WHO HAVE A HISTORY OF SINGLETON SPONTANEOUS PRETERM BIRTH	Not Converted - Application Withdrawn	4/6/2023
NDA 022334 Supplement 6	AFINITOR	EVEROLIMUS	NOVARTIS PHARMACEUTICALS	4/30/2010	10/29/2010	6.0	FOR THE TREATMENT OF SUBEPENDYMAL GIANT CELL ASTROCYTOMA (SEGA) ASSOCIATED WITH TUBEROUS SCLEROSIS (TS) WHO REQUIRE THERAPEUTIC INTERVENTION BUT ARE NOT CANDIDATES FOR CURATIVE SURGICAL RESECTION	Converted	1/29/2016
NDA 021986 Supplement 8	SPRYCEL	DASATINIB	BRISTOL MYERS SQUIBB	4/28/2010	10/28/2010	6.0	FOR THE TREATMENT OF NEWLY DIAGNOSED ADULTS WITH PHILADELPHIA CHROMOSOME-POSITIVE (PH+) CML IN CHRONIC PHASE	Converted	8/12/2015
NDA 022068 Supplement 5	TASIGNA	NILOTINIB	NOVARTIS PHARMACEUTICALS	12/21/2009	6/17/2010	5.9	FOR THE TREATMENT OF NEWLY DIAGNOSED ADULT PATIENTS WITH PHILADELPHIA CHROMOSOME POSITIVE CHRONIC MYELOID LEUKEMIA IN CHRONIC PHASE	Converted	1/27/2015
NDA 022059 Supplement 7	TYKERB	LAPATINIB	NOVARTIS PHARMACEUTICALS	3/31/2009	1/29/2010	10.0	TYKERB IN COMBINATION WITH LETROZOLE IS FOR THE TREATMENT OF POST MENOPAUSAL WOMEN WITH HORMONE RECEPTOR POSITIVE METASTATIC BREAST CANCER THAT OVEREXPRESS THE HER2 RECEPTOR FOR WHOM HORMONAL THERAPY IS INDICATED	Converted	12/6/2018
BLA 125326	ARZERRA	OFATUMUMAB	NOVARTIS PHARMACEUTICALS	1/30/2009	10/26/2009	8.8	FOR THE TREATMENT OF PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) REFRACTORY TO FLUDARABINE AND ALEMTUZUMAB	Converted	4/17/2014

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NDA 022468	FOLOTYN	PRALATREXATE	ALLOS THERAPEUTICS	3/24/2009	9/24/2009	6.0	FOR THE TREATMENT OF RELAPSED OR REFRACTORY PERIPERAL T-CELL LYMPHOMA	Not Yet Converted	
BLA 125085 Supplement 169	AVASTIN	BEVACIZUMAB	GENENTECH	11/3/2008	5/5/2009	6.0	FOR THE TREATMENT OF GLIOBLASTOMA WITH PROGRESSIVE DISEASE FOLLOWING PRIOR THERAPY	Converted	12/5/2017
NDA 021588 Supplement 25	GLEEVEC	IMATINIB MESYLATE	NOVARTIS PHARMACEUTICALS	6/24/2008	12/19/2008	5.9	FOR THE ADJUVANT TREATMENT OF ADULT PATIENTS FOLLOWING COMPLETE GROSS RESECTION OF KIT (CD117) POSITIVE GASTROINTESTINAL STROMAL TUMORS (GIST)	Converted	1/31/2012
NDA 022273	OFORTA	FLUDARABINE PHOSPHATE	SANOFI AVENTIS	11/19/2007	12/18/2008	13.0	FOR THE TREATMENT OF ADULTS PTS WITH B CELL CHRONIC LYMPHOCYTIC LEUEMIA (CLL) WHOSE DISEASE HAS NOT RESPONDED TO OR WHO HAVE NOT RESPONDED TO OR HAS PROGRESSED DURING OR AFTER TREATMENT WITH AT LEAST ONE STANDARD ALKYLATING-AGENT CONTAINING REGIMEN	Not Converted - Application Withdrawn	12/31/2011
NDA 022291	PROMACTA	ELTROMBOPAG	NOVARTIS PHARMACEUTICALS	12/19/2007	11/20/2008	11.1	FOR THE TREATMENT THROMBOCYTOPNEIA IN PATIENTS WITH CHRONIC IMMUNE (IDIOPATHIC) THROMBOCYTOPENIA (ITP) WHO HAVE HAD AN INSUFFICIENT RESPONSE TO CORTICOSTEROIDS, IMMUNOGLOBULINS, OR SPLENECTOMY	Converted	2/25/2011
NDA 021462 Supplement 15	ALIMTA	PEMETREXED DISODIUM	ELI LILLY AND COMPANY	8/28/2007	9/26/2008	13.0	FOR THE TREATMENT OF • NONSQUAMOUS NON-SMALL CELL LUNG CANCER: INITIAL TREATMENT IN COMBINATION WITH CISPLATIN. (1.1) • NONSQUAMOUS NON-SMALL CELL LUNG CANCER AS A SINGLE-AGENT AFTER PRIOR CHEMOTHERAPY (1.2)	Converted	7/2/2009
NDA 020634 Supplement 47	LEVAQUIN	LEVOFLOXACIN	JANSSEN PHARMACEUTICALS	7/5/2007	5/5/2008	10.0	TO REDUCE THE INCIDENCE OR PROGRESSION OF DISEASE FOLLOWING EXPOSURE TO AEROSOLIZED BACILLUS ANTHRACIS IN PEDIATRIC PATIENTS (>6 MONTH OF AGE AND OLDER)	Not Converted - Application Withdrawn	1/22/2021
NDA 020635 Supplement 51	LEVAQUIN	LEVOFLOXACIN	JANSSEN PHARMACEUTICALS	7/5/2007	5/5/2008	10.0	TO REDUCE THE INCIDENCE OR PROGRESSION OF DISEASE FOLLOWING EXPOSURE TO AEROSOLIZED BACILLUS ANTHRACIS IN PEDIATRIC PATIENTS (>6 MONTH OF AGE AND OLDER)	Not Converted - Application Withdrawn	7/21/2017
NDA 021721 Supplement 15	LEVAQUIN (oral solution)	LEVOFLOXACIN	JANSSEN PHARMACEUTICALS	7/5/2007	5/5/2008	10.0	TO REDUCE THE INCIDENCE OR PROGRESSION OF DISEASE FOLLOWING EXPOSURE TO AEROSOLIZED BACILLUS ANTHRACIS IN PEDIATRIC PATIENTS (>6 MONTH OF AGE AND OLDER)	Not Converted - Application Withdrawn	7/21/2017
BLA 125085 Supplement 91	AVASTIN	BEVACIZUMAB	GENENTECH	5/24/2006	2/22/2008	21.0	NEW INDICATION FOR USE IN COMBINATION WITH PACLITAXEL FOR THE TREATMENT OF PATIENTS WHO HAVE NOT RECEIVED CHEMOTHERAPY FOR METASTATIC HER2 NEGATIVE BREAST CANCER	Not Converted - Indication Withdrawn	11/18/2011
NDA 022187	INTELENCE	ETRAVIRINE	JANSSEN PRODUCTS LP	7/18/2007	1/18/2008	6.0	IN COMBINATION WITH OTHER ANTIRETROVIRAL AGENTS FOR THE TREATMENT OF HIV-1 IINFECTION IN TREATMENT-EXPERIENCED ADULT PATIENTS WHO HAVE EVIDENCE OF VIRAL REPLICATIONS AND HIV-1 STRAINS RESISTANT TO NON-NUCLELOSIDE REVERSE TRANSCRIPTASE INHIBITOR (NNRTI) AND OTHER ANTIRETROVIRAL AGENT	Converted	11/24/2009
NDA 022068	TASIGNA	NILOTINIB	NOVARTIS PHARMACEUTICALS	9/29/2006	10/29/2007	13.0	FOR THE TREATMENT OF CHRONIC PHASE (CP) AND ACCELERATED PHASE (AC) PHILADELPHIA CHROMOSONE POSITIVE CHRONIC MYELOGENOUS LEUKEMIA(CML)IN ADULT PATIENTS RESISTANT TO OR INTOLERANT TO PRIOR THERAPY THAT INCLUDED GLEEVEC (IMATINIB)	Converted	1/14/2011
NDA 022145	ISENTRESS	RALTEGRAVIR	MERCK SHARP & DOHME	4/13/2007	10/12/2007	6.0	IN COMBINATION WITH OTHER ANTIRETROVIRAL AGENTS, FOR THE TREATMENT OF HIV 1 INFECTION IN TREATMENT-EXPERIENCED ADULT PATIENTS WHO HAVE EVIDENCE OF VIRAL REPLICATION AND HIV-1 STRAINS RESISTANT TO MULTIPLE ANTIRETORVIRAL AGENTS	Converted	1/29/2009
NDA 022128	SELZENTRY	MARAVIROC	VIIV HEALTHCARE	12/20/2006	8/6/2007	7.5	FOR THE TREATMENT OF PATIENTS WITH CCR5-TROPIC HIV-1	Converted	11/25/2008
NDA 021588 Supplement 16	GLEEVEC	IMATINIB MESYLATE	NOVARTIS PHARMACEUTICALS	3/28/2006	9/27/2006	6.0	FOR THE TREATMENT OF NEWLY DIAGNOSED PHILADELPHIA POSITIVE CML IN PEDIATRIC PATIENTS	Converted	4/1/2011
BLA 125147	VECTIBIX	PANITUMUMAB	AMGEN	3/29/2006	9/27/2006	6.0	FOR THE TREATMENT OF EGFR-EXPRESSING, METASTATIC COLORECTAL CARCINOMA WITH DISEASE PROGRESSION ON OR FOLLOWING FLUOROPYRIMIDINE-, OXALIPLATIN-, AND IRINOTECAN-CONTAINING CHEMOTHERAPY REGIMENS	Converted	5/23/2014
NDA 021986	SPRYCEL	DASATINIB	BRISTOL MYERS SQUIBB	12/28/2005	6/28/2006	6.0	FOR THE TREATMENT OF CHRONIC MYELOID LEUKEMIA WITH RESISTANCE OR INTOLERANCE TO PRIOR THERAPY INCLUDING IMATINIB	Converted	5/21/2009
NDA 021976	PREZISTA	DARUNAVIR	JANSSEN PRODUCTS LP	12/23/2005	6/23/2006	6.0	FOR THE TREATMENT OF HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION IN ANTIRETROVIRAL TREATMENT-EXPERIENCED ADULT PATIENTS, SUCH AS THOSE WITH HIV-1 STRAINS RESISTANT TO MORE THAN ONE PROTEASE INHIBITOR	Converted	10/21/2008
NDA 021430 Original 1	THALOMID	THALIDOMIDE	CELGENE	12/23/2003	5/25/2006	29.1	FOR THE TREATMENT OF PATIENTS WITH NEWLY DIAGNOSED MULTIPLE MYELOMA	Converted	6/19/2014
NDA 021968 Original 1	SUTENT	SUNITINIB MALEATE	CP PHARMACEUTICALS INTERNATIONAL	8/11/2005	1/26/2006	5.5	FOR THE TREATMENT OF ADVANCED RENAL CELL CARCINOMA	Converted	2/2/2007
NDA 020726 Supplement 12	FEMARA	LETROZOLE	NOVARTIS PHARMACEUTICALS	6/28/2005	12/28/2005	6.0	FOR THE ADJUVANT TREATMENT OF POSTMENOPAUSAL WOMEN WITH HORMONE RECEPTOR POSITIVE EARLY BREAST CANCER	Converted	4/30/2010

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NDA 021882	EXJADE	DEFERASIROX	NOVARTIS PHARMACEUTICALS	5/2/2005	11/2/2005	6.0	FOR THE TREATMENT OF CHRONIC IRON OVERLOAD DUE TO BLOOD TRANSFUSIONS IN PATIENTS 2 YEARS OF AGE AND OLDER	Converted	5/11/2018
NDA 021877	ARRANON	NELARABINE	GLAXOSMITHKLINE	4/29/2005	10/28/2005	6.0	FOR THE TREATMENT OF PATIENTS WITH T-CELL ACUTE LYMPHOBLASTIC LEUKEMIA AND T-CELL LYMPHOBLASTIC LYMPHOMA WHOSE DISEASE HAS NOT RESPONDED TO OR HAS RELAPSED FOLLOWING TREATMENT WITH AT LEAST TWO CHEMOTHERAPY REGIMENS	Converted	7/31/2019
NDA 021814	APTIVUS	TIPRANAVIR	BOEHRINGER INGELHEIM PHARMACEUTICALS	12/22/2004	6/22/2005	6.0	CO-ADMINISTERED WITH 200 MG OF RITONAVIR FOR COMBINATION ANTIRETROVIRAL TREATMENT OF HIV-1 INFECTED ADULT PATIENTS WITH EVIDENCE OF VIRAL REPLICATION, WHO ARE HIGHLY TREATMENT-EXPERIENCED OR HAVE HIV-1 STRAINS RESISTANT TO MULTIPLE PROTEASE INHIBITORS	Converted	10/4/2007
NDA 021673	CLOLAR	CLOFARABINE	GENZYME	3/30/2004	12/28/2004	9.0	FOR THE TREATMENT OF PEDIATRIC PATIENTS 1 TO 21 YEARS OLD WITH RELAPSED OR REFRACTORY ACUTE LYMPHOCYTIC LEUKEMIA AFTER AT LEAST TWO PRIOR REGIMENS	Converted	7/18/2022
BLA 125011 Supplement 24	BEXXAR	TOSITUMOMAB AND IODINE I 131 TOSITUMOMAB	GLAXOSMITHKLINE	7/3/2004	12/22/2004	5.7	EXPAND THE INDICATION TO INCLUDE PATIENTS WITH RELAPSED OR REFRACTORY, LOW GRADE, FOLLICULAR OR TRANSFORMED CD20 POSITIVE NON-HODGKIN'S LYMPHOMA WHO HAVE NOT RECEIVED RITUXIMAB	Not Converted - Indication Withdrawn	10/23/2013
NDA 020634 Supplement 35	LEVAQUIN	LEVOFLOXACIN	JANSSEN PHARMACEUTICALS	5/26/2004	11/24/2004	6.0	FOR THE TREATMENT OF INHALATIONAL ANTHRAX (POST-EXPOSURE)	Not Converted - Application Withdrawn	1/22/2021
NDA 020635 Supplement 35	LEVAQUIN	LEVOFLOXACIN	JANSSEN PHARMACEUTICALS	5/26/2004	11/24/2004	6.0	FOR THE TREATMENT OF INHALATIONAL ANTHRAX (POST-EXPOSURE)	Not Converted - Application Withdrawn	7/21/2017
NDA 021721 Supplement 3	LEVAQUIN (oral solution)	LEVOFLOXACIN	JANSSEN PHARMACEUTICALS	11/12/2004	11/24/2004	0.4	FOR THE TREATMENT OF INHALATIONAL ANTHRAX (POST-EXPOSURE)	Not Converted - Application Withdrawn	7/21/2017
NDA 021272 Supplement 2	REMODULIN	TREPROSTINIL SODIUM	UNITED THERAPEUTICS	1/30/2004	11/24/2004	9.8	PROVIDES FOR ADDING THE INFUSION OF REMODULIN (TREPROSTINIL SODIUM) 1, 2.5, 5 & 10 MG/ML INJECTION VIA AN INDWELLING CENTRAL VENOUS CATHETER TO THE LABELING FOR THE TREATMENT OF PULMONARY ARTERIAL HYPERTENSION (PAH)	Converted	3/20/2006
BLA 125104	TYSABRI	NATALIZUMAB	BIOGEN	5/24/2004	11/23/2004	6.0	FOR THE TREATMENT OF PATIENTS WITH RELAPSING FORMS OF MULTIPLE SCLEROSIS (MS) TO REDUCE THE FREQUENCY OF CLINICAL EXACERBATIONS	Converted	6/5/2006
NDA 020726 Supplement 11	FEMARA	LETROZOLE	NOVARTIS PHARMACEUTICALS	4/29/2004	10/29/2004	6.0	FOR THE EXTENDED ADJUVANT TREATMENT OF EARLY BREAST CANCER IN POSTMENOPAUSAL WOMEN WHO HAVE RECEIVED FIVE YEARS OF ADJUVANT TAMOXIFEN THERAPY	Converted	4/30/2010
NDA 021322	LUVERIS	LUTROPIN ALPHA	EMD SERONO	5/1/2001	10/8/2004	41.3	CONCOMITANTLY ADMINIISTERED WITH GONAL-F (FOLLITROPIN ALFA FOR INJECTION) FOR STIMULATION OF FOLLICULAR DEVELOPMENT IN INFERTILE HYPOGONADOTROPIC HYPOGONADAL WOMEN WITH PROFOUND LH DEFICIENCY(LH < 1.2 IU/L)	Not Converted - Application Withdrawn	4/12/2016
NDA 021677 Original 1	ALIMTA	PEMETREXED DISODIUM	ELI LILLY AND COMPANY	11/4/2003	8/19/2004	9.5	AS A SINGLE AGENT FOR THE TREATMENT OF PATIENTS WITH LOCALLY ADVANCED OR METASTATAIC NON-SMALL CELL LUNG CANCER AFTER PRIOR CHEMOTHERPY	Converted	7/2/2009
NDA 021752	TRUVADA	TENOFOVIR DISOPROXIL FUMARATE; EMTRICITABINE	GILEAD SCIENCES	3/12/2004	8/2/2004	4.7	IN COMBINATION WITH OTHER ANTIRETROVIRAL AGENTS FOR THE TREATMENT OF HIV INFECTION IN ADULTS	Converted	3/8/2006
BLA 125084	ERBITUX	CETUXIMAB	ELI LILLY AND COMPANY	8/14/2003	2/12/2004	6.0	IN COMBINATION WITH IRINOTECAN FOR THE TREATMENT OF EGFR-EXPRESSING METASTATIC COLORECTAL CARCINOMA IN PATIENTS WHO ARE REFRACTORY TO IRINOTECAN-BASED CHEMOTHERAPY	Converted	7/6/2012
BLA 125084	ERBITUX	CETUXIMAB	ELI LILLY AND COMPANY	8/14/2003	2/12/2004	6.0	AS A SINGLE AGENT FOR THE TREATMENT OF EGFR-EXPRESSING, METASTATIC COLORECTAL CARCINOMA IN PATIENTS WHO ARE INTOLERANT TO IRINOTECAN-BASED CHEMOTHERAPY	Converted	10/2/2017
NDA 021335 Supplement 3	GLEEVEC	IMATINIB MESYLATE	NOVARTIS PHARMACEUTICALS	6/28/2002	5/20/2003	10.7	FOR THE TREATMENT OF PEDIATRIC PATIENTS WITH PH+ CHRONIC PHASE CML WHOSE DISEASE HAS RECURRED AFTER STEM CELL TRANSPLANT OR WHO ARE RESISTANT TO INTERFERON ALPHA THERAPY	Converted	9/27/2006
NDA 021602	VELCADE	BORTEZOMIB	MILLENNIUM PHARMACEUTICALS	1/21/2003	5/13/2003	3.7	FOR THE TREATMENT OF MULTIPLE MYELOMA PATIENTS WHO HAVE RECEIVED AT LEAST TWO PRIOR THERAPIES AND HAVE DEMONSTRATED DISEASE PROGRESSION ON THE LAST THERAPY	Converted	3/25/2005
NDA 021399	IRESSA	GEFITINIB	ASTRAZENECA UK LTD	8/5/2002	5/5/2003	9.0	AS A MONOTHERAPY FOR THE TREATMENT OF PATIENTS WITH LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER AFTER FAILURE OF BOTH PLATINUM-BASED AND DOCETAXEL CHEMOTHERAPY	Not Converted - Application Withdrawn	4/25/2012
BLA 103979	FABRAZYME	AGALSIDASE BETA	GENZYME	6/23/2000	4/24/2003	34.0	FOR THE TREATMENT OF FABRY DISEASE	Converted	3/11/2021
NDA 021481	FUZEON	ENFUVIRTIDE	HOFFMAN LA ROCHE	9/16/2002	3/13/2003	5.9	IN COMBINATION WITH OTHER ANTIRETROVIRAL AGENTS FOR THE TREATMENT OF HIV-1 INFECTION IN TREATMENT EXPERIENCED PATIENTS WITH EVIDENCE OF HIV-1 REPLICATION DESPITE ONGOING ANTIRETROVIRAL THERAPY	Converted	10/15/2004

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NDA 021335 Supplement 4	GLEEVEC	IMATINIB MESYLATE	NOVARTIS PHARMACEUTICALS	6/28/2002	12/20/2002	5.8	FOR THE TREATMENT OF NEWLY DIAGNOSED ADULT PATIENTS WITH PHILADELPHIA CHROMOSOME POSITIVE CHRONIC MYELOID LEUKEMIA (CML)	Converted	5/27/2009
NDA 020541 Supplement 10	ARIMIDEX	ANASTROZOLE	ANI PHARMACEUTICALS	3/5/2002	9/5/2002	6.0	FOR THE ADJUVANT TREATMENT OF POSTMENOPAUSAL WOMEN WITH HORMONE RECEPTOR POSITIVE EARLY BREAST CANCER	Converted	9/16/2005
NDA 021492	ELOXATIN	OXALIPLATIN	SANOFI AVENTIS	6/24/2002	8/9/2002	1.5	IN COMBINATION WITH INFUSIONAL 5-FU/LV FOR THE TREATMENT FOR PATIENTS WITH METASTATIC CARCINOMA OF THE COLON OR RECTUM WHOSE DISEASE HAS PROGRESSED DURING OR WITHIN 6 MONTHS OF COMPLETION OF FIRST LINE THERAPY WITH THE COMBINATION OF BOLUS 5 -FU/LV AND IRINOTECAN	Converted	1/9/2004
NDA 021272	REMODULIN	TREPROSTINIL SODIUM	UNITED THERAPEUTICS	10/16/2000	5/21/2002	19.1	TREATMENT OF PULMONARY ARTERIAL HYPERTENSION	Converted	3/20/2006
BLA 125019	ZEVALIN	IBRITUMOMAB TIUXETAN	SPECTRUM PHARMACEUTICALS	11/1/2000	2/19/2002	15.6	FOR THE TREATMENT OF PATIENTS WITH RELAPSED OR REFRACTORY LOW-GRADE, FOLLICULAR, OR TRANSFORMED B-CELL NON-HODGKIN'S LYMPHOMA(NHL) OTHER THAN THOSE PATIENTS WITH RITUXIMAB REFRACTORY FOLLICULAR NHL	Converted	9/3/2009
NDA 021335 Supplement 1	GLEEVEC	IMATINIB MESYLATE	NOVARTIS PHARMACEUTICALS	10/16/2001	2/1/2002	3.6	FOR THE TREATMENT OF PATIENTS WITH KIT (CD117) POSITIVE UNRESECTABLE AND/OR METASTATIC MALIGNANT GASTROINTESTINAL STROMAL TUMORS (GIST)	Converted	9/26/2008
NDA 021356	VIREAD	TENOFOVIR DISOPROXIL FUMARATE	GILEAD SCIENCES	5/1/2001	10/26/2001	5.9	FOR THE TREATMENT OF HIV-1 INFECTION IN ADULTS	Converted	3/8/2006
NDA 021335	GLEEVEC	IMATINIB MESYLATE	NOVARTIS PHARMACEUTICALS	2/27/2001	5/10/2001	2.4	FOR THE TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKEMIA(CML) IN BLAST CRISIS, ACCELERATED PHASE, OR IN CHRONIC PHASE AFTER FAILURE OF INTERFERON-ALPHA THERAPY	Converted	12/8/2003
BLA 103948	CAMPATH	ALEMTUZUMAB	GEMZYME	12/23/1999	5/7/2001	16.5	FOR THE TREATMENT OF B-CELL CHRONIC LYMPHOCYTIC LEUKEMIA (B-CLL) IN PATIENTS WHO HAVE BEEN TREATED WITH ALKYLATING AGENTS AND WHO HAVE FAILED FLUDARABINE THERAPY	Converted	9/19/2007
NDA 021205	TRIZIVIR	ABACAVIR SULFATE; LAMIVUDINE; ZIDOVUDINE	VIIV HEALTHCARE	12/17/1999	11/14/2000	10.9	ALONE OR IN COMBINATION WITH OTHER ANTIRETROVIRAL AGENTS FOR THE TREATMENT OF HIV-1 INFECTION	Converted	5/13/2005
NDA 021226	KALETRA (capsules)	LOPINAVIR: RITONAVIR	ABBVIE	6/1/2000	9/15/2000	3.5	IN COMBINATION WITH OTHER ANTIRETROVIRAL AGENTS FOR THE TREATMENT OF HIV-1 INFECTION IN ADULTS AND PEDIATRIC PATIENTS AGE SIX MONTHS OR OLDER	Converted	11/27/2002
NDA 021251	KALETRA (oral solution)	LOPINAVIR: RITONAVIR	ABBVIE	6/1/2000	9/15/2000	3.5	IN COMBINATION WITH OTHER ANTIRETROVIRAL AGENTS FOR THE TREATMENT OF HIV-1 INFECTION IN ADULTS AND PEDIATRIC PATIENTS AGE SIX MONTHS OR OLDER	Converted	11/27/2002
NDA 019858 Supplement 21	CIPRO	CIPROFLOXACIN	BAYER HEALTHCARE PHARMACEUTICALS	3/2/2000	8/30/2000	6.0	FOR THE TREATMENT OF INHALATIONAL ANTHRAX (POST-EXPOSURE)	Not Converted - Application Withdrawn	6/4/2004
NDA 020780 Supplement 8	CIPRO	CIPROFLOXACIN	BAYER HEALTHCARE PHARMACEUTICALS	3/2/2000	8/30/2000	6.0	FOR THE TREATMENT OF INHALATIONAL ANTHRAX (POST-EXPOSURE)	Not Converted - Application Withdrawn	6/4/2004
NDA 019537 Supplement 38	CIPRO	CIPROFLOXACIN	BAYER HEALTHCARE PHARMACEUTICALS	3/1/2000	8/30/2000	6.0	FOR THE TREATMENT OF INHALATIONAL ANTHRAX (POST-EXPOSURE)	Converted	1/7/2005
NDA 019847 Supplement 24	CIPRO	CIPROFLOXACIN	BAYER HEALTHCARE PHARMACEUTICALS	3/2/2000	8/30/2000	6.0	FOR THE TREATMENT OF INHALATIONAL ANTHRAX (POST-EXPOSURE)	Converted	1/7/2005
NDA 019857 Supplement 27	CIPRO	CIPROFLOXACIN	BAYER HEALTHCARE PHARMACEUTICALS	3/2/2000	8/30/2000	6.0	FOR THE TREATMENT OF INHALATIONAL ANTHRAX (POST-EXPOSURE)	Converted	1/7/2005
NDA 021174	MYLOTARG	GEMTUZUMAB OZOGAMICIN	WYETH PHARMACEUTICALS	10/29/1999	5/17/2000	6.6	FOR THE TREATMENT OF PATIENTS WITH CD33 POSITIVE ACUTE MYELOID LEUKEMIA IN FIRST RELAPSE WHO ARE 60 YEARS OF AGE OR OLDER AND WHO ARE NOT CONSIDERED CANDIDATES FOR CYTOTOXIC CHEMOTHERAPY	Not Converted - Application Withdrawn	11/28/2011
NDA 021156 Original 1	CELEBREX	CELECOXIB	GD SEARLE	6/25/1999	12/23/1999	6.0	TO REDUCE THE NUMBER OF ADENOMATOUS COLORECTAL POLYPS IN FAMILIAL ADENOMATOUS POLYPOSIS PATIENTS, AS AN ADJUNCT TO USUSAL CARE	Not Converted - Indication Withdrawn	6/8/2012
NDA 050747	SYNERCID	DALFOPRISTIN/QUINUPRISTIN	KING PHARMACEUTICALS	9/5/1997	9/21/1999	7.8†	FOR THE TREATMENT OF VANCOMYCIN-RESISTANT ENTEROCOCCUS FAECIUM (VREF)	Not Converted - Application Withdrawn	11/12/2010 [2]
NDA 021029	TEMODAR	TEMOZOLOMIDE	MERCK SHARP & DOHME	8/13/1998	8/11/1999	11.9	FOR THE TREATMENT OF ADULT PATIENTS WITH REFRACTORY ANAPLASTIC ASTROCYTOMA	Converted	3/15/2005
NDA 050718 Supplement 6	DOXIL	DOXORUBICIN HYDROCHLORIDE	JANSSEN PRODUCTS LP	12/29/1998	6/28/1999	6.0	FOR THE TREATMENT OF METASTATIC CARCINOMA OF THE OVARY IN PATIENTS WITH DISEASE THAT IS REFRACTORY TO BOTH PACILTAXEL-AND PLATINUM-BASED CHEMOTHERAPY REGIMENS	Converted	1/28/2005
NDA 021007	AGENERASE (capsules)	AMPRENAVIR	GLAXOSMITHKLINE	10/16/1998	4/15/1999	6.0	IN COMBINATION WITH OTHER ANTIRETROVIRAL AGENTS, FOR THE TREATMENT OF HIV-1 INFECTION	Converted	5/11/2001
NDA 021039	AGENERASE (oral solution)	AMPRENAVIR	GLAXOSMITHKLINE	12/8/1998	4/15/1999	4.2	IN COMBINATION WITH OTHER ANTIRETROVIRAL AGENTS, FOR THE TREATMENT OF HIV-1 INFECTION	Converted	5/11/2001
NDA 021041	DEPOCYT	CYTARABINE(liposomal)	PACIRA PHARMACEUTICALS	10/5/1998	4/1/1999	5.9	FOR THE INTRATHECAL TREATMENT OF LYMPHOMATOUS MENINGITIS	Converted	4/19/2007
BLA 103767	ONTAK	DENILEUKIN DIFTITOX	EISAI	12/9/1997	2/5/1999	13.9	FOR THE TREATMENT OF PERSISTENT OR RECURRENT CUTANEOUS T-CELL LYMPHOMA WHOSE MALIGNANT CELLS EXPRESS THE CD25 COMPONENT OF THE IL-2 RECEPTOR	Converted	10/15/2008

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NDA 020977	ZIAGEN (tablets)	ABACAVIR SULFATE	VIIV HEALTHCARE	6/24/1998	12/17/1998	5.8	IN COMBINATION WITH OTHER ANTIRETROVIRAL AGENTS, FOR THE TREATMENT OF HIV-1 INFECTION	Converted	4/15/2004
NDA 020978	ZIAGEN (oral solution)	ABACAVIR SULFATE	VIIV HEALTHCARE	6/24/1998	12/17/1998	5.8	IN COMBINATION WITH OTHER ANTIRETROVIRAL AGENTS, FOR THE TREATMENT OF HIV-1 INFECTION	Converted	4/15/2004
NDA 020972	SUSTIVA	EFAVIRENZ	BRISTOL MYERS SQUIBB	6/11/1998	9/17/1998	3.2	IN COMBINATION WITH OTHER ANTIRETROVIRAL AGENTS, FOR THE TREATMENT OF HIV-1 INFECTION	Converted	2/9/2000
NDA 020636 Supplement 9	VIRAMUNE	NEVIRAPINE	BOEHRINGER INGELHEIM PHARMACEUTICALS	3/16/1998	9/11/1998	5.9	PROVIDES FOR AN ORAL SUSPENSION IN COMBINATION WITH OTHER ANTIRETROVIRAL AGENTS FOR THE TREATMENT OF HIV-1 INFECTION	Converted	3/27/2002
NDA 020933	VIRAMUNE	NEVIRAPINE	BOEHRINGER INGELHEIM PHARMACEUTICALS	4/20/1998	9/11/1998	4.7	IN COMBINATION WITH OTHER ANTIRETROVIRAL AGENTS FOR TREATMENT OF HIV-1 INFECTION	Converted	3/27/2002
BLA 103772	REMICADE	INFLIXIMAB	JANSSEN BIOTECH	12/30/1997	8/24/1998	7.8	FOR THE TREATMENT OF MODERATELY TO SEVERELY ACTIVE CROHN'S DISEASE FOR THE REDUCTION OF THE SIGNS AND SYMPTOMS, IN PATIENTS WHO HAVE AN INADEQUATE RESPONSE TO CONVENTIONAL THERAPIES AND TREATMENT OF PATIENTS WITH FISTULIZING CROHN'S DISEASE FOR THE REDUCTION IN THE NUMBER OF DRAINING ENTEROCUTANEOUS FISTULAS	Converted	4/1/2003
NDA 021024	PRIFTIN	RIFAPENTINE	SANOFI AVENTIS	12/22/1997	6/22/1998	6.0	FOR THE TREATMENT OF PULMONARY TUBERCULOSIS	Converted	6/1/2009
NDA 019832	SULFAMYLON	MAFENIDE ACETATE	MYLAN INSTITUTIONAL	3/31/1997	6/5/1998	14.2†	FOR USE AS ADJUNCTIVE TOPICAL ANTIMICROBIAL AGENT TO CONTROL BACTERIAL INFECTION WHEN USED UNDER MOIST DRESSINGS OVER MESHED AUTOGRAPFTS ON EXCISED BURN WOUNDS	Not Converted - Application Withdrawn	11/30/2022
NDA 020896	XELODA	CAPECITABINE	HOFFMAN LA ROCHE	10/31/1997	4/30/1998	6.0	FOR THE TREATMENT OF METASTATIC BREAST CANCER RESISTANT TO BOTH PACILTAXEL AND AN ANTHRACYCLINE-CONTAINING CHEMOTHERAPY REGIMEN OR RESISTANT TO PACILTAXEL AND FOR WHOM FURTHER ANTHRACYCLINE THERAPY AY BE CONTRAINDICATED	Converted	9/7/2001
NDA 020705	RESCRIPTOR	DELAVIRDINE MESYLATE	VIIV HEALTHCARE	7/15/1996	4/4/1997	8.6	FOR THE TREATMENT OF HIV-1 INFECTION IN COMBINATION WITH APPROPRIATE ANTIRETROVIRAL AGENTS WHEN THERPAY IS WARRANTED	Converted	5/16/2001
NDA 020778	VIRACEPT (oral powder)	NELFINAVIR MESYLATE	AGOURON PHARMACEUTICALS	12/26/1996	3/14/1997	2.6	FOR THE TREATMENT OF HIV INFECTION WHEN THERAPY IS WARRANTED	Converted	5/17/2000
NDA 020779	VIRACEPT (tablets)	NELFINAVIR MESYLATE	AGOURON PHARMACEUTICALS	12/26/1996	3/14/1997	2.6	FOR THE TREATMENT OF HIV INFECTION WHEN ANTIRETROVIRAL THERAPY IS WARRANTED	Converted	5/17/2000
NDA 019815	PROAMATINE	MIDODRINE HYDROCHLORIDE	SHIRE DEVELOPMENT	9/25/1995	9/6/1996	11.4†	FOR THE TREATMENT OF SYMPTOMATIC ORTHOSTATIC HYPROTENSION (OH)	Not Yet Converted	
NDA 020604	SEROSTIM	SOMATROPIN	EMD SERONO	9/11/1995	8/23/1996	11.4	FOR THE TREATMENT OF AIDS WASTING AND CACHEXIA	Converted	8/29/2003
NDA 020636	VIRAMUNE	NEVIRAPINE	BOEHRINGER INGELHEIM PHARMACEUTICALS	2/23/1996	6/21/1996	3.9	IN COMBINATION WITH NUCLEOSIDE ANALOGUES FOR THE TREATMENT OF HIV-1 INFECTED ADULTS WHO HAVE EXPREIENCED CLINICAL AND/OR IMMUNOLOGICAL DETERIORATION	Converted	3/27/2002
NDA 020571	CAMPTOSAR	IRINOTECAN HCL TRIHYDROTE	PFIZER	12/28/1995	6/14/1996	5.6	FOR THE TREATMENT OF METASTATIC CARCINOMA OF THE COLON OR RECTUM WHOSES DIEASE HAS PROGRESSED FOLLOWING 5-FU-BASED THERAPYC	Converted	10/22/1998
NDA 020449	TAXOTERE	DOCETAXEL	SANOFI AVENTIS	7/27/1994	5/14/1996	21.6	FOR THE TREATMENT OF PATIENTS WITH LOCALLY ADVANCED OR METASTATIC BREAST CARCINOMA WHO HAVE PROGRESSED DURING ANTHRACYCLINE-BASED THERAPY OR HAVE RELAPSED DURING ANTHRACYCLINE-BASED ADJUVANT THERAPY	Converted	6/22/1998
NDA 020221 Supplement 2	ETHYOL	AMIFOSTINE	CLINIGEN HEALTHCARE	2/9/1996	3/15/1996	1.2	TO REDUCT CUMULATIVE RENAL TOXICITY ASSOCIATED WITH REPEATED ADMINSTATIONS OF CISPLATIN IN PATIENTS WITH NON-SMALL CELL LUNG CANCER	Not Converted - Indication Withdrawn	3/28/2006 [3]
NDA 020685	CRIXIVAN	INDINAVIR SULFATE	MERCK SHARP & DOHME	1/31/1996	3/13/1996	1.4	FOR THE TREATMENT OF HIV-1 INFECTION IN ADULTS WHEN THERAPY IS WARRANTED	Converted	2/6/1998
NDA 020659	NORVIR (oral solution)	RITONAVIR	ABBOTT LABORATORIES	12/21/1995	3/1/1996	2.3	IN COMBINATION WITH NUCLEOSIDE ANALOGS OR AS MONOTHERPY FOR THE TREATMENT OF HIV INFECTION WHEN THERAPY IS WARRANTED	Converted	5/26/1999
NDA 020680	NORVIR (oral solution)	RITONAVIR	ABBOTT LABORATORIES	12/21/1995	3/1/1996	2.3	IN COMBINATION WITH NUCLEOSIDE ANALOGS OR AS MONOTHERPY FOR THE TREATMENT OF HIV INFECTION WHEN THERAPY IS WARRANTED	Converted	5/26/1999
NDA 020628	INVIRASE	SAQUINAVIR MESYLATE	HOFFMAN LA ROCHE	8/31/1995	12/6/1995	3.2	IN COMBINATION WITH NUCLEOSIDE ANALOGS FOR THE TREATMENT OF ADVANCED HIV INFECTION IN SELECTED PATIENTS	Converted	9/27/1996
NDA 050718	DOXIL	DOXORUBICIN HYDROCHLORIDE	JANSSEN PRODUCTS LP	9/7/1994	11/17/1995	14.3	FOR THE TREATMENT OF KAPOSI'S SARCOMA IN AIDS PATIENTS WITH DISEASE THAT HAS PROGRESSED ON PRIOR COMBINATION CHEMOTHERAPY OR IN PATIENTS WHO ARE INTOLERANT TO SUCH THERAPY	Converted	6/10/2008
NDA 020564	EPIVIR	LAMIVUDINE	VIIV HEALTHCARE	7/7/1995	11/17/1995	4.4	IN COMBINATION WITH RETROVIR (ZIDOVUDINE) FOR THE TREATMENT OF HIV INFECTION WHEN THERAPY IS WARRANTED BASED ON CLINICAL AND/OR IMMUNOLOGICAL EVIDENCE OF DISEASE PROGRESSION	Converted	4/11/1997
NDA 020596	EPIVIR	LAMIVUDINE	VIIV HEALTHCARE	7/7/1995	11/17/1995	4.4	IN COMBINATION WITH RETROVIR (ZIDOVUDINE) FOR THE TREATMENT OF HIV INFECTION WHEN THERAPY IS WARRANTED BASED ON CLINICAL AND/OR IMMUNOLOGICAL EVIDENCE OF DISEASE PROGRESSION	Converted	4/11/1997

CDER Drug and Biologic Accelerated Approvals Based on a Surrogate Endpoint
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NDA 020498	CASODEX	BICALUTAMIDE	ANI PHARMACEUTICALS	9/14/1994	10/4/1995	12.7	IN COMBINATION THERAPY WITH AN LHRH ANALOGUE FOR THE TREATMENT OF ADVANCED PROSTATE CANCER	Converted	12/12/1997
NDA 020212	ZINECARD	DEXRAZOXANE HYDROCHLORIDE	PHARMACIA AND UPJOHN	8/5/1994	5/26/1995	9.7†	FOR THE PREVENTION OF CARDIOMYOPATHY ASSOCIATED WITH DOXORUBICIN ADMINISTRATION	Converted	10/31/2002
NDA 020412	ZERIT	STAVUDINE	BRISTOL MYERS SQUIBB	12/28/1993	6/24/1994	5.9	FOR THE TREATMENT OF ADULT PATIENTS WITH ADVANCED HIV INFECTION WHO ARE INTOLERANT OF APPROVED THERAPIES WITH PROVEN CLINICAL BENEFIT OR WHO HAVE EXPERIENCED SIGNIFICANT CLINICAL OR IMMUNOLOGICAL DETERIORATION WHILE RECEIVING THESE THERAPIES OR FOR WHOM SUCH THERAPIES ARE CONTRAINDICATED	Converted	12/21/1995
NDA 050697 Original 1	BIAXIN	CLARITHROMYCIN	ABBVIE	11/2/1992	12/23/1993	13.7	FOR THE TREATMENT OF DISSEMINATED MYCOBACTERIAL INFECTIONS DUE TO MYCOBACTERIUM AVIUM AND MYCOBACTERIUM INTRACELLULARE	Converted	5/24/2002
NDA 050698	BIAXIN	CLARITHROMYCIN	ABBVIE	11/2/1992	12/23/1993	13.7	FOR THE TREATMENT OF DISSEMINATED MYCOBACTERIAL INFECTIONS DUE TO MYCOBACTERIUM AVIUM AND MYCOBACTERIUM INTRACELLULARE	Converted	5/24/2002
BLA 103471	BETASERON	INTERFERON BETA-1B	BAYER HEALTHCARE PHARMACEUTICALS	6/18/1992	7/23/1993	13.2	USE IN AMBULATORY PATIENTS WITH RELAPSING-REMITTING MULTIPLE SCLEROSIS TO REDUCE THE FREQUENCY OF CLINICAL EXACERBATIONS	Converted	3/14/2003
NDA 020199	HIVID	ZALCITABINE	HOFFMAN LA ROCHE	10/31/1991	6/19/1992	7.6	IN COMBINATION WITH ZIDOVUDINE FOR THE TREATMENT OF ADULT PATIENTS WITH ADVANCED HIV INFECTION (CD4 CELL COUNTS < 300 CELLS/MM3) WHO HAVE DEMONSTRATED SIGNIFICANT CLINICAL OR IMMUNOLOGIC DETERIORATION	Converted	6/26/1996

†-- Total approval time was adjusted based on management decision. This is a legacy practice and is no longer exercised.

1. Proprietary name yet to be determined
2. Federal Register Date, which may be different than applicant submission or FDA action date
3. Date of the labeling supplement approval that removed this indication
4. This accelerated approval is for a new dosing regimen that is applicable across multiple indications. See FDA Press Release of 8-APR-20 for more details
5. Indication withdrawn on 10-JUN-22

The Therapeutic Biologic Products transferred from CBER to CDER effective 1-Oct-03