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Brand Name	**Generic Name**	**Application Number**	**Commitment Date (Approval Date)**	**PMC identifier**	**Description of Postmarketing Commitment**	**ORIGINAL Targeted Completion Date**	**Status**
Afinitor	everolimus	22334	3/30/2009	610-1	Conduct a trial in patients with severe hepatic impairment (Child Pugh Class C). This trial need not be conducted in patients with cancer and a single dose evaluation will be appropriate. The protocol should be submitted prior to initiation for review and concurrence.	4/14/2011	Fulfilled
Afinitor	everolimus	22334	3/30/2009	610-2	Submit the final, per-protocol overall survival analysis of protocol C2240 which was to be conducted 2 years after randomization of the last patient.	6/30/2010	Fulfilled
Afinitor	everolimus	22334	5/5/2011	1756-2	Submit the results of the final analysis of overall survival data from RAD001C2325 to further characterize the safety and efficacy profile of everolimus in carcinoid tumors.	7/31/2012	Fulfilled
Afinitor	Everolimus BHT	22334	7/20/2012	PMC#1899-1	Submit a final report, including datasets, for the final overall survival results from trial CRAD001Y2301 (BOLERO-2).	6/30/2015	Fulfilled
Afinitor	Everolimus BHT	22334	3/30/2009	PMR#1756-1	Submit the results of the final analysis of overall survival data from RAD001C2324 to further characterize the safety and efficacy profile of everolimus in pancreatic neuroendocrine tumors.	7/31/2014	Fulfilled
Afinitor	Everolimus BHT	22334	3/30/2009	PMR#1700-2	Submit long term follow-up efficacy and safety data from C2485	11/30/2014	Fulfilled
Afinitor	Everolimus BHT	22334	30-Mar-2009	PMR#1700-4	Evaluate risk of long term effects on growth for pediatric patients; submit long term data on patients enrolled on C2485	11/30/2014	Fulfilled
Afinitor	Everolimus BHT	22334	3/30/2009	PMR#1700-1	Submit final report and datasets from M2301	3/31/2015	Fulfilled
Afinitor	Everolimus BHT	22334	3/30/2009	PMR#1700-3	Evaluate risk of long term effects on growth for pediatric patients; submit long term data on patients enrolled on M2301	3/31/2015	Fulfilled
Afinitor	Everolimus BHT	22334	3/30/2009	PMR#1892-1	Submit final report from M2302	8/31/2015	Fulfilled
Afinitor	Everolimus BHT	22334	30-Mar-2009	PMC#1899-2	Conduct a 3-arm trial of eve+exe vs. eve vs. capecitabine in HR+ advanced BC	31-Aug-2017	Fulfilled

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Afinitor	Everolimus BHT	22334	10-Apr-2018	PMC #3355-1	Extension phase data in TSC-seizures; Submit the clinical report and datasets once all patients have completed the extnesion phase of Trial CRAD001M2304	31-Aug-2018	Fulfilled
Afinitor	Everolimus BHT	203985	10-Apr-2018	PMC #3355-1	Extension phase data in TSC-seizures; Submit the clinical report and datasets once all patients have completed the extnesion phase of Trial CRAD001M2304	31-Aug-2018	Fulfilled
Arranon	Nelarabine	021877	28-Oct-2005	Subpart H PMC	Submit results of Phase III trial AALL0434	31-Dec-2016	Fulfilled
Arranon	Nelarabine	021877	28-Oct-2005	PMC 3447-1	Characterize the neurological adverse reactions to nelarabine with regard to time to onset, maximum grade and duration. Submit a description of the results of the analysis, data files used to perform the analysis, and labeling updated with the additional information about the characteristics of the neurological adverse reactions.	31-Aug-2018	Fulfilled
Coartem	artemether/ lumefantrine	22268	4/7/2009	1142-3	Conduct a neurotoxicity study of oral artemether in juvenile rats including neurologic functional batteries, toxicokinetics, and extensive brain histopathology.	-Dec-2011	Fulfilled
Coartem	artemether/ lumefantrine	22268	4/7/2009	1142-4	Conduct bacterial reverse mutation studies (Ames assays) for lumefantrine impurities [...] and artemether impurities [...]. Lumefantrine impurities [...] and artemether impurities [...] have structural alerts for genotoxicity, and the proposed release limits for these compounds are higher than levels that are qualified by available toxicology studies.	6/1/2010	Fulfilled

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Coartem	artemether/ lumefantrine	22268	4/7/2009	1142-5	Perform spectral characterization of all specified impurities for lumefantrine impurities [...] and artemether impurities [...]. The structure of lumefantrine impurities [...] and artemether impurities [...] should be characterized using spectral procedures such as lH- and l3C-NMR (nuclear magnetic resonance), infrared (IR), ultraviolet and mass spectroscopy. Tabulated, interpreted data for all spectra, and copies of IR and 1H-NMR spectra should be submitted.	12/1/2009	Fulfilled
Coartem	artemether/ lumefantrine	22268	4/7/2009	1142-6	Conduct an in vitro study to characterize the induction potential of artemether, dihydroartemisinin (DHA), and lumefantrine on the metabolism of substrates of CYP3A4. Conduct an in vitro study to evaluate the induction potential of artemether, DHA, and lumefantrine on the metabolism of co-administered drugs that are substrates of the Cytochrome P450 3A4 (CYP3A4) enzyme system (e.g., oral contraceptives). . If the results of this in vitro study are positive, a clinical trial will be needed to further assess this risk.	3/1/2011	Fulfilled
Coartem	artemether/ lumefantrine	22268	4/7/2009	1142-7	Conduct an in vitro study to characterize the potential interaction between artemether and lumefantrine, the components of Coartem Tablets, and rifampin. If, upon review, it is determined that theclinical trial adequately addresses the potential interaction between artemether and lumefantrine and rifampin, then this in vitro study will not be needed.	1/1/2013	Released

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Coartem	artemether/ lumefantrine	22268	4/7/2009	1142-8	Conduct an in vitro study to characterize the potential interaction between artemether and lumefantrine, the components of Coartem Tablets, and protease inhibitors (PIs). If, upon review, it is determined that the clinical trial adequately addresses the potential interaction between artemether and lumefantrine and PIs, then this in vitro study will not be needed.	1/1/2013	Released
Coartem	artemether/ lumefantrine	22268	4/7/2009	1142-9	Conduct an in vitro study to characterize the potential interaction between artemether and lumefantrine, the components of Coartem Tablets, and nonnucleoside reverse transcriptase inhibitors (NNRTIs). If, upon review, it is determined that the clinical trial adequately addresses the potential interaction between artemether and lumefantrine and NNRTIs, then this in vitro study will not be needed.	1/1/2013	Released
Coartem	artemether/ lumefantrine	22268	4/7/2009	1142-10	Complete the currently ongoing trial "An open label, single center study of the effects of Coartem, Malarone and artesunate-mefloquine on auditory function following the treatment of acute uncomplicated P. j falciparum malaria in patients 12 years of age or older in Columbia."	3/1/2010	Fulfilled
Coartem	artemether/ lumefantrine	22268	4/7/2009	1142-11	Complete a clinical drug interaction trial to evaluate the effect of a co-administered CYP3A4 inducer on the pharmacokinetics of artemether and lumefantrine, the components of Coartem Tablets. Complete a clinical drug interaction trial using a potent CYP3A4 inducer, such as rifampin, to evaluate the effect of co-administering the inducer on the pharmacokinetics ofarte.mether and lumefantrine.	3/1/2011	Fulfilled

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Coartem	artemether/ lumefantrine	22268	4/7/2009	1142-12	Complete a clinical drug interaction trial to evaluate the two-way interaction between artemether and lumefantrine, the components of Coartem Tablets, and a protease inhibitor (PI). Complete a clinical drug interaction trial using a representative PI, such as lopinavir/ritonavir or ritonavir, to evaluate the two-way interaction between artemether and lumefantrine and a PI.	3/1/2011	Fulfilled
Coartem	artemether/ lumefantrine	22268	~~39910~~ 4/7/2009	1142-13	Complete a clinical trial to evaluate the two-way interaction between artemether and lumefantrine, the components of Coartem Tablets, and a non-nucleoside reverse transcriptase inhibitor (NNRTI). Complete a clinical drug interaction trial using a representative NNRTI, such as efavirenz or nevirapine, to evaluate the two-way interaction between artemether and lumefantrine and a NNRTI.	3/1/2011	Fulfilled
Coartem	artemether/ lumefantrine	22268	4/7/2009	1142-14	Conduct a clinical interaction trial to evaluate the induction potential of artemether and lumefantrine, the components of Coartem Tablets, on CYP3A4 substrates. If the results of the in vitro study (see Item 6 above) are positive, a clinical trial will be needed to further characterize the effect of artemether and lumefantrine on the pharmacokinetics of co-administered drugs that are metabolized by the CYP3A4 enzyme system, such as oral contraceptives.	10/1/2012	Released
Coartem	artemether/ lumefantrine	22268	4/7/2009	1142-15	Develop a dissolution test method for Coartem Tablets to acheive a minimum [...] dissolution of each component, artemether and lumefantrine.	12/1/2011	Fulfilled
Coartem	Artemether, Lumefantrine	22268	4/7/2009	PMR 1142-1	Conduct a descriptive study of the use of Coartem Tablets in non-immune travelers (Protocol CCOA566A2424)	30-Apr-16	Fulfilled

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Coartem	Artemether, Lumefantrine	22286	4/7/2009	PMR 1142-2	Submit surveillance reports to evaluate the potential development of resistance to Coartem Tablets	31-Aug-16	Fullfilled
Cosentyx	Secukinumab	BLA 125,504	21-Jan-2015	PMC# 2848-5	To Assess whether secukinumab alters the metabolism or pharmacokinetics of CYP substrates in psoriasis patients treated with secukinumab	31-May-2016	Fulfilled
Exjade	Deferasirox	21882	11/2/2005	PMC 750-1	Pediatric Registry Postmarketing study	2/29/2016	Fulfilled
Exjade	deferasirox	21882	11/2/2005	750-2	Complete the extension portion of Studies 0105E2, 0106E1, 0107E1, 0108E1, and 0109E1 for a total of 4 years after the core trial (5 years total in patients initially treated with ICL670, 4 years for patients initially treated with DFO).	6/1/2009	Fulfilled
Exjade	deferasirox	21882	11/2/2005	750-3	Conduct a single arm study in patients with congenital or acquired anemias and chronic iron overload to obtain additional data in patients with LIC < 7 treated with Exjade doses of 20 or 30 mg/kg per day.	3/1/2010	Fulfilled
Exjade	deferasirox	21882	11/2/2005	750-4	Provide the full study report, including safety and efficacy datasets, for Study 0109, a study in patients with sickle cell disease.	Janaury 2006	Fulfilled
Exjade	deferasirox	21882	11/2/2005	750-5	Provide an adequate proposal for assessing iron concentration and cardiac function in patients treated with Exjade.	6/1/2008	Fulfilled
Exjade	deferasirox	21882	11/2/2005	750-6	Complete a study to collect safety and efficacy data for Exjade in patients with elevated baseline serum creatinine (> or = 2X ULN) in patients with low or intermediate risk MDS (e.g., Study US03, amended to include patients with baseline serum creatinine values up to 2X ULN). Duration of followup on Exjade should be at least 3 years.	12/1/2009	Fulfilled
Exjade	deferasirox	21882	11/2/2005	750-7	Conduct a single dose pharmacokinetics study of Exjade in subjects with hepatic impairment.	6/1/2007	Fulfilled

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Exjade	deferasirox	21882	11/2/2005	750-8	Conduct a drug-drug-interaction study with midazolam to investigate the potential of Exjade to inhibit CYP4503A4.	Jun-2007	Fulfilled
Exjade	deferasirox	21882	11/2/2005	750-11	Adequately address the high specification limit of 5 ppm for maximum allowable level of 4-Hydrazinobenzoic acid (4-HBA) in the drug substance. To qualify the presence of this impurity of 5 ppm, conduct a 4-week repeated dose oral toxicity sutdy with 4-HBA in rats and demonstrate that the no effect dose is at least 50 ppm, i.e., >=10 fold higher concentration than the proposed qualification level of 5 ppm. The study should employ pure 4-HBA. (Refer to the ICH Q3A document entitled, "Guidance on Impurities in New Drug Substances, February 2003).	12/1/2006	Fulfilled
Exjade	Deferasirox	21882	11/2/2005	PMC 1994-7	Characterize the relationship between LIC and serum ferritin in patients with NTDT at the various times when a decision on whether to initiate treatment with Exjade® (deferasirox) is being made, and during treatment at times when dose adjustment(s) may be made or when a decision on treatment discontinuation may be made. Perform an analysis of paired LIC and serum ferritin measurements obtained in studies 2209 and 2209E before, during or after treatment with Exjade to determine the positive and negative predictive values of specific thresholds of serum ferritin for LIC values of LIC >5, LIC >7, LIC >15 and LIC <3 mg Fe/g dw.	11/31/2013	Fulfilled
Exjade	Deferasirox	21882	11/1/2005	PMR 1994-5	NTDT (Non-Transfusion Dependent Thalassemia syndromes)	30-Jun-19	Fullfilled
Exjade	Deferasirox	21882	2-Nov-2005	PMC 750-9	MDS Postmarketing study	31-Dec-09	Fulfilled

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Exjade	Deferasirox	21882	2-Nov-2005	PMR 1994-3	NTDT Conduct a prospective, randomized trial in at least 210 patients with low to intermediate risk myelodysplastic syndromes (MDS) receiving Exjade® (deferasirox) for transfusional iron overload (approximately 140) or placebo (approximately 70) to determine the efficacy and safety of Exjade® (deferasirox) in this population. The trial will continue for 3 years from the date the last patient is enrolled.	30-Sep-18	Fulfilled
Famvir	famciclovir	20363	6/29/1994	1186-1	Deferred pediatric study under PREA for the treatment of HSV or VZV infection and/or suppressive therapy for HSV in pediatric patients ages 1 month to <18 years of age.	6/1/2009	Fulfilled
Famvir	famciclovir	20363	6/29/1994	1186-2	Conduct a study to investigate the treatment effect of famciclovir single-day therapy in Blacks with recurrent herpes infection.	9/1/2009	Fulfilled
Fanapt	iloperidone	22192	5/6/2009	3	Complete the ongoing P95 carcinogenicity study.	5/31/2010	Fulfilled
Fanapt	iloperidone	22192	5/6/2009	4	Conduct a study investigating the possible in vitro interaction of iloperidone and P-Glycoprotein (P-Gp).	12/4/2009	Fulfilled
Fanapt	iloperidone	22192	5/6/2009	5	A repeat of clinical trial CIL0522A0103, conducted with a group of subjects with mildly and moderately impaired hepatic function, comparing them to normals in the same trial.	5/31/2011	Fulfilled
Fanapt	Iloperidone	22192	5/6/2009	PMC #6	Conduct, and submit the results of, a randomized withdrawal clinical trial to address longer-term efficacy at appropriate doses.	5/1/2013	Will not be fullfilled/Product Divested as of 01-01-2015

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Fanapt	Iloperidone	22192	5/6/2006	PMR#1	A pediatric study under PREA for the treatment of schizophrenia in pediatric patients ages 13 to 17. A study to obtain pharmacokinetic data and provide information pertinent to dosing of iloperidone tablets in the relevant pediatric population.	3/1/2014	Will not be fullfilled/Product Divested 01-01-2015
Fanapt	Iloperidone	22192	5/6/2009	PMR#2	A deferred pediatric study under PREA for the treatment of schizophrenia in pediatric patients ages 13 to 17. A study of the efficacy and safety of iloperidone tablets in the relevant pediatric population.	3/1/2014	Will not be fullfilled/Product Divested 01-01-2015
Femara	letrozole	20726	10/29/2004	1179-1	To continue collection of safety and efficacy data from the patients who were enrolled in the pivotal trial MA-17 and to summarize the findings in annual reports to the agency. Each patient should be followed until death or for at least five years and a final study report should be submitted.	N/A	Fulfilled
Femara	letrozole	20726	10/29/2004	1179-2	To submit the final study report, for trial MA-17, 6 months after all patients have received 5 years of letrozole therapy.	N/A	Fulfilled
Femara	letrozole	20726	10/29/2004	1179-3	To submit a final study report from the now closed BIG 18-98 trial in order to further evaluate the long term safety of 5 years treatment with letrozole. The final study report should be submitted no more than 6 months after the protocol specified final analysis.	N/A	Fulfilled
Femara	letrozole	20726	12/28/2005	1155-1	To follow all patients in the BIG 1-98 trial for safety and efficacy until death or at least 5 years from randomization.	3/1/2009	Fulfilled
Femara	letrozole	20726	12/28/2005	1155-2	Complete the MA.17 trial sub- studies of Femara effect on bones (MA.17B) and serum lipids (MA.17L).	6/30/2008	Fulfilled

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Femara	letrozole	20726	12/28/2005	1155-4	Complete the BIG 1-98 post-baseline sub study (with post-baseline BMD & bone marker data), following patients up until 1 year after completion of the 5 years of adjuvant treatment.	12/1/2010	Fulfilled
Femara	letrozole	20726	4/30/2010	1155-5	Complete study CFEM345D2407: An open-label, randomized, multi-center study to evaluate the skeletal and lipid profile effects of letrozole and tamoxifen in postmenopausal women with resected, hormone receptor positive breast cancer.	12/1/2011	Fulfilled
Focalin XR Extended-Release Capsules	methylphenidate	21-802	5/26/2005	1558-1	An in vitro interaction study with clinically relevant alcohol concentrations is requested to examine the effect of ethanol on dose dumping.	10/1/2005	Fulfilled
Focalin XR Extended-Release Capsules	methylphenidate	21-802	5/26/2005	1558-2	A thorough QT study examining relevant doses in adults is required.	3/1/2007	Fulfilled
Focalin XR Extended-Release Capsules	methylphenidate	21-802	5/26/2005	1558-3	Conduct a pediatric fixed-dose response study.	12/1/2007	Fulfilled

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Farydak	Panobinostat	205-353	23-Feb-2015	PMR 2181-1	Randomized Phase 2 clinical trial of panobinostat in combination with subcutaneous bortezomib and dexamethasone Conduct a randomized Phase 2 clinical trial of panobinostat in combination with subcutaneous bortezomib and dexamethasone to characterize the safety and efficacy of at least two different doses of panobinostat. Eligible patients will include patients with relapsed multiple myeloma who have been previously exposed to immunomodulatory agents. The primary objective is to assess the overall response rate (ORR) in all treatment arms according to International Myeloma Working Group (IMWG) criteria by investigator assessment. The trial should include one interim analysis. The results of this trial will be used to inform the dose selection for the confirmatory Phase 3 trial. Submit a final report with full datasets.	8/31/2019	Will not be Fulfilled (Divested to Secura Bio Inc. as of following Date (3-Jun-2019))

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Farydak	Panobinostat	205-353	23-Feb-2015	PMR 2181-2	Phase 3 Trial of panobinostat in combination with subcutaneous bortezomib and dexamethasone Conduct a multicenter, randomized, placebo-controlled Phase 3 trial comparing panobinostat in combination with subcutaneous bortezomib and dexamethasone with subcutaneous bortezomib and dexamethasonein patients with relapsed multiple myeloma who have been previously exposed to immunomodulatory agents. The panobinostat dose selection will be based upon the interim analysis of the trial described in PMR 2181-1. Eligible patients will have previously treated multiple myeloma, 1-3 prior lines of therapy, prior immunomodulatory agent exposure (either thalidomide, lenalidomide, or pomalidomide), and measurable disease. The primary objective is to compare the progression free survival (PFS) in both treatment arms by investigator assessment.	12/31/2021	Will not be Fulfilled (Divested to Secura Bio Inc. as of following Date (3-Jun-2019))
Foradil Aerolizer	Formoterol	20831	16-Feb-2001	PMR 1752-1	LABA Safety Study	30-Jun-2017	Released
Foradil Aerolizer	formoterol fumarate	20831	2/16/2001	1	Evaluation of the safety and efficacy of regular, twice daily administration of one or more dose levels of Foradil Aerolizer above that of the approved dose (12 mcg twice daily), in comparison to the safety and efficacy of the approved dose.	8/16/2003	Fulfilled
Foradil Aerolizer	formoterol fumarate	21279	9/5/2001	1	Foradil Aerolizer: Holter monitoring in patients with COPD. Protocol Submission: Within 6 months; Study Start: Within 12 months; Final Report Submission: Within 34 months.	Jul-2004	Fulfilled
Foradil Aerolizer	Formoterol	20831	2/16/2001	PMR 1752-2	LABA safety	30-Apr-18	Fulfilled
Gilenya	fingolimod	22527	9/21/2010	1679-4	An in vitro study to evaluate the potential for fingolimod-P to induce CYP450 isoenzymes.	Dec-2011	Fulfilled

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Gilenya	fingolimod	22527	9/21/2010	1679-5	An in vitro study to evaluate the potential for fingolimod to inhibit CYP2C8 and for fingolimod-P to inhibit CYP2B6.	Oct-2010	Fulfilled
Gilenya	fingolimod	22527	9/21/2010	1679-7	Upon completion of Study FTY720D2309, provide an integrated summary of safety for Studies FTY720D2301, FTY720D2302, and FTY720D2309.	Jan-2012	Fulfilled
Gilenya	fingolimod	22527	9/21/2010	1679-8	A juvenile rat toxicology study. The study should utilize animals of an age range and stage(s) of development that are comparable to the intended pediatric population; the duration of dosing should cover the intended length of treatment in the pediatric population. In addition to the usual toxicological parameters, this study should evaluate effects of fingolimod on growth, reproductive development, and neurological and neurobehavioral development.	Mar-2012	Fulfilled
Gilenya	fingolimod	22527	9/21/2010	1679-6	An in vitro study to evaluate the potential for statins (e.g. simvastatin, lovastatin) to induce CYP4F2, an enzyme that metabolizes fingolimod.	Dec-2011	Fulfilled
Gilenya	Fingolimod hydrochloride	22527	21-Sep-2010	PMR#1679-1	Deferred pediatric study	1-Jan-2016	Fulfilled
Gleevec	imatinib mesylate	21588	10/19/2006	154-1	To meet with the Division and the FDA Center for Devices and Radiological Health (CDRH) Office of In Vitro Diagnostics within 3 months to discuss the feasibility of a validated test kit for PDGFR gene rearrangements for patients with MDS/MPD.	Jan-2007	Fulfilled
Gleevec	imatinib mesylate	21588	10/19/2006	650-1	To meet with the Division and the FDA CDRH Office of In Vitro Diagnostics within 3 months and propose a plan with timelines thereafter for the development of a validated test kit for the detection of the D816V c-kit mutation in aggressive systemic mastocytosis.	Jan-2007	Fulfilled

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Gleevec	imatinib mesylate	21588	10/19/2006	321-1	To meet with the Division and FDA CDRH Office of In Vitro Diagnostics within 3 months and propose a plan with timelines thereafter for the development of a validated test kit for the detection of the FIP 1L1-PDGFR-alpha fusion protein in HES/CEL.	Jan-2007	Fulfilled
Gleevec	imatinib mesylate	21588	10/19/2006	321-2	Develop, in consultation with the FDA Center for Devices and Radiological Health (CDRH) Office a validated test kit for the detection of the FIP1L1-PDGFR-alpha fusion protein in HES/CEL.	Apr-2013	Released
Gleevec	imatinib mesylate	21588	9/27/2006	1068-1	To follow up safety and efficacy information for Study 2108. Updated status reports to be submitted in March 2007 and March 2008. Provision of further long term data will be reassessed following the submission of the March 2008 study status report and will depend on the number of patients still on study at that time.	Apr-2011	Fulfilled
Gleevec	imatinib mesylate	21588	4/18/2003	1326-3	Submit the PK/PD data from the comparison of 400 mg/day versus 800 mg/day in GIST patients in the two ongoing multicenter trials of imatinib (EORTC and NCI sponsored trials)	N/A	Fulfilled
Gleevec	imatinib mesylate	21588	12/19/2008	111-1	To complete the ongoing clinical trial entitled "A single phase III randomized double-blind study of adjuvant imatinib versus placebo in patients who had complete gross resection of their primary gastrointestinal stromal tumor (GIST)" and provide a report and datasets at four years of follow-up for relapse-free survival.	Nov-2010	Fulfilled

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Gleevec	imatinib mesylate	21588	12/19/2008	111-2	To complete the ongoing clinical trial entitled "A single phase III randomized double-blind study of adjuvant imatinib versus placebo in patients who had complete gross resection of their primary gastrointestinal stromal tumor (GIST)" and provide a report and datasets at five years of follow-up for relapse-free survival.	Nov-2011	Fulfilled
Gleevec	imatinib mesylate	21588	19-Dec-2008	111-3	To complete the ongoing clinical trial entitled "A single phase III randomized double-blind study of adjuvant imatinib versus placebo in patients who had complete gross resection of their primary gastrointestinal stromal tumor (GIST)" and provide a report and datasets after collection of 5 years of overall survival data.	30-Nov-2011	Fulfilled
Gleevec	imatinib mesylate	21588	19-Dec-2008	111-4	To complete the clinical trial entitled "Short (12 months) versus long (36 months) duration of adjuvant treatment with the tyrosine kinase inhibitor imatinib mesylate of operable GIST with a high risk of recurrence (SSG XVIII/AIO)" and provide a report and datasets.	30-Nov-2011	Fulfilled
Gleevec	imatinib mesylate	21588	18-Apr-2003	1992-1	Provide updated data for subjects in Cohort 5 of the pivotal trial in order to provide a more robust estimate of 4-year event free survival (EFS) and overall survival (OS). This data will be submitted as a dataset containing the most recent data available in the Children's Oncology Group database.	1-Aug-2013	Fulfilled
Gleevec	Imatinib mesilate	21588	4/18/2003	PMC#650-2	Rare disease diagnostic ASM	4/15/2013	Fulfilled
Gleevec	Imatinib mesilate	21588	4/18/2003	PMC#154-2	Rare disease diagnostric MDS/MPD	4/15/2013	Fulfilled
Gleevec	Imatinib mesilate	21588	4/18/2003	PMC#1870-1	Submit OS data from SSG study	3/31/2015	Fulfilled

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Brand Name	**Generic Name**	**Application Number**	**Commitment Date (Approval Date)**	**PMC identifier**	**Description of Postmarketing Commitment**	**ORIGINAL Targeted Completion Date**	**Status**
Ilaris	Canakinumab	125319	6/17/2009	PMC#1	Develop a study protocol for establishing new working cell banks using human serum albumin obtained from a U.S.-licensed source. The protocol should include acceptance criteria for cell culture metrics and canakinumab quality attributes, and provide limits that assure that validated cell generation time from the Master Cell Bank will be maintained. Timetable submitted: Final Protocol: Feb 2010; New WCB established: Jul 2010; Final report submission: July 2010	Jul-2010	Fulfilled
Ilaris	canakinumab	125319	6/17/2009	2	Complete and report the ongoing, open-label, clinical trial D2306 investigating the safety of higher doses of Ilaris (canakinumab).	Sep-2010	Fulfilled
Ilaris	Canakinumab	125319	6/17/2009	PMR#3: Dose-up titration safety study D2201	Complete and report the ongoing, multicenter, open-label, 6-month, clinical trial D2201 investigating the safety of higher doses of Ilaris (canakinumab). Patients in trial D2201 will receive a dose of 4 mg/kg subcutaneously for patients weighing less than 15 to 40 kg.	1/31/2011	Fulfilled
Ilaris	Canakinumab	125319	6/17/2009	PMC#1 (SJIA)	Develop new ADA assay	9/30/2014	Fulfilled
Ilaris	Canakinumab	125319	6/17/2009	FDA PMC#4 3120-1 - Final CSR N2301 Epoch 3 Data	Submit data from the randomized withdrawal period (Epoch 3) of the ongoing phase 3 study, CACZ885N2301 (N2301). Include an assessment of the maintenance of efficacy of canakinumab at a reduced dosing frequency in the study report.	10/31/2016	Fullfilled

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Brand Name	**Generic Name**	**Application Number**	**Commitment Date (Approval Date)**	**PMC identifier**	**Description of Postmarketing Commitment**	**ORIGINAL Targeted Completion Date**	**Status**
Jadenu	Deferasirox	206910	3/30/2015	PMR 2888-1	Establish a registry for children aged 2 to < 6 years to enroll approximately 200 patients receiving deferasirox and follow them for 5 years. Collect data at least monthly for renal function and blood pressure and yearly for growth and development, and analyze the data for adverse renal reactions and delayed growth and development. Submit your monitoring scheme for our review and comment.	29-Feb-2016	Fulfilled
Jadenu	Deferasirox	206910	3/30/2015	PMR 2888-6	Conduct an enhanced pharmacovigilance study, including proactive surveillance and follow-up of spontaneous reports, to characterize the frequency and severity of adverse Events of Special Interest (ESIs), defined as all deaths and severe or serious events of kidney or liver toxicity, in adults receiving deferasirox for documented iron overload related to multiple transfusions for myelodysplastic syndrome with anemia requiring transfusions.	6/30/2019	Fulfilled
Jadenu	Deferasirox	207968	5/18/2017	PMR 3342-1	Establish a registry for children aged 2 to < 6 years to enroll approximately 200 patients receiving deferasirox and follow them for 5 years. Collect data at least monthly for renal function and blood pressure and yearly for growth and development, and analyze the data for adverse renal reactions and delayed growth and development. Submit your monitoring scheme for our review and comment.	2/29/2016	Fulfilled

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Brand Name	**Generic Name**	**Application Number**	**Commitment Date (Approval Date)**	**PMC identifier**	**Description of Postmarketing Commitment**	**ORIGINAL Targeted Completion Date**	**Status**
Jadenu	Deferasirox	206910	3/30/2015	PMR 2888-4	Conduct a prospective, randomized trial in at least 210 patients with low to intermediate risk myelodysplastic syndromes (MDS) receiving deferasirox for transfusional iron overload (approximately 140 patients) or placebo (approximately 70 patients) to determine the efficacy and safety of deferasirox in this population. The trial will continue for 3 years from the date the last patient is enrolled.	30-Sep-18	Fulfilled
Jadenu	Deferasirox	206910	3/30/2015	PMR 2888-7	Complete a study of long-term follow-up (3 years) in 150 patients with myelodysplastic syndromes (MDS) receiving deferasirox to evaluate safety (including cardiac, hepatic, endocrine and renal) and hematologic and clinical benefit of deferasirox in these patients.	31-Dec-19	Fulfilled
Kisqali	Ribociclib	209092	13-Mar-2017	PMR-3168-2	Complete on-going clinical pharmacokinetic trial CLEE011A2116 (part 1) to determine an appropriate dose of ribociclib in patients with severe renal impairment.	30-Apr-2018	Fulfilled
Kisqali	Ribociclib	209092	13-Mar-2017	PMC-3168-4	Conduct additional in vitro studies to evaluate the discriminating ability of the dissolution acceptance criterion (Q = 80% at 45 min) using the approved dissolution method with a validated HPLC analytical method for drug quantification in combination with collecting in vivo PK data using film-coated tablet batches.	30-Sep-2018	Fulfilled
Mekinist	Trametinib	204114	5/29/2013	PMR 2045-4	QT/QTc Interval Prolongation	4/30/2015	Fulfilled

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Brand Name	**Generic Name**	**Application Number**	**Commitment Date (Approval Date)**	**PMC identifier**	**Description of Postmarketing Commitment**	**ORIGINAL Targeted Completion Date**	**Status**
Mekinist	Trametinib	204114/S-001	1/8/2014	PMC 2117-2	Complete and submit the final report, including datasets, for the ongoing MEK116513 trial, "A Phase III, Randomised, Open-Label Study Comparing the Combination of the BRAF Inhibitor Dabrafenib and the MEK Inhibitor Trametinib to the BRAF Inhibitor Vemurafenib in Subjects with Unresectable (Stage IIIC) or Metastatic (Stage IV) BRAF V600E/K Mutation-Positive Cutaneous Melanoma."	6/30/2015	Fulfilled
Mekinist	Trametinib	204114/S-001	1/8/2014	PMR 2117-1	To submit an efficacy supplement containing the final report, including summary analyses, datasets, and revised labeling based on the results of the ongoing MEK115306 trial, "A Phase III, Randomized, Double-Blinded Study, Comparing the Combination of the BRAF inhibitor, Dabrafenib and the MEK inhibitor, Trametinib to Dabrafenib and Placebo as First-Line Therapy in Subjects with unresectable (Stage IIIC) or Metastatic (Stage IV) BRAF V600E/K Mutation-Positive Cutaneous Melanoma."	8/31/2014	Fulfilled
Neoral	cyclosporine	50715, 50716	7/14/1995	1	Assess the long term safety and tolerability of Neoral in allogeneic liver transplant recipients (randomized, controlled, 24 mo. follow-up).	6/29/2000	Fulfilled
Neoral	cyclosporine	50737, 50738	6/19/1997	1	Obtain additional data on the use of Neoral in African American patients treated for severe, recalcitrant plaque psoriasis. A proposal for the design of an uncontrolled (or historically controlled) trial will be submitted to FDA within six months.	12/6/2003	Fulfilled
Neoral	cyclosporine	50715, 50716	7/14/1995	2	The long term safety and tolerability of Neoral in allogeneic heart transplant recipients (randomized, controlled, 24 mo. follow-up).	6/19/2000	Fulfilled

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Neoral	cyclosporine	50715, 50716	7/14/1995	3	Evaluate for the potential of drug interactions between Neoral and oral contraceptive.	1/18/2005	Fulfilled
Neoral	cyclosporine	50715, 50716	7/14/1995	4	Evaluate the appropriate starting dose of Neoral in the different transplant populations for patients receiving various combinations of concomitant immunosuppressive medications. In particular evaluate the starting dose of Neoral when used in dual and triple combination with other approved immunosuppressants, in recipients of primary kidney, liver and heart allogeneic grafts.	6/29/2000	Fulfilled
Neoral	cyclosporine	50715, 50716	7/14/1995	5	Perform a PK evaluation of Neoral in stable and de novo allogeneic liver transplant recipients.	6/23/2000	Fulfilled
Neoral	cyclosporine	50715, 50716	7/14/1995	6	Evaluate the effect of formulation (Neoral vs. SIM) on metabolism of CyA in liver transplant recipients.	6/23/2000	Released
Neoral	cyclosporine	50715, 50716	7/14/1995	7	Perform a PK evaluation of Neoral in stable and de novo allogeneic heart transplant recipients	6/23/2000	Fulfilled
Neoral	cyclosporine	50715, 50716	7/14/1995	8	Evaluate PK and safety of Neoral in pediatric transplant recipients.	8/1/2000	Fulfilled
Neoral	cyclosporine	50715, 50716	7/14/1995	9	Evaluate the relationship between CyA whole blood concentrations and efficacy/toxicity.	7/19/2000	Fulfilled
Neoral	cyclosporine	50735, 50736	5/22/1997	1	Conduct a three arm prospective registry invoving a total of 1500 patients, with follow-up of 5 years. Arm 1-Neoral; Arm 2-Neoral plus Methotrexate; Arm 3-Control.	7/22/2005	Released
Neoral	cyclosporine	50735, 50736	5/22/1997	2	Amend ongoing Neoral plus Methotrexate (MTX) combination studies where the control arm is Methotrexate alone, in MTX-inadequate responders (studies OLR 351 and NEO BSL-08) to increase the enrollment and extended for a period of up to 5 years.	7/22/2005	Released

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Neoral	cyclosporine	50735, 50736	5/22/1997	5	Submit an itemized update of all neoral Transplantation Phase 4 activities with time lines for study completion and availability of data.	5/5/1997	Fulfilled
Neoral	cyclosporine	50737	14-Jul-1995	PMC#3	Pregnancy registry for Rheumatoid Arthritis and Psoriasis patients	12/1/2050	Fulfilled
Odomzo	Sonidegib	205266	24-Jul-2015	PMR#2931-4	Study CLDE225A2113 pharmacokinetic trial in patients with moderate to severe hepatic impairment	31-Jul-2016	Fulfilled
Odomzo	Sonidegib	205266	24-Jul-2015	PMR#2931-5	Study CLDE225A2118 pharmacokinetic (drug interaction) trial with esomeprazole	31-Jan-16	Fulfilled
Odomzo	Sonidegib	205266	24-Jul-2015	PMR#2931-1	A 6-month carcinogenicity study in the transgenic mouse. Submit the carcinogenicity protocol for a Special Protocol Assessment (SPA) prior to initiating the study.	31-Dec-22	Will not be fullfilled - product divested as of Mar-2017
Odomzo	Sonidegib	205266	24-Jul-2015	PMR#2931-2	A long-term rodent carcinogenicity study in the rat. Submit the carcinogenicity protocol for a Special Protocol Assessment (SPA) prior to initiating the study.	31-Dec-22	Will not be fullfilled - product divested as of Mar-2017
Odomzo	Sonidegib	205266	24-Jul-2015	PMR#2931-3	A Pregnancy Pharmacovigilance Study to evaluate pregnancy outcomes and infant outcomes following exposure to Odomzo (sonidegib)	31-Jul-26	Will not be fullfilled - product divested as of Mar-2017
Reclast	zoledronic acid	21817	16-Apr-2007	1295-1	Perform a registry study to determine the incidence of hypocalcemia post Reclast treatment in patients with Paget's Disease.	Sep-2010	Fulfilled
Signifor	Pasireotide	200667	14-Dec-2012	PMR#1985-2	An assessment and analysis of spontaneous reports of serious (resulting in death, hospitalization, life-threatening, or disability) hyperglycemia, acute liver injury, and adrenal insufficiency in patients with Cushing's disease treated with Signifor (pasireotide) for a period of five years from the date of approval. Specialized follow-up should be obtained on these cases to collect additional information on the events.	6/29/2018	Fulfilled
Tafinlar	Dabrafenib	202806	29-May-2013	PMR 2044-4	QT/QTc Interval Prolongation	12/31/2015	Fulfilled

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Tafinlar	Dabrafenib	202806	29-May-2013	PMR 2044-5	Hepatic Impairment Pharmacokinetic Trial: Complete a clinical pharmacokinetic trial to determine the appropriate Tafinlar (dabrafenib) dose in patients with moderate to severe hepatic impairment in accordance with the FDA Guidance for Industry entitled "Pharmacokinetics in Patients with Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling".	30-Jun-2015	Retired
Tafinlar	Dabrafenib	202806	29-May-2013	PMR 2044-7	Drug-Drug Interaction Trial	30-Jun-15	Fulfilled
Tafinlar	Dabrafenib	202806	29-May-2013	PMC 2044-11	Drug-Drug Interaction Trial	31-Dec-2016	Fulfilled
Tafinlar	Dabrafenib	202806/S-002	9-Jan-2014	PMC 2115-2	Complete and submit the final report, including datasets, for the ongoing MEK116513 trial, "A Phase III, Randomised, Open-Label Study Comparing the Combination of the BRAF Inhibitor Dabrafenib and the MEK Inhibitor Trametinib to the BRAF Inhibitor Vemurafenib in Subjects with Unresectable (Stage IIIC) or Metastatic (Stage IV) BRAF V600E/K Mutation-Positive Cutaneous Melanoma."	30-Jun-2015	Fulfilled
Tafinlar	Dabrafenib	202806/S-002	9-Jan-2014	PMR 2115-1	To submit an efficacy supplement containing the final report, including summary analyses, datasets, and revised labeling based on the results of the ongoing MEK115306 trial, "A Phase III, Randomized, Double-Blinded Study, Comparing the Combination of the BRAF inhibitor, Dabrafenib and the MEK inhibitor, Trametinib to Dabrafenib and Placebo as First-Line Therapy in Subjects with unresectable (Stage IIIC) or Metastatic (Stage IV) BRAF V600E/K Mutation-Positive Cutaneous Melanoma."	31-Aug-2014	Fulfilled

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Tasigna	nilotinib	22068	29-Oct-2007	1225-1	To submit the complete study report (with at least 24 months follow-up of all patients) and data from study 2101, a phase 2 multicenter study of nilotinib in patients with imatinib resistant or intolerant chronic myeloid leukemia in chronic and accelerated phases respectively (arms 4 & 3, respectively).	1-Aug-2010	Fulfilled
Tasigna	nilotinib	22068	29-Oct-2007	1225-3	Conduct a relative bioavailability study (using a liquid formulation as the reference).	1-Jul-2010	Fulfilled
Tasigna	nilotinib	22068	29-Oct-2007	1225-5	Conduct a clinical study to evaluate if H2 blockers/proton pump inhibitors alter the pharmacokinetics of nilotinib.	1-Jun-2009	Fulfilled
Tasigna	nilotinib	22068	29-Oct-2007	1225-6	Submit a supplement containing a revised version of the complete RiskMAP (goals and objectives, tools, implementation plan, evaluation plan and reports to the agency) including all supporting materials. This should incorporate the amendments agreed to in correspondence of October 22 and October 26, 2007.	1-Nov-2007	Released
Tasigna	nilotinib	22068	17-Jun-2010	1650-1	A clinical trial to determine dosing regimens with a) H2 blockers and nilotinib, and b) antacids and nilotinib, that minimize alterations of the pharmacokinetics of nilotinib. Include steps that dose H2 blockers and antacids at a specified period before nilotinib dosing, as well as at specified periods following nilotinib dosing.	1-Jun-2012	Fulfilled
Tasigna	nilotinib	22068	29-Oct-2007	PMC# 1651-1	submit Study 2303 60 mo CSR	31-Mar-2014	Fulfilled
Tasigna	nilotinib	22068	29-Oct-2007	PMC 1225-4	clinical study-CYP2C9 and 3A4 substrates	31-Oct-2011	Fulfilled

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Brand Name	**Generic Name**	**Application Number**	**Commitment Date (Approval Date)**	**PMC identifier**	**Description of Postmarketing Commitment**	**ORIGINAL Targeted Completion Date**	**Status**
Tekturna	aliskiren	21985	5-Mar-2007	91-5	To include intestinal procedures and neoplasms and angioedema as events of special interest in proposed ALTITUDE trial. Providing safety information and periodic summaries during the ALTITUDE trial for the parameters of special interest. The data should be submitted when the final study report comes in. The periodic summaries will include: * Monthly line listings of suspected/non suspected SAE and non serious AE (reported in the previous month) * Aggregate summaries (cumulative) of suspected/non suspected SAE and non serious AE in PSUR semi-annually for the first 2 years post-launch and annually thereafter.	1-Mar-2012	Fulfilled
Tekturna	aliskiren	21985	5-Mar-2007	91-6	To incorporate a colonoscopy substudy into proposed long-term outcome study. The colonoscopy substudy should include colonoscopies performed at baseline and after drug treatment for 12 months or longer. This study should be powered to rule out a doubling in the rate of cancerous or precancerous lesions.	1-May-2009	Fulfilled
Tekturna	aliskiren	21985	5-Mar-2007	91-7	Provide evidence that it is not likely to be clinically useful to give aliskiren in a twice-daily dosing regimen to patients whose blood pressure is not controlled on the highest recommended dose given once daily. These data could come from a study comparing once- and twice-daily dosing, but the Division would consider alternative strategies to address this issue.	Feb-2009	Fulfilled
Tekturna	Aliskiren	21985	5-Mar-2007	PMC#91-1	Pediatric studies	3/9/2009	Will not be fullfilled - product divested as of 05-Oct-2016
Tekturna	Aliskiren	21985	5-Mar-2007	PMC#8	Food Effect Study	6/28/2013	Fullfilled

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Brand Name	**Generic Name**	**Application Number**	**Commitment Date (Approval Date)**	**PMC identifier**	**Description of Postmarketing Commitment**	**ORIGINAL Targeted Completion Date**	**Status**
Tobi Podhaler	Tobramycin	201688	22-Mar-2013	1928-1	Postmarketing requirement 1928-1 Observational 5 year study in the United States after marketing authorization	31-Jul-2021	Will not be Fulfilled (Divested to Mylan as of following Date (31-Oct-2018))
Tobi Podhaler	Tobramycin	201668	22-Mar-2013	1928-2	Postmarketing requirement 1928-2 Observational study in the United States of CF patients chronically colonized with P. aeruginosa	31-Jul-2017	Will not be Fulfilled (Divested to Mylan as of following Date (31-Oct-2018))
Tobi Podhaler	Tobramycin	201688	22-Mar-2013	PMR 1928-5	PMR 1928-5 A multicenter, human factors validation study in cystic fibrosis patients aged 6 years and older to evaluate the user interface of TOBI® Podhaler™ (tobramycin inhalation powder) using placebo capsules	31-May-2019	Will not be Fulfilled (Divested to Mylan as of following Date (31-Oct-2018))
Tobi Podhaler	Tobramycin	201688	22-Mar-2013	PMR 1928-3	IFU Validation study	8/31/2015	Fulfilled
Tobi Podhaler	Tobramycin	201688	22-Mar-2013	PMR 1928-4	Create adjunct instructions for use using alternative media and validate these instructions	11/30/2015	Retired
Tykerb	Lapatinib	022059	29-Jan-2010	PMR 3483-1:	Study CLAP016A2307 (EGF114299) Efficacy study in postmenopausal women with HR+ MBC that overexpresses the HER2 receptor and who have received prior trastuzumab and endocrine therapies.	31-May-2018	Fulfilled
Tyzeka	telbivudine	22011	25-Oct-2006	4	Conduct and submit a final study report to evaluate the use of LdT in the treatment of chronic HBV infection in minority racial/ethnic groups that were under-represented in the pivotal clinical trials (Blacks/African Americans, Hispanics).	Jun-2010	Released
Tyzeka	telbivudine	22011	25-Oct-2006	5	Conduct and submit a final study report for an efficacy and safety study of telbivudine in subjects who are coinfected with HIV and HBV. It should include evaluation of safety, and evaluation of HBV and HIV resistance.	Jun-2010	Released

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Tyzeka	telbivudine	22011	25-Oct-2006	6	Complete and submit the final study report for Study NV-02B-011, the double-blind trial comparing the efficacy and safety of telbivudine to lamivudine in subjects with chronic hepatitis B and decompensated liver disease.	Apr-2010	Fulfilled
Tyzeka	telbivudine	22011	25-Oct-2006	8	Complete and submit the final study report fior study NV-02B-022, the open-label, non-comparative trial assessing the long-term antiviral efficacy and safety of telbivudine in subjects with HBeAg-positive and HBeAg-negative compensated and decompensated chronic hepatitis B that have been previously treated in Idenix-sponsored telbivudine studies.	1-Jun-2012	Fulfilled
Tyzeka	telbivudine	22011	25-Oct-2006	14	Conduct and submit a final study report for a study to determine the susceptibility in cell culture of HBV harboring the following mutations of highly conserved amino acid residues among HBV isolates: R22C, W58G, L69P, L82M, P99L, L180M, L209V, T240I, I254F, P261L, G295E, A307V, L331F, or A342T.	1-Dec-2009	Fulfilled
Tyzeka	telbivudine	22011	25-Oct-2006	16	Complete and submit a final study report for ongoing genotypic and phenotypic analyses of HBV DNA from patients who experience virologic failure to longterm telbivudine therapy (serum HBV DNA levels > or =1,000 copies/mL) in ongoing clinical trials.	28-Sep-2007	Fulfilled
Tyzeka	Telbivudine	22-011 and 22-154	25-Oct-2006	PMR 2035-2:	Conduct pediatric PK, dose selection, and treatment trial(s) in patients from birth to < 2 years of age	31-Dec-2020	Retired
Tyzeka	Telbivudine	22-011 and 22-154	25-Oct-2006	PMR 2035-1:	Conduct pediatric PK, dose selection, safety, and treatment trial(s) in patients from 2 to < 18 years of age	30-Sep-2017	Retired

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Tyzeka Tab + Tyzeka Oral Solution	telbivudine	22154/22011	4/28/2009/ REVISED 5/07/2013	1	Deferred pediatric study/substudy for the treatment of chronic hepatitis B with evidence of active liver inflammation in pediatric subjects from 2 to <18 years of age. This study will determine the telbivudine exposure (pharmacokinetics profile) for pediatric subjects from 2 to < 18 years of age to support dose-selection for the efficacy and safety assessment.	30-Sep-2010	Released
Zelnorm	tegaserod maleate	21200	21-Aug-2004	1404-3	Deferred pediatric study under PREA for the treatment of chronic idiopathic constipation in pediatric patients ages 0 to 18 years.	2-Jan-2008	Terminated
Zofran	Ondansetron	20007	4-Jan-1991	PMR#1712-1	A thorough QT study. A randomized, double-blind, placebo-controlled and active-controlled, four-period crossover trial in normal patients, of two doses of ondansetron, a positive control (moxifloxicin 400 mg), and placebo	31-Jul-2015	Fulfilled
Zortress Tablets	everolimus	21560	20-Apr-2010	1624	Trial RAD001A2309 "A 24-month, multicenter, randomized, open-label noninferiority study of efficacy and safety comparing concentration-controlled Certican in two doses (1.5 and 3.0 mg/day starting doses) with reduced Neoral versus 1.44 g Myfortic with standard dose Neoral in de novo renal transplant recipients" which contains the 24-month follow-up safety data on all patients enrolled in the trial.	18-Aug-2009	Fulfilled
Zykadia	Ceritinib	205755	4/29/2014	PMR 2146-6	Clinical Study LDK378A2113 with concomitant gastric acid reducing agents	31-Mar-2016	Fulfilled
Zykadia	Ceritinib	205755	4/29/2014	PMR 2146-1	Clinical Study LDK378A2301 and/or LDK378A2303 establishing superiority over standard therapy	31-Oct-2019	Fulfilled

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Zykadia	Ceritinib	205755	4/29/2014	PMR 2146-2	Conduct a clinical trial to evaluate the systemic exposure and safety of 450 mg Zykadia (ceritinib) taken with a meal and 600 mg Zykadia (ceritinib) taken with a light meal as compared with that of 750 mg Zykadia (ceritinib) taken in the fasted state in metastatic ALK-positive NSCLC patients.	30-Sep-2017	Fulfilled
Zykadia	Ceritinib	205755	4/29/2014	PMR 2146-3	Complete a pharmacokinetic trial to determine the appropriate dose of Zykadia (ceritinib) in patients with hepatic impairment in accordance with the FDA Guidance for Industry entitled "Pharmacokinetics in Patients with Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling."	30-Jun-2016	Fulfilled
Zykadia	Ceritinib	205755	29-Apr-2014	PMR 2146-4	Clinical Study LDK378A2103 Midazolam Drug interaction Pharmacokinetic study: Conduct a clinical trial to evaluate the effect of repeat doses of Zykadia (ceritinib)on the single dose pharmacokinetics of midazolam (a sensitive CYP3A4 substrate) in accordance with the FDA Guidance for Industry entitled "Drug Interaction Studies – Study Design, Data Analysis, Implications for Dosing, and Labeling Recommendations."	31-Mar-2017	Fulfilled
Zykadia	Ceritinib	205755	29-Apr-2014	PMR 2146-5	Clinical Study LDK378A2103 Warfarin Drug Interaction pharmacokinetic study. Conduct a clinical trial to evaluate the effect of repeat doses of Zykadia (ceritinib)on the single dose pharmacokinetics of warfarin (a sensitive CYP2C9 substrate)in accordance with the FDA Guidance for Industry entitled "Drug Interaction Studies – Study Design, Data Analysis, Implications for Dosing, and Labeling Recommendations."	31-Mar-2017	Fulfilled

*** H = CFR Subpart H; F = FDAAA (o) (3) (PMR); P = PREA (required pediatric studies); C = PMC only**