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Novartis Pharmaceuticals Corporation - US Postmarketing Commitments Ongoing – [October 2018]						
Brand Name	**Generic Name**	**Application Number**	**Commitment Approval Date**	**Commitment Number/Description**	**Commitment Due Date**	**Status**
Afinitor	Everolimus BHT	22334	30-Mar-2009	PMR#3031-1: To submit the clinical study report and datasets for the final analysis of overall survival (OS) for CRAD001T2302 and include final OS data in the product label	1-Dec-2022	Ongoing
Arranon	Nelarabine	021877	28-Oct-2005	Subpart H PMC Submit results of Phase III trial AALL0434	31-Dec-2016	Delayed
Arranon	Nelarabine	021877	3-Jul-2018	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	31-Aug-2018	Submitted HA response required
Cosentyx	Secukinumab	BLA 125,504	21-Jan-2015	PMR 2848-1 Conduct a study to evaluate the safety and efficacy of secukinumab in pediatric subjects ≥ 6 years of age with plaque psoriasis.	28-Feb-2026	Ongoing
Cosentyx	Secukinumab	BLA 125,504	21-Jan-2015	PMR 2848-2 Long term safety of secukinumab compared to other therapies (CORRONA Registry Study)	30-Jun-2030	Ongoing
Cosentyx	Secukinumab	BLA 125,504	21-Jan-2015	PMR #2848-3 Completion of the treatment and evaluation of subjects enrolled in the ongoing CAIN457A2302E1 trial for a duration of 4 years	30-Sep-2018	Submitted HA response required
Cosentyx	Secukinumab	BLA 125,504	21-Jan-2015	PMR# 2848-4 Completion of the treatment and evaluation of subjects enrolled in the ongoing CAIN457A2304E1 trial for a duration of 4 years	31-Jul-2018	Submitted HA response required
Cosentyx	Secukinumab	BLA 125,504	21-Jan-2015	PMC# 2848-6 Evaluate the treatment effect and safety profile of a higher exposure (e.g., 450 mg) of secukinumab in psoriasis subjects	31-Jul-2023	Ongoing
Entresto	Sacubitril, Valsartan	207620	7-Jul-2015	PMR#2924-1 Epidemiologic study evaluating the incidence of angioedema in Black patients	31-Jul-2019	Ongoing

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Entresto	Sacubitril, Valsartan	207620	7-Jul-2015	PMR# 2924-2 Clinical study CLCZ696B2320, evaluating the effects of Entresto compared to valsartan on cognitive function	31-Mar-2022	Ongoing
Exjade	Deferasirox	21882	2-Nov-2005	PMC 750-9 MDS Postmarketing study	31-Dec-2009	Submitted HA response required
Exjade	Deferasirox	21882	2-Nov-2005	PMC 750-10 Opthamologic Postmarketing study	30-Sep-2012	Delayed
Exjade	Deferasirox	21882	2-Nov-2005	PMR 1994-1 NTDT	30-Nov-2019	Ongoing
Exjade	Deferasirox	21882	2-Nov-2005	PMR 1994-2 NTDT	30-Nov-2019	Ongoing
Exjade	Deferasirox	21882	2-Nov-2005	PMR 1994-3 NTDT	30-Sep-2018	Submitted HA response required
Exjade	Deferasirox	21882	2-Nov-2005	PMR 1994-4 NTDT	31-Dec-2021	Ongoing
Exjade	Deferasirox	21882	2-Nov-2005	PMR 1994-6 NTDT	30-Nov-2019	Ongoing
Farydak	Panobinostat	205-353	23-Feb-2015	PMR 2181-1 Randomized Phase 2 clinical trial of panobinostat in combination with subcutaneous bortezomib and dexamethasone	31-Aug-2019	Ongoing
Farydak	Panobinostat	205-353	23-Feb-2015	PMR 2181-2 Phase 3 Trial of panobinostat in combination with subcutaneous bortezomib and dexamethasone	31-Dec-2021	Ongoing
Gilenya	Fingolimod hydrochloride	22527	21-Sep-2010	PMR#1679-2 Postmarketing observational prosepective, parallel cohort study in relapsing MS patients	15-Dec-2020	Ongoing
Gilenya	Fingolimod hydrochloride	22527	21-Sep-2010	PMR#1679-3 Prospective, observational pregnancy exposure registry	30-Oct-2017	Delayed
Gilenya	Fingolimod hydrochloride	22527	21-Sep-2010	PMC#1679-10 A prospective, randomized, controlled study of fingolimod 0.5 mg, fingolimod 0.25 mg, and an appropriate control	30-Jul-2015	Delayed
Ilaris	Canakinumab	125319	17-Jun-2009	PMR #2 (SJIA) - SJIA Patient Registry	30-Jun-2023	Ongoing
Jadenu	Deferasirox	206910	30-Mar-2015	PMR 2888-2	30-Nov-2019	Ongoing
Jadenu	Deferasirox	206910	30-Mar-2015	PMR 2888-3	30-Nov-2019	Ongoing

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Jadenu	Deferasirox	206910	30-Mar-2015	PMR 2888-4	30-Sep-2018	Submitted HA response required
Jadenu	Deferasirox	206910	30-Mar-2015	PMR 2888-5	31-Dec-2021	Ongoing
Jadenu	Deferasirox	206910	30-Mar-2015	PMR 2888-7	31-Dec-2019	Submitted HA response required
Jadenu	Deferasirox	206910	30-Mar-2015	PMR 2888-8	31-Dec-2019	Ongoing
Jadenu	Deferasirox	206910	30-Mar-2015	PMR 2888-9	30-Nov-2019	Ongoing
Jadenu	Deferasirox	207968	18-May-2017	PMR 3342-2	30-Nov-2019	Ongoing
Jadenu	Deferasirox	207968	18-May-2017	PMR 3342-3	30-Nov-2019	Ongoing
Jadenu	Deferasirox	207968	18-May-2017	PMR 3342-4	30-Sep-2018	Submitted HA response required
Kisqali	Ribociclib	209092	13-Mar-2017	PMR-3168-1 - Conduct clinical trial of alternative dosing regimen to mitigate QT prolongation risk.	31-Oct-2022	Pending
Kisqali	Ribociclib	209092	13-Mar-2017	PMR-3168-2 - Complete renal impairment trial A2116	30-Apr-2018	Submitted HA response required
Kisqali	Ribociclib	209092	13-Mar-2017	PMC-3168-3 - Submit third and final OS data and analysis A2301	30-Jun-2022	Pending
Kisqali	Ribociclib	209092	13-Mar-2017	PMC-3168-4 - Conduct in vitro studies to evaluate discriminatory ability of dissolution acceptance criterion and collect in vivo PK data	30-Sep-2018	Submitted HA response required
Kisqali	Ribociclib	209092	18-Jul-2018	3453-1 Submit the interim overall survival (OS) report with data and analysis; the final OS report with data and analysis from clinical trial MONALEESA-7	30-Jun-2021	Ongoing
Kisqali	Ribociclib	209092	18-Jul-2018	3453-2 Submit the interim overall survival (OS) report with data and analysis; the final OS report with data and analysis, from clinical trial MONALEESA-3	31-Mar-2023	Ongoing

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Brand Name	**Generic Name**	**Application Number**	**Commitment Approval Date**	**Commitment Number/Description**	**Commitment Due Date**	**Status**
Kymriah	Tisagenlecleucel	125646	30-Aug-2017	PMR Clinical Study CCTL019B2401: A post-marketing, prospective, multi-center, observational study to assess the long-term safety of tisagenlecleucel and the risk of all secondary malignancies occurring after treatment with tisagenlecleucel.	31-Dec-2038	Pending
Kymriah	Tisagenlecleucel	125646	1-May-2018	PMR Clinical Study CCTL019B2401: A post-marketing, prospective, multi-center, observational study to assess the long-term safety of tisagenlecleucel	31-Dec-2038	Pending
Mekinist	Trametinib	204114	29-May-2013	PMR 2045-1 Cardiomyopathy	30-Sep-2020	Ongoing
Mekinist	Trametinib	204114	29-May-2013	PMR 2045-2 Ocular Toxicity	30-Sep-2016	Delayed
Mekinist	Trametinib	204114	29-May-2013	PMR 2045-3 Hepatic Impairment Pharmacokinetic Trial	31-Dec-2015	Delayed
Mekinist	Trametinib	204114	22-Jun-2017	PMC 3228-1 Final Anlyasis of Study BRF113928 /CDRB436E2201	31-Jan-2020	Ongoing
Mekinist	Trametinib	204114	4-May-2018	PMC 3378-1: Final Report/Analysis for BRF117019 / CDRB436X2201	31-Mar-2021	Ongoing
Mekinist	Trametinib	204114	4-May-2018	PMC 3378-2: Establish in-vitro diagnostic device for ATC	29-May-2020	Ongoing
Rydapt	Midostaurin	207997	28-Apr-2017	PMR 3210-1 Establish a worldwide Pregnancy Surveillance Program (enhanced pharmacovigilance) to collect and analyze information for a min of 10 years on pregnancy complications and birth outcomes	30-Jun-2027	Ongoing
Rydapt	Midostaurin	207997	28-Apr-2017	PMC 3210-2: Efficacy Analysis by Genomic Muation Subgroups	31-Oct-2018	Ongoing
Rydapt	Midostaurin	207997	28-Apr-2017	PMC 3210-3: Effiacay analysis by cytogenetic/molecular prognostic information for patients in RATIFY	31-Oct-2018	Ongoing
Signifor	Pasireotide	200667	14-Dec-2012	PMR#1985-1: Registry	29-Nov-2024	Ongoing
Signifor	Pasireotide	200667	14-Dec-2012	PMR#1985-2: Pharmacovigilance	29-Jun-2018	Submitted HA response required

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Signifor	Pasireotide	200667	14-Dec-2012	PMR#1985-3: Hyperglycemia Study	29-Jun-2018	Delayed
Tafinlar	Dabrafenib	202806	29-May-2013	PMR 2044-2 Secondary Malignancies	31-Oct-2020	Ongoing
Tafinlar	Dabrafenib	202806	29-May-2013	PMR 2044-3 Cardiac Valve Abnormalities	30-Nov-2020	Ongoing
Tafinlar	Dabrafenib	202806	29-May-2013	PMR 2044-5 Hepatic Impairment Pharmacokinetic Trial	30-Jun-2015	Delayed
Tafinlar	Dabrafenib	202806	29-May-2013	PMR 2044-6 Renal Impairment Pharmacokinetic Trial	30-Jun-2015	Delayed
Tafinlar	Dabrafenib	202806	22-Jun-2017	PMC 3227-1 Final Analysis of Study BRF113928 / CDRB436E2201	31-Jan-2020	Ongoing
Tafinlar	Dabrafenib	20286	4-May-2018	PMC 3376-1: Final Report/Analysis for BRF117019 / CDRB436X2201	31-Mar-2021	Ongoing
Tafinlar	Dabrafenib	20286	4-May-2018	PMC 3376-2: Establish in-vitro diagnostic device for ATC	29-May-2020	Ongoing
Tasigna	Nilotinib hydrochloride monohydrate	22068	22-Dec-2017	PMR 3323-1 - Characterize the risk of relapse after TFR - 60 months follow-up	31-Oct-2020	Ongoing
Tasigna	Nilotinib hydrochloride monohydrate	22068	22-Dec-2017	PMR 3323-2 - Characterize the potential risk of resistance to treatment after discontinuation - 10 years total	26-Feb-2026	Ongoing
Tasigna	Nilotinib hydrochloride monohydrate	22068	22-Dec-2017	PMR 3323-3 - Characterize safety for patients still in remission or experienced loss of MMR - 10 years total	26-Feb-2026	Ongoing
Tasigna	Nilotinib hydrochloride monohydrate	22068	22-Mar-2018	PMR 3359-1 Characterize the long-term safety of treatment	30-Jun-2021	Ongoing
Tasigna	Nilotinib hydrochloride monohydrate	22068	22-Mar-2018	PMR 3359-2 Characterize the effect of treatment with Tasigna on growth and development	30-Jun-2021	Ongoing
Tobi Podhaler	Tobramycin	201688	22-Mar-2013	Postmarketing requirement 1928-1 Observational 5 year study in the United States after marketing authorization	31-Jul-2021	Ongoing

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Tobi Podhaler	Tobramycin	201668	22-Mar-2013	Postmarketing requirement 1928-2 Observational study in the United States of CF patients chronically colonized with P. aeruginosa	31-Jul-2017	Submitted HA response required
Tobi Podhaler	Tobramycin	201688	22-Mar-2013	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	Ongoing
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	Submitted HA response required
Zykadia	Ceritinib	205755	29-Apr-2014	FDA PMR 2146-4 Clinical Study LDK378A2103 Midazolam Drug interaction Pharmacokinetic study	31-Mar-2017	Submitted HA response required
Zykadia	Ceritinib	205755	29-Apr-2014	FDA PMR 2146-5 Clinical Study LDK378A2103 Warfarin Drug Interaction pharmacokinetic study	31-Mar-2017	Submitted HA response required
*** H = CFR Subpart H; F = FDAAA (o) (3) (PMR); P = PREA (required pediatric studies); C = PMC only**						