NOVARTIS

Novartis Pharmaceuticals Corporation - US Postmarketing Commitments Ongoing – [July, 2020]						
Brand Name	**Generic Name**	**Application Number**	**Commitment Approval Date**	**Commitment Number/Description**	**Commitment Due Date**	**Status**
Adakveo	Crizanlizumab	761128	15-Nov-2019	3741-1 Develop and validate a neutralizing antibody assay (NADA)	31-Dec-2020	Ongoing
Adakveo	Crizanlizumab	761128	15-Nov-2019	3741-2 Assess neutralizing anti-drug antibody (NADA) responses with a validated	31-Dec-2025	Ongoing
Adakveo	Crizanlizumab	761128	15-Nov-2019	3741-3 Complete Study A2202: Phase 2 Multicenter, Open-Label Study to Assess	31-Dec-2025	Ongoing
Adakveo	Crizanlizumab	761128	15-Nov-2019	3741-4 Complete Study B2201: Phase II, Multicenter, Open-label study of Pediatric Sickle Cell Disease Patients	31-Dec-2025	Ongoing
Adakveo	Crizanlizumab	761128	15-Nov-2019	3741-5 Complete Study A2301 of Crizanlizumab in Adolescents and Adults	31-Dec-2029	Ongoing
Adakveo	Crizanlizumab	761128	15-Nov-2019	3741-6 Assess immunogenicity of crizanlizumab in Study A2301	31-Dec-2025	Ongoing
Adakveo	Crizanlizumab	761128	15-Nov-2019	3741-8 Submit an Integrated Summary of Immunogenicity	31-Dec-2025	Ongoing
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

Novartis Pharmaceuticals Corporation - US Postmarketing Commitments Ongoing – [July, 2020]						
Brand Name	**Generic Name**	**Application Number**	**Commitment Approval Date**	**Commitment Number/Description**	**Commitment Due Date**	**Status**
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
Egaten	Triclabendazole	208711	13-Feb-2019	PMR-1: Conduct a thorough QT/QTc trial of Egaten	31-Oct-2020	Ongoing
Egaten	Triclabendazole	208711	13-Feb-2019	PMC-2: Conduct an open-label, single-arm study to assess outcomes of treatment with	31-Dec-2025	Ongoing
Entresto	Sacubitril, Valsartan	207620	7-Jul-2015	PMR#2924-1 Epidemiologic study evaluating the incidence of angioedema in Black patients	31-Jul-2019	Delayed
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

Novartis Pharmaceuticals Corporation - US Postmarketing Commitments Ongoing – [July, 2020]						
Brand Name	**Generic Name**	**Application Number**	**Commitment Approval Date**	**Commitment Number/Description**	**Commitment Due Date**	**Status**
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	Submitted HA response required
Exjade	Deferasirox	21882	2-Nov-2005	PMR 1994-2 NTDT	30-Nov-2019	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	Submitted HA response required
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
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	Submitted HA response required

Novartis Pharmaceuticals Corporation - US Postmarketing Commitments Ongoing – [July, 2020]						
Brand Name	**Generic Name**	**Application Number**	**Commitment Approval Date**	**Commitment Number/Description**	**Commitment Due Date**	**Status**
Jadenu	Deferasirox	206910	30-Mar-2015	PMR 2888-3	30-Nov-2019	Submitted HA response required
Jadenu	Deferasirox	206910	30-Mar-2015	PMR 2888-5	31-Dec-2021	Ongoing
Jadenu	Deferasirox	206910	30-Mar-2015	PMR 2888-8	31-Dec-2019	Delayed
Jadenu	Deferasirox	206910	30-Mar-2015	PMR 2888-9	30-Nov-2019	Submitted HA response required
Jadenu	Deferasirox	207968	18-May-2017	PMR 3342-2	30-Nov-2019	Submitted HA response required
Jadenu	Deferasirox	207968	18-May-2017	PMR 3342-3	30-Nov-2019	Submitted HA response required
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	PMC-3168-3 - Submit third and final OS data and analysis A2301	30-Jun-2022	Submitted HA response required

Novartis Pharmaceuticals Corporation - US Postmarketing Commitments Ongoing – [July, 2020]						
Brand Name	**Generic Name**	**Application Number**	**Commitment Approval Date**	**Commitment Number/Description**	**Commitment Due Date**	**Status**
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	Submitted HA response required
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	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
Mayzent	Siponimod	209884	26-Mar-2019	PMR#3591-3 A prospective, parallel cohort study in patients with relapsing forms of multiple sclerosis to assess the potentially serious risk of pulmonary toxicity	31-Dec-2027	Pending
Mayzent	Siponimod	209884	26-Mar-2019	PMR#3591-4 Conduct prospective pregnancy exposure registry cohort analyses in the United States	30-Sep-2032	Pending
Mayzent	Siponimod	209884	26-Mar-2019	PMR#3591-5 Conduct a pregnancy outcomes study	30-Sep-2032	Pending
Mayzent	Siponimod	209884	26-Mar-2019	PMC#3591-6 Establish an in-vitro diagnostic device to guide the use of siponimod in patients with relapsing forms of multiple sclerosis	31-Dec-2023	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

Novartis Pharmaceuticals Corporation - US Postmarketing Commitments Ongoing – [July, 2020]						
Brand Name	**Generic Name**	**Application Number**	**Commitment Approval Date**	**Commitment Number/Description**	**Commitment Due Date**	**Status**
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	Delayed
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	Delayed
Mekinist	Trametinib	204114	30-Apr-2018	PMC 3377-1: Final report for Study BRF115532 / CDRB436F2301	30-May-2024	Ongoing
Piqray	Alpelisib	212526	24-May-2019	PMC 3573-1 final OS data and analysis	28-Feb-2022	Pending
Piqray	Alpelisib	212526	24-May-2019	PMC 3573-2 CYP3A4 inducer on PK of alpelisib	30-Apr-2022	Pending
Piqray	Alpelisib	212526	24-May-2019	PMC 3573-3 CYP2B6, CYP3A4 and CYP2C-family DDI	30-Sep-2022	Pending
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	30-Jun-2027	Ongoing

Novartis Pharmaceuticals Corporation - US Postmarketing Commitments Ongoing – [July, 2020]						
Brand Name	**Generic Name**	**Application Number**	**Commitment Approval Date**	**Commitment Number/Description**	**Commitment Due Date**	**Status**
Tabrecta	Capmatinib	213591	6-May-2020	PMR#3828-1 Study CINC280A2201 final report to confirm and further characterize the clinical benefit of capmatinib	28-Feb-2022	Ongoing
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 2044-6 Renal Impairment Pharmacokinetic Trial	30-Jun-2015	Submitted HA response required
Tafinlar	Dabrafenib	202806	22-Jun-2017	PMC 3227-1 Final Analysis of Study BRF113928 / CDRB436E2201	31-Jan-2020	Delayed
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	Delayed
Tafinlar	Dabrafenib	20286	30-Apr-2018	PMC 3375-1: Final report for Study BRF115532 / CDRB436F2301	30-May-2024	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

Novartis Pharmaceuticals Corporation - US Postmarketing Commitments Ongoing – [July, 2020]						
Brand Name	**Generic Name**	**Application Number**	**Commitment Approval Date**	**Commitment Number/Description**	**Commitment Due Date**	**Status**
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
*** H = CFR Subpart H; F = FDAAA (o) (3) (PMR); P = PREA (required pediatric studies); C = PMC only**						