	Drug	NME or Novel Biologic?	Sponsor	Indication	AA Approval Year	AA endpoint	RA Approval Year	RA endpoint
NSCLC	Pemetrexed	No	Lilly	Locally advanced or metastatic non-squamous NSCLC after previous chemotherapy	2004	RR	2009	OS
	Bevacizumab	No	Genentech	Locally advanced or metastatic non-squamous NSCLC in combination with carboplatin and paclitaxel			2006	OS
	Pemetrexed	No	Lilly	Locally advanced or metastatic non-squamous NSCLC with cisplatin	2008	RR	2009	OS
	Crizotinib	Yes	Pfizer	Locally advanced or metastatic ALK mutation-positive NSCLC	2011	RR	2013	PFS
	Ceritinib	Yes	Novartis	Treatment of ALK-positive metastatic NSCLC after progression or intolerance to crizotinib	2014	RR	2017	PFS
	Ramucirumab	No	Lilly	2nd line metastatic NSCLC in combination with docetaxel			2014	OS
	Pembrolizumab	No	Merck	PDL1-positive metastatic NSCLC after platinum-containing chemotherapy	2015	RR	2016	OS
	Nivolumab	No	BMS	2nd Line squamous metastatic NSCLC			2015	OS
	Nivolumab	No	BMS	2nd Line non-squamous metastatic NSCLC			2015	OS
	Necitumumab	Yes	Lilly	1st line squamous metastatic NSCLC with gemcitabine and cisplatin			2015	OS
	Osimertinib	Yes	Astra Zeneca	Metastatic EGFR T790M mutation-positive NSCLC after progression on or after EGFR TKI	2015	RR	2017	PFS
	Crizotinib	No	Pfizer	Metastatic ROS1+ NSCLC			2016	RR
	Dabrafenib + Trametinib	No	Novartis	Metastatic BRAF V600E NSCLC			2017	RR
	Alectinib	Yes	Genentech	Metastatic ALK+ NSCLC after progression on crizotinib	2015	RR	2017	PFS
	Atezolizumab	No	Genentech	2nd line metastatic NSCLC			2016	OS
	Alectinib	No	Genentech	Metastatic ALK+ NSCLC first-line			2017	PFS
	Ceritinib	No	Novartis	Metastatic ALK+ NSCLC first-line			2017	PFS
	Brigatinib	Yes	Ariad	Metastatic ALK+ NSCLC after progression on crizotinib	2017	RR		
	Lorlatinib	Yes	Pfizer	Metastatic ALK+ NSCLC after progression on two ALK inhibitors	2018	RR		
	Erlotinib	No	Genentech	Metastatic EGFRm+ NSCLC			2013	PFS
	Afatinib	Yes	BI	Metastatic EGFRm+ NSCLC			2013	PFS
	Gefitinib	No	AZ	Metastatic EGFRm+ NSCLC			2015	ORR/PFS
	Dacomitinib	Yes	Pfizer	Metastatic EGFRm+ NSCLC			2018	PFS
	Pembrolizumab + chemo	No	Merck	Metastatic non squamous NSCLC first line	2017	PFS	2018	OS
	Atezolizumab	No	Genentech	In combo w/bevacizumab, paclitaxel and carboplatin for 1st line metastatic non-squamous NSCLC			2018	OS and PFS
	Durvalumab	No	AZ	Locally advanced NSCLC after chemoraiation			2018	OS
	Atezolizumab	No	Genentech	In combo w/carboplatin and etoposide for 1st line extensive-stage NSCLC			2019	OS and PFS
	Atezolizumab	No	Genentech	In combo w/paclitaxel protein-bound and carboplatin for 1st-line metastatic non-squamous NSCLC without EGFR or ALK genomic tumor aberrations			2019	OS and PFS
	Entrectinib	Yes	Genentech	ROS-1+ NSCLC	2019	RR		
	Pembrolizumab	No	Merck	1st-line metastatic NSCLC			2019	OS

	Drug	NME or Novel Biologic?	Sponsor	Indication	AA Approval Year	AA endpoint	RA Approval Year	RA endpoint
CML	Imatinib	Yes	Novartis	CML in BC, AP, or CP after failure of interferon alfa therapy	2001	RR	2003	RR
	Imatinib	No	Novartis	Newly diagnosed, PH-positive CML	2002	PFS (≥ 12m follow-up)	2009	PFS (7y update)
	Imatinib	No	Novartis	Pediatric, Ph-positive CP CML resistant to interferon or recurrent after SCT	2003	RR	2006	RR
	Dasatinib	Yes	BMS	CML (CP, AP, and BC) that is resistant or intolerant to prior therapy, including imatinib	2006	RR (CP: MCyR ≥ 6m follow-up, AP/BC: MaHR ≥ 6m follow-up)	2009	RR (CP: MCyR ≥ 2y follow-up, AP/BC: 2y update)
	Imatinib	No	Novartis	Newly diagnosed, pediatric, Ph-positive CML	2006	RR (CCyR cutoff date Jun 2005)	2011	RR (long-term update Jun 2010)
	Nilotinib	Yes	Novartis	Ph-positive CML CP or AP resistant or intolerant to imatinib	2007	RR (CP: MCyR ≥ 6m follow-up, AP: HR ≥ 6m follow-up)	2011	RR (CP: MCyR ≥ 24m follow-up, AP: HR ≥24m follow-up)
	Bosutinib	Yes	Pfizer	PH-positive CML resistant or intolerant to prior therapy			2012	RR (MCyR within first 24 weeks)
	Nilotinib	No	Novartis	Newly diagnosed, Ph-positive CML in CP	2010	RR (MMR and CCyR ≥ 12m follow-up)	2014	RR (MMR ≥ 60m follow-up)
	Dasatinib	No	BMS	Newly diagnosed, Ph-positive CML in CP	2010	RR (CCyR and MMR ≥ 12m follow-up)	2015	RR (MMR ≥ 60m follow-up
	Omacetaxine	Yes	Cephalon	Chronic or accelerated CML after resistance or intolerance to 2 or more TKIs	2012	RR (CP: MCyR at least 14m follow-up, AP: MaHR median fu 9.6m)	2014	RR (CP: MCyR at least 24m follow-up, AP: MaHR 24m update)
	Ponatinib	Yes	Ariad	CP, AP, or BC CML resistant or intolerant to prior TKI or Ph-positive ALL resistant or intolerant to prior TKIs	2012	RR (CP: MCyR ≥ 6m follow-up, AP/BC: MaHR and CHR ≥ 6m follow-up)	2016	RR (CP: MCyR ≥ 48m follow-up, AP/BC: MaHR and CHR ≥ 48m follow-up)
	Bosutinib	No	Pfizer	Newly-diagnosed CP-CML	2017	RR (MMR at 12m)	pending (final report Nov 2020)	RR (MMR with 60m follow-up)

AP (accelerated phase), CP (chronic phase), BC (blast crisis), MCyR (major cytogenetic response), CCyR (complete cytogenetic response), MMR (major molecular response), HR (hematologic response), MaHR (major hematologic response), CHR (complete hematologic response)

	Drug	NME or Novel Biologic?	Sponsor	Indication	AA Approval Year	AA endpoint	RA Approval Year	RA endpoint
Melanoma	Dabrafenib	Yes	GSK	unresectable or metastatic melanoma with BRAF V600E mutation	-	-	2013	PFS
	Trametinib	Yes	GSK	unresectable or metastatic melanoma with BRAF V600E or V600K mutations	-	-	2013	PFS
	Trametinib	No	GSK	In combination with dabrafenib for unresectable or metastatic melanoma with BRAF V600E or K mutation	2014	RR	2015	OS
	Dabrafenib	No	GSK	In combination with trametinib for unresectable or metastatic melanoma with BRAF V600E or K mutation	2014	RR	2015	OS
	Pembrolizumab	Yes	Merck	Unresectable or metastatic melanoma after ipilimumab and a BRAF inhibitor if BRAF mutation +	2014	RR	2015	PFS
	Nivolumab	Yes	BMS	Unresectable or metastatic melanoma after ipilimumab and a BRAF inhibitor if BRAF mutation +	2014	RR	2015	OS
	Nivolumab	No	BMS	In combination with ipilimumab for unresectable or metastatic melanoma	2015	RR	2018	OS
	Ipilimumab	No	BMS	Adjuvant treatment of melanoma melanoma with pathologic involvement of regional lymph nodes of more than 1 mm, who have undergone complete resection including total lymphadenectomy	-	-	2015	RFS
	Talimogene laherparepvec	Yes	Amgen	for the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery	-	-	2015	RR (durable)
	Nivolumab	No	BMS	Adjuvant treatment of patients with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection.	-	-	2017	RFS
	Dabrafenib	No	Novartis	In combination with trametinib for adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations, as detected by an FDA-approved test, and involvement of lymph node(s), following complete resection	-	-	2018	RFS
	Trametinib	No	Novartis	In combination with dabrafenib for adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations, as detected by an FDA-approved test, and involvement of lymph node(s), following complete resection	-	-	2018	RFS
	Encorafenib	Yes	Array	in combination with binimetinib for unresectable or metastatic melanoma with BRAF V600E or K mutation	-	-	2018	PFS
	Binimetinib	Yes	Array	in combination with encorafenib for unresectable or metastatic melanoma with BRAF V600E or K mutation	-	-	2018	PFS
	Pembrolizumab	No	Merck	adjuvant treatment of patients with melanoma with involvement of lymph node(s) following complete resection	-	-	2019	RFS