

Changes to the development pipeline

Q2 2019 update

New to phase I	New to phase II	New to phase III	New to registration
3 NMEs: RG7921 - wAMD RG6244 - asthma RG6179 - DME 2 AIs: RG7440 ipatasertib + rucaparib - mCRPC, solid tumors RG7601 Venclexta + AMG176 - AML	1 NME : IONIS ASO factor B - geographic atrophy 1NME transitioned from Ph1: RG6147 - geographic atrophy		
Removed from phase I	Removed from phase II	Removed from phase III	Removed from registration
1 NME: RG6174 - inflammatory diseases 1 AI: RG7446 Tecentriq + radium 223 - mCRPC		2 AIs: RG7421 Cotellic + Tecentriq - 1L BRAF WT melanoma RG7446 Tecentriq + enzalutamide - mCRPC	

Roche Group development pipeline



Phase I (41 NMEs + 20 AIs)

RG6026	CD20 x CD3 / combos	heme tumors	RG7769	PD1-TIM3 biMAb	solid tumors
RG6107	crovalimab (C5 inh MAb)	PNH	RG7802	cibisatamab ± T	solid tumors
RG6109	-	AML	RG7827	FAP-4-1BBL FP	solid tumors
RG6114	mPI3K alpha inh	HR+ BC	RG7828	mosunetuzumab / combos	heme tumors
RG6123	-	solid tumors	RG7876	selicrelumab + Avastin	solid tumors
RG6146	BET inh combos	solid & heme tumors	CHU	Raf/MEK dual inh	solid tumors
RG6148	-	HER2 expressing BC	CHU	glypican-3 x CD3	solid tumors
RG6160	-	multiple myeloma	CHU	codrituzumab	HCC
RG6171	SERD (3)	ER+ (HER2-) mBC	RG6151	-	asthma
RG6180	iNeST*± T	solid tumors	RG6173	-	asthma
RG6185	pan-RAF inh + Cotellic	solid tumors	RG6244	-	asthma
RG6194	HER2 x CD3	BC	RG7835	-	autoimmune diseases
RG7159	anti-CD20 combos	heme tumors	RG7880	IL-22Fc	inflammatory diseases
RG7421	Cotellic + Zelboraf + T	melanoma	RG6004	HBV LNA	HBV
	Cotellic + T	2L BRAF WT mM	RG6084	-	HBV
	Cotellic + T	RCC, bladder, head & neck ca	RG6217	-	HBV
RG7440	ipatasertib + Taxane + T	TNBC	RG7854	TLR7 agonist (3)	HBV
	ipatasertib + rucaparib	mCRPC, solid tumors	RG7861	anti-S. aureus TAC	infectious diseases
RG7446	Tecentriq (T)	solid tumors	RG7907	HBV CpAM (2) (Capsid)	HBV
	T-based Morpheus platform	solid tumors	RG7992	FGFR1/KLB MAb	metabolic diseases
	T + Avastin + Cotellic	2/3L CRC	RG6000	-	ALS
	T ± Avastin ± chemo	HCC, GC, PaC	RG6237	-	neuromuscular disorders
	T + Tarceva/Alecensa	NSCLC	RG7816	GABA Aa5 PAM	autism
	T + anti-CD20 combos	heme tumors	RG6179	-	DME
	T + K/HP	HER2+ BC	RG7774	-	retinal disease
	T + rucaparib	ovarian ca	RG7921	-	wAMD
	FAP IL2v FP combos	solid tumors	CHU	PTH1 recep. ago	hypoparathyroidism
RG7601	Venclexta + idasanutlin	AML	CHU	-	hyperphosphatemia
	Venclexta + AMG176	AML	CHU	-	endometriosis
	Venclexta ± azacitidine	r/r MDS			
	Venclexta + gilteritinib	r/r AML			
	Venclexta + Cotellic + T	MM			

RG-No - Roche/Genentech

NOV- Novimmune managed

CHU- Chugai managed

*Individualized NeoAntigen Specific Immunotherapy

Phase II (15 NMEs + 10 AIs)

RG6180	iNeST* + pembrolizumab	malignant melanoma
RG6058	tiragolumab ± T	NSCLC
RG7388	idasanutlin	polycythemia vera
	idasanutlin	AML fit 1L
RG7421	Cotellic + Tecentriq ± taxane	TNBC
RG7440	ipatasertib	TNBC neoadj
RG7446	Tecentriq	SC NSCLC
RG7596	Polivy (polatuzumab vedotin)	r/r FL
RG7601	Venclexta + Rituxan	DLBCL
	Venclexta + azacitidine	1L MDS
	Venclexta + fulvestrant	2L HR+BC
RG6149	ST2 MAb	asthma
RG7159	Gazyva	lupus
RG7625	petesicatib	autoimmune diseases
RG7845	fenebrutinib	RA, lupus, CSU
CHU	nemolizumab*	pruritus in dialysis patients
NOV	TLR4 MAb	autoimmune diseases
RG1662	basimisanil	CIAS
RG6100	Tau MAb	Alzheimer's
RG7412	crenezumab	familial Alzheimer's healthy pts
RG7916	risdiplam [§]	SMA
RG7906	-	psychiatric disorders
RG7935	prasinezumab	Parkinson's
RG6147	-	geographic atrophy
IONIS	ASO factor B	geographic atrophy

NMEs
Additional Indication (AI)
Oncology / Hematology
Immunology
Infectious Diseases

CardioMetabolism
Neuroscience
Ophthalmology
Other

[§] Ph2 pivotal

out-licensed to Galderma and Maruho AD

T=Tecentriq

Roche Group development pipeline



Phase III (11 NMEs + 32 AIs)

RG3502	Kadcyla + Perjeta	HER2+ eBC	RG7446/RG7853/RG6268	Tecentriq or Alecensa or entrectinib	1L NSCLC Dx+
RG6264	Perjeta + Herceptin FDC SC	HER2+ BC		Venclexta + bortezomib	MM
RG7388	idasanutlin + chemo	AML	RG7601	Venclexta	r/r MM t(11:14)
RG7440	ipatasertib + abiraterone	1L CRPC		Venclexta + HMA	1L AML
	ipatasertib + chemo	1L TNBC/HR+ BC	RG7853	Alecensa	NSCLC adj
RG7421	Cotellic + Zelboraf + T	1L BRAFm melanoma	RG3648	Xolair	nasal polyps
RG7596	Polivy (polatuzumab vedotin)	1L DLBCL	RG7413	etrolizumab	ulcerative colitis
RG7446	Tecentriq	NSCLC adj		etrolizumab	Crohn's
	Tecentriq	MIBC adj	RG6152	Xofluza	influenza, hospitalized pts
	Tecentriq	NMIBC, high risk		Xofluza	influenza, pediatric
	Tecentriq Dx+	1L sq + non-sq NSCLC		Xofluza	influenza post exposure prophylaxis
	Tecentriq	RCC adj	RG1450	gantenerumab	Alzheimer's
	T + chemo + Avastin	1L ovarian cancer	RG6042	HTT ASO	Huntington's
	T + pemetrexed	1L non-sq NSCLC	RG6168	satralizumab	NMOSD
	T + nab-paclitaxel	1L sq NSCLC	RG6206	anti-myostatin adnectin	DMD
	T ± chemo	SCCHN adj	RG7314	balovaptan	autism
	Tecentriq	HER2+ BC neoadj	RG6321	port delivery system with ranibizumab	wAMD
	T + paclitaxel	1L TNBC	RG7716	faricimab	DME
	T + capecitabine or carbo/gem	1L TNBC		faricimab	wAMD
	T + paclitaxel	TNBC adj			
	T + nab-paclitaxel	TNBC neoadj			
	T + Avastin	1L HCC			
	T + Avastin	1L RCC			
	T ± chemo	1L mUC			

Registration (3 NMEs + 7 AIs)

RG3502	Kadcyla ¹	HER2+ eBC
RG6268	Rozlytrek (entrectinib)	NSCLC ROS1+
	Rozlytrek (entrectinib)	NTRK1 tumor agnostic
RG7446	T + nab-paclitaxel	1L non-sq NSCLC
	T + nab-paclitaxel ¹	1L TNBC
	T + chemo ¹	1L extensive stage SCLC
RG7596	Polivy (polatuzumab vedotin) ¹	r/r DLBCL
RG7601	Venclexta + Gazyva ¹	1L CLL
RG6152	Xofluza ¹	influenza
	Xofluza ²	influenza, high risk

¹ Approved in US

² Filed in US

New Molecular Entity (NME)
 Additional Indication (AI)
 Oncology / Hematology
 Immunology
 Infectious Diseases

CardioMetabolism
 Neuroscience
 Ophthalmology
 Other

NME submissions and their additional indications

Projects currently in phase II and III

RG7916	risdiplam SMA	RG7413	etrolizumab ulcerative colitis					RG6152	Xofluza influenza, hospitalized pts				
RG6168	satralizumab NMOSD	RG6152	Xofluza influenza, pediatric					RG6058	tiragolumab + Tecentriq NSCLC	RG6042	HTT ASO Huntington's	RG7716	faricimab DME
RG6152	Xofluza (EU) influenza	RG6206	anti-myostatin adnectin DMD					RG6180	iNeST* oncology	RG1450	gantenerumab Alzheimer's	RG7716	faricimab wAMD
RG6152	Xofluza (EU) influenza, high risk	RG6264	Perjeta + Herceptin FDC SC HER2+ BC					RG7388	idasanutlin AML fit 1L	RG1662	basmisanil CIAS	RG6149	ST2 Mab asthma
RG6152	Xofluza influenza post-exposure prophylaxis	RG7388	idasanutlin + chemo AML					RG7388	idasanutlin polycythemia vera	RG6100	Tau MAb Alzheimer's	RG7413	etrolizumab Crohn's
RG6268	Rozlytrek (entrectinib) (EU) ✓ NSCLC ROS1+	RG7440	ipatasertib + abiraterone 1L CRPC	RG6321	Port Delivery System with ranibizumab wAMD		RG7440	ipatasertib TNBC neoadj	RG7314	balovaptan autism	RG7625	petesicatib autoimmune diseases	
RG6268	Rozlytrek (entrectinib) (EU) ✓ NTRK1 tumor agnostic	RG7440	ipatasertib +chemo 1L TNBC / HR+ BC	RG7596	Polivy (polatuzumab vedotin) 1L DLBCL		RG7596	Polivy (polatuzumab vedotin) r/r FL	RG7935	prasinezumab Parkinson's	RG7845	fenebrutinib autoimmune diseases	
2019		2020		2021		2022 and beyond							

✓ Indicates submission to health authorities has occurred
Unless stated otherwise submissions are planned to occur in US and EU

	New Molecular Entity (NME)
	Additional Indication (AI)
	Oncology / Hematology
	Immunology
	Infectious Diseases

	CardioMetabolism
	Neuroscience
	Ophthalmology
	Other

FDC =fixed-dose combination

*Individualized NeoAntigen Specific Immunotherapy

✓ Indicates submission to health authorities has occurred
Unless stated otherwise submissions are planned to occur in US and EU

	New Molecular Entity (NME)
	Additional Indication (AI)
	Oncology / Hematology

Immunology
Infectious Diseases
CardioMetabolism

Topic	Percentage
Neuroscience	40%
Ophthalmology	35%
Other	25%

Cancer immunotherapy pipeline overview

Phase I (11 NMEs + 21 AIs)

RG6026	CD20 x CD3 / combos	heme tumors
RG6123	-	solid tumors
RG6160	-	multiple myeloma
RG6180	iNeST* ± T	solid tumors
RG6194	HER2 x CD3	BC
RG7421	Cotellic + Zelboraf + T	melanoma
	Cotellic + T	2L BRAF WT mM
	Cotellic + T	RCC, bladder, head & neck ca
RG7440	ipatasertib + Taxane + T	TNBC
RG7446	Tecentriq (T)	solid tumors
	T-based Morpheus platform	solid tumors
	T + Avastin + Cotellic	2/3L CRC
	T ± Avastin ± chem	HCC, GC, PaC
	T + Tarceva/Alecensa	NSCLC
	T + anti-CD20 combos	heme tumors
	T + K/HP	HER2+ BC
	T + rucaparib	ovarian ca
RG7461	FAP IL2v FP combos	solid tumors
RG7601	Venclexta + Cotellic + T	MM
RG7769	PD1-TIM3 biMAb	solid tumors
RG7802	cibisatamab ± T	solid tumors
RG7827	FAP-4-1BBL FP	solid tumors
RG7828	mosunetuzumab / combos	heme tumors
RG7876	selicrelumab + Avastin	solid tumors
CHU	glypican-3 x CD3	solid tumors

AMGN**	Tecentriq + talimogene laherp	TNBC, CRC
BLRX**	Tecentriq + BL-8040	AML, solid tumors
CRVS**	Tecentriq + CPI-444	solid tumors
EXEL**	Tecentriq + cabozantinib	solid tumors
HALO**	Tecentriq + PEGPH20	CCC, GBC
INO**	Tecentriq + INO5401+INO9012	bladder ca
KITE**	Tecentriq + KTE-C19	r/r DLBCL

MORPHEUS Platform - Phase Ib/II (7 AIs)

RG7446	T-based Morpheus	pancreatic cancer
	T-based Morpheus	gastric cancer
	T-based Morpheus	HR+ BC
	T-based Morpheus	NSCLC
	T-based Morpheus	2L TNBC
	T-based Morpheus	CRC
	T-based Morpheus	mUC

Phase II (2 NMEs + 5 AIs)

RG6180	iNeST* + pembrolizumab	malignant melanoma
RG6058	tiragolumab ± T	NSCLC
RG7421	Cotellic + Tecentriq ± taxane	TNBC
RG7446	Tecentriq SC	NSCLC
Gradalis**	Tecentriq + Vigil	ovarian ca
GTHX**	Tecentriq + trilaciclib	SCLC
IMDZ**	Tecentriq + NY-ESO-1	soft tissue sarcoma

Phase III (20 AIs)

RG7421	Cotellic+Zelboraf+T	1L BRAFm melanoma
RG7446	Tecentriq	NSCLC adj
	Tecentriq	MIBC adj
	Tecentriq	high risk NMIBC
	Tecentriq	NMIBC
	Tecentriq Dx+	1L sq + non-sq SCLC
	Tecentriq	RCC adj
	T + chemo+ Avastin	1L ovarian cancer
	T + pemetrexed	1L non-sq NSCLC
	T + nab-paclitaxel	1L sq NSCLC
	T ± chemo	SCCHN adj
	Tecentriq	HER2-pos. BC neoadj
	T + nab-paclitaxel 1L	TNBC
	T + capecitabine or carbo/gem	1L TNBC
	T + paclitaxel	TNBC adj
	T + nab-paclitaxel	TNBC neoadj
RG7446/RG7853/ RG6268	T + Avastin	RCC
	T + Avastin	1L HCC
	T ± chemo	1L mUC
Tecentriq or Alecensa or entrectinib		1L NSCLC Dx+

Registration (3 AIs)

RG7446	T + nab-paclitaxel	1L non-sq NSCLC
	T + chemo	1L extensive stage SCLC
	T + nab-paclitaxel	1L TNBC

** External collaborations: AMGN – Amgen oncolytic virus; BLRX – BioLine Rx CXCR4 antagonist; CRVS – Corvus ADORA2A antagonist; EXEL – Exelexis' TKI; Gradalis – EATC therapy; GTHX – G1 Therapeutics CDK4/6; HALO – Halozyme PEGPH20; IMDZ – Immune Design CMB305; INO – Inovio T cell activating immunotherapy (INO-5401), IL-12 activator (INO-9012); JNJ – Janssen CD38 MAb; KITE – Kite KTE-C19

	New Molecular Entity (NME)
	Additional Indication (AI)
	Oncology

RG-No Roche/Genentech
*Individualized NeoAntigen Specific Immunotherapy
T=Tecentriq

Major pending approvals 2019

US		EU		China		Japan-Chugai	
RG7446	Tecentriq + nab-paclitaxel 1L non sq NSCLC Filed Nov 2018	RG7596	Polivy (polatuzumab vedotin) r/r DLBCL Filed Dec 2018	RG99	CellCept lupus nephritis Filed Aug 2018	RG7446	Tecentriq + nab-paclitaxel 1L TNBC Filed Dec 2018
RG6268	Rozlytrek (entrectinib) NSCLC ROS1+ Filed Dec 2018	RG7446	Tecentriq + nab-paclitaxel 1L non sq NSCLC Filed Oct 2018	RG6264	Perjeta HER2+ eBC neoadj Filed Aug 2018	RG7446	Tecentriq + chemo 1L extensive stage SCLC Filed Dec 2018
RG6268	Rozlytrek (entrectinib) NTRK+ solid tumors Filed Dec 2018	RG7446	Tecentriq + nab-paclitaxel 1L TNBC* Filed Sep.2018	RG105	MabThera CLL Filed Apr 2019	RG6268	Rozlytrek (entrectinib) NSCLC ROS1+ Filed Mar 2019
RG6152	Xofluza Influenza, high risk pts Filed Dec. 2018	RG7446	Tecentriq + chemo 1L extensive stage SCLC Filed Sep. 2018	RG6264	Perjeta + Herceptin 1L HER2+ mBC Filed Dec 2018	RG7853	Alecensa r/r ALK+ ALCL Filed Jun 2019
		RG6268	Rozlytrek (entrectinib) NSCLC ROS1+ Filed Jan 2019	RG405	Avastin 1L/2L glioblastoma Filed Jan 2019		
		RG6268	Rozlytrek (entrectinib) NTRK1 tumor agnostic Filed Jan 2019	RG3502	Kadcyla HER2+ eBC Filed Feb 2019		
		RG3502	Kadcyla HER2+EBC Filed Feb 2019	RG7159	Gazyva 1L FL Filed Feb 2019		
		RG7601	Venclexta+Gazyva 1L CLL Filed Jul 2019	RG7159	Gazyva r/r FL Filed Feb 2019		
				RG105	MabThera FL Filed Apr 2019		

New Molecular Entity (NME)

Additional Indication (AI)

Oncology / Hematology

Immunology

Infectious Diseases

CardioMetabolism

Neuroscience

Ophthalmology

Other

*CHMP positive opinion

Major granted approvals 2019

US		EU		China		Japan-Chugai	
RG597	Herceptin SC Hylecta Feb 2019	RG105	MabThera pemphigus vulgaris Mar 2019	RG1569	Herceptin BC neoadj Jan 2019	RG105	Rituxan CD20 + CLL Mar 2019
RG7446	Tecentriq + nab-paclitaxel 1L TNBC Mar 2019	RG6013	Hemlibra hemophilia A FVIII non-inh Mar 2019			RG6268	Rozlytrek (entrectinib) NTRK+ solid tumors June 2019
RG7446	Tecentriq + chemo 1L extensive stage SCLC Mar 2019	RG6013	Hemlibra Q4W hemophilia A Mar 2019			RG1569	Actemra CRS Mar 2019
RG7601	Venclexta + Gazyva 1L CLL May 2019	RG7446	Tecentriq + chemo + Avastin 1L non-sq NSCLC Mar 2019			RG1569	Actemra Adult Onset Still's disease Mar 2019
RG3502	Kadcyla HER2+ eBC May 2019						
RG7596	Polivy (polatuzumab vedotin) r/r DLBCL June 2019						

	New Molecular Entity (NME)		CardioMetabolism
	Additional Indication (AI)		Neuroscience
	Oncology / Hematology		Ophthalmology
	Immunology		Other
	Infectious Diseases		