

# Changes to the development pipeline

## Q2 2020 update

### New to phase I

#### 5 NMEs:

**RG6279** PD1-IL2v - solid tumors  
**RG6247** 4D-R110 - choroideremia  
**RG6296** BCMA x CD16a - r/r MM  
**RG7637** NME - neurodevelopmental disorders  
**RG6115** TLR7 agonist (4) - HCC

### New to phase II

#### 3 NMEs: (transitioned from phase I)

**RG7774** NME - retinal disease  
**RG7854** TLR7 agonist (3) + **RG7907** CpAM (2) combination - HBV

#### 3 AIs:

**RG6058** tiragolumab+Tecentriq - cervical cancer  
**RG6149** or **RG7880** ST2 MAb or IL22-Fc - COVID-19 pneumonia  
**IONIS** ASO factor B - IgA-nephropathy

### New to phase III

#### 1 AI:

**RG1569** Actemra+remdesivir - COVID-19 pneumonia

### New to registration

#### 2 AIs:

**RG7421** Cotellic+Zelboraf+Tecentriq - 1L+ BRAFm melanoma  
**RG7601** Venclexta+azacitidine - 1L AML

### Removed from phase I

#### 1 NME:

**RG6217** - HBV

#### 4 AIs:

**RG7421** Cotellic+Tecentriq - RCC, bladder, head & neck ca  
**RG7421** Cotellic+Zelboraf+Tecentriq - melanoma  
**RG7421** Cotellic+Tecentriq - 2L BRAF WT MM  
**RG7601** Venclexta+idasanutlin - r/r AML

### Removed from phase II

#### 2 NMEs:

**RG7314** balovaptan - autism  
**RG7388** idasanutlin - 1L AML

### Removed from phase III

#### 1 AI:

**RG3502** Kadcyca+Perjeta - Her2+ EBC

### Approvals

#### 1 NME approved in US

**RG6264** Phesgo Perjeta+Herceptin FDC SC - HER2+ BC

#### 2 AIs approved in US

**RG7446** Tecentriq+Avastin - 1L HCC  
**RG7446** Tecentriq - 1L non-sq + sq NSCLC Dx+

#### 1 AI approved in EU

**RG1594** Ocrevus Short infusion - RMS & PPMS

# Roche Group development pipeline

## Phase I (43 NMEs + 14 AIs)

RG6026	glofitamab / combos	heme tumors	RG7769	PD1 x TIM3	solid tumors
RG6058	tiragolumab combos	heme & solid tumors	RG7802	cibisatamab ± T	solid tumors
RG6076	CD19-4-1BBL	heme tumors	RG7827	FAP-4-1BBL FP	solid tumors
RG6107	crovalimab	PNH	RG7828	mosunetuzumab/combos	heme tumors
RG6115	TLR7 agonist (4)	HCC	RG7876	selicrelumab combos	solid tumors
RG6139	PD1 x LAG3	solid tumors	CHU	FIXa x FX	hemophilia
RG6160	FcRH5/ x CD3	r/r MM	CHU	glypican-3 x CD3	solid tumors
RG6171	SERD (3)	ER+/HER2- mBC	CHU	codrituzumab	HCC
RG6180	iNeST*± T	solid tumors	SQZ	PBMC vaccine	solid tumors
RG6185	belvarafenib (pan-RAF inh)+Cotellic	solid tumors	RG6151	-	asthma
RG6194	HER2 x CD3	BC	RG6244	-	asthma
RG6279	PD1-IL2v	solid tumors	RG6287	-	IBD
RG6290	MAGE-A4 ImmTAC	solid tumors	RG7835	IgG-IL2	autoimmune diseases
RG6292	CD25 MAb	solid tumors	RG6084	-	HBV
RG6296	BCMA x CD16a	r/r MM	RG6346	HBV siRNA	HBV
RG6323	IL15/IL15Ra-Fc	solid tumors	RG7861	anti-S. aureus TAC	infectious diseases
RG7440	ipatasertib + Taxane + T	TNBC	RG7992	FGFR1 x KLB MAb	metabolic diseases
	ipatasertib + rucaparib	mCRPC, solid tumors	RG6000	DLK inh	ALS
	T-based Morpheus platform	solid tumors	RG6102	brain shuttle gantenerumab	Alzheimer's
	T + Avastin + Cotellic	2/3L CRC	RG6237	-	neuromuscular disorders
	T ± Avastin ± chemo	HCC, GC, PaC	RG7637	-	neurodevelopmental disorders
RG7446	T + anti-CD20 combos	heme tumors	RG7816	GABA Aa5 PAM	autism
	T + K/HP	HER2+ BC	RG6179	-	DME
	T + rucaparib	ovarian cancer	RG6247	4D-R110	choroideremia
	T + CD47 MAb	r/r AML	RG7921	-	nAMD
RG7461	simlukafusp alpha (FAP IL2v FP) / combos	solid tumors	CHU	PTH1 recep. ago	hypoparathyroidism
	Venclexta + AMG176	AML	CHU	-	hyperphosphatemia
RG7601	Venclexta ± azacitidine	r/r MDS	CHU	-	endometriosis
	Venclexta + gilteritinib	r/r AML			

RG-No - Roche/Genentech  
 CHU- Chugai managed  
 IONIS - IONIS managed  
 SQZ- SQZ Biotechnology managed  
 NOV- Novimmune managed

\*Individualized Neoantigen Specific  
 Immunotherapy  
 T=Tecentriq

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

CardioMetabolism  
 Neuroscience  
 Ophthalmology  
 Other

## Phase II (20 NMEs + 12 AIs)

RG6180	iNeST* + pembrolizumab	malignant melanoma
RG6357	SPK-8011	hemophilia A
RG6358	SPK-8016	hemophilia A with inhibitors to factor VIII
RG6058	tiragolumab + T	NSCLC
	tiragolumab + T	cervical cancer
RG7421	Cotellic + T ± taxane	TNBC
RG7446	Tecentriq	SC NSCLC
RG7596	Polivy	r/r FL
RG7601	Venclexta + azacitidine	1L MDS
	Venclexta + fulvestrant	2L HR+BC
	Venclexta + carfilzomib	r/r MM t(11:14)
RG6149	ST2 MAb	asthma
RG6173	anti-tryptase	asthma
RG6354	rh pentraxin-2 (PRM-151)	myelofibrosis
	rh pentraxin-2 (PRM-151)	idiopathic pulmonary fibrosis
RG7159	Gazyva	lupus nephritis
RG7845	fenebrutinib	RA
RG7880	IL22-Fc	inflammatory diseases
RG6149/RG7880	ST2 MAb or IL22-Fc	COVID-19 pneumonia
NOV	TLR4 MAb	autoimmune diseases
RG7854+RG7907	TLR7 ago(3) + CpAM (2)	HBV
IONIS	ASO factor B	IgA nephropathy
RG6100	semorinemab	Alzheimer's
RG6356	microdystrophin (SRP-9001)	DMD
RG7412	crenezumab	familial Alzheimer's healthy pts
RG7906	ralmitaront	schizophrenia
RG7935	prasinezumab	Parkinson's
RG6147	-	geographic atrophy
RG6367	SPK-7001	choroideremia
RG7774	-	retinal disease
IONIS	ASO factor B	geographic atrophy

# Roche Group development pipeline

## Phase III (8 NMEs + 30 AIs)

RG6013	Hemlibra	mild to moderate hemophilia A	RG7446/ RG6268	Tecentriq bTMB-high or entrectinib ROS1+	1L NSCLC
RG6058	tiragolumab + T + chemo	1L SCLC	RG7601	Venclexta	r/r MM t(11:14)
RG6114	tiragolumab + T	1L PD-L1+ NSCLC	RG7853	Alecensa	ALK+ NSCLC adj
RG7440	mPI3K alpha inh	1L HR+ mBC	RG1569	Actemra	COVID-19 pneumonia
	ipatasertib + abiraterone	1L CRPC	RG1569	Actemra + remdesivir	COVID-19 pneumonia
	ipatasertib + chemo	1L TNBC/HR+ BC	RG3648	Xolair	food allergy
	ipatasertib + fulvestrant + palbociclib	1L HR+ mBC	RG7413	etrolizumab	ulcerative colitis
	ipatasertib + Tecentriq + taxane	1L TNBC		etrolizumab	Crohn's
RG7596	Polivy	1L DLBCL	RG6152	Xofluza	influenza, hospitalized pts
RG7446	Tecentriq	NSCLC adj		Xofluza	influenza, pediatric (0-1 year)
	Tecentriq	NMIBC, high risk		Xofluza	influenza direct transmission
	Tecentriq	RCC adj	RG1450	gantenerumab	Alzheimer's
	T + chemo + Avastin	1L ovarian cancer	RG6042	tominersen	Huntington's
	T ± chemo	SCCHN adj	RG6321	port delivery system with ranibizumab	wAMD
	Tecentriq	HER2+ BC neoadj		port delivery system with ranibizumab	DME
	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	HCC adj			
	T ± chemo	1L mUC			

## Registration (5 NMEs + 11 AIs)

RG6264	Phesgo <sup>1</sup> Perjeta + Herceptin FDC SC	HER2+ BC
RG6268	Rozlytrek (entrectinib) <sup>1</sup>	ROS1+ NSCLC
RG7446	Rozlytrek (entrectinib) <sup>1</sup>	NTRK+ tumor-agnostic
	Tecentriq Dx+ <sup>1</sup>	1L sq + non-sq NSCLC
RG7421	Tecentriq+ Avastin <sup>1</sup>	1L HCC
RG7601	Cotellic + Zelboraf + T <sup>2</sup>	1L+ BRAFm melanoma
RG7853	Venclexta + azacitidine	1L AML
RG3648	Alecensa	1L NSCLC Dx+
	Xolair <sup>2</sup>	nasal polyps
RG6152	Xofluza <sup>1</sup>	influenza
	Xofluza <sup>1</sup>	influenza, high risk
	Xofluza <sup>2</sup>	influenza post exposure prophylaxis
	Xofluza <sup>2</sup>	influenza, pediatric (1-12 yrs)
RG1594	Ocrevus <sup>3</sup>	short infusion RMS & PPMS
RG6168	satralizumab	NMOSD
RG7916	risdiplam <sup>2</sup>	SMA

<sup>1</sup> Approved in US, filed in EU

<sup>2</sup> Filed in US

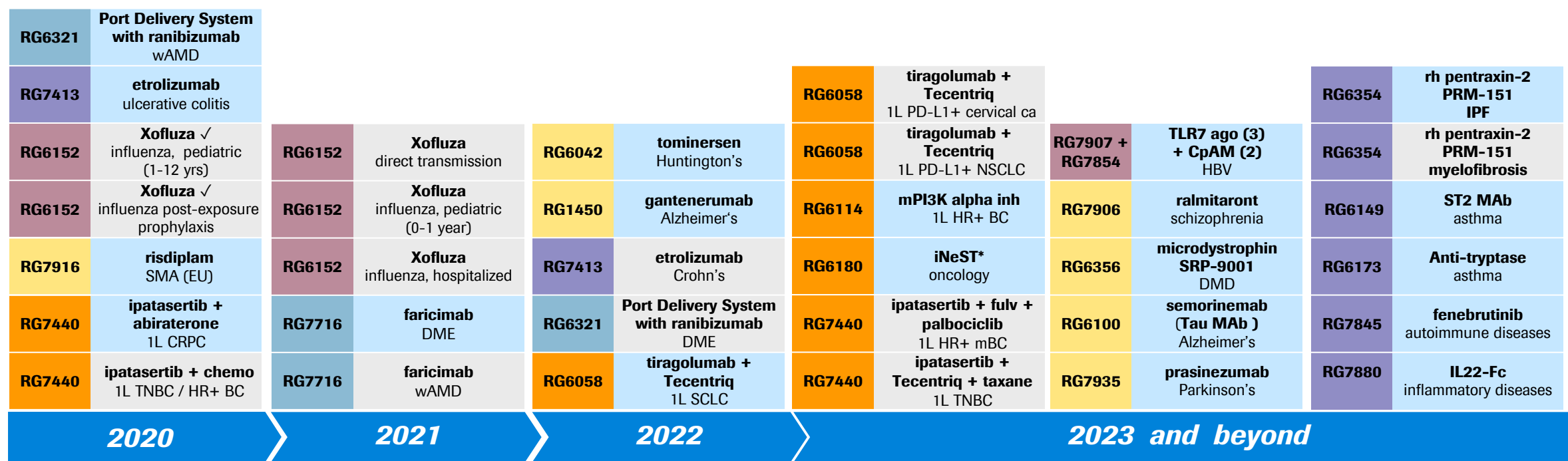
<sup>3</sup> Filed in US, approved in EU

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

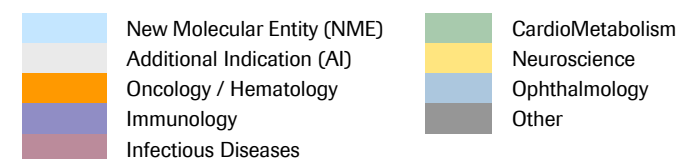
	CardioMetabolism
	Neuroscience
	Ophthalmology
	Other

# NME submissions and their additional indications

## Projects in phase II and III



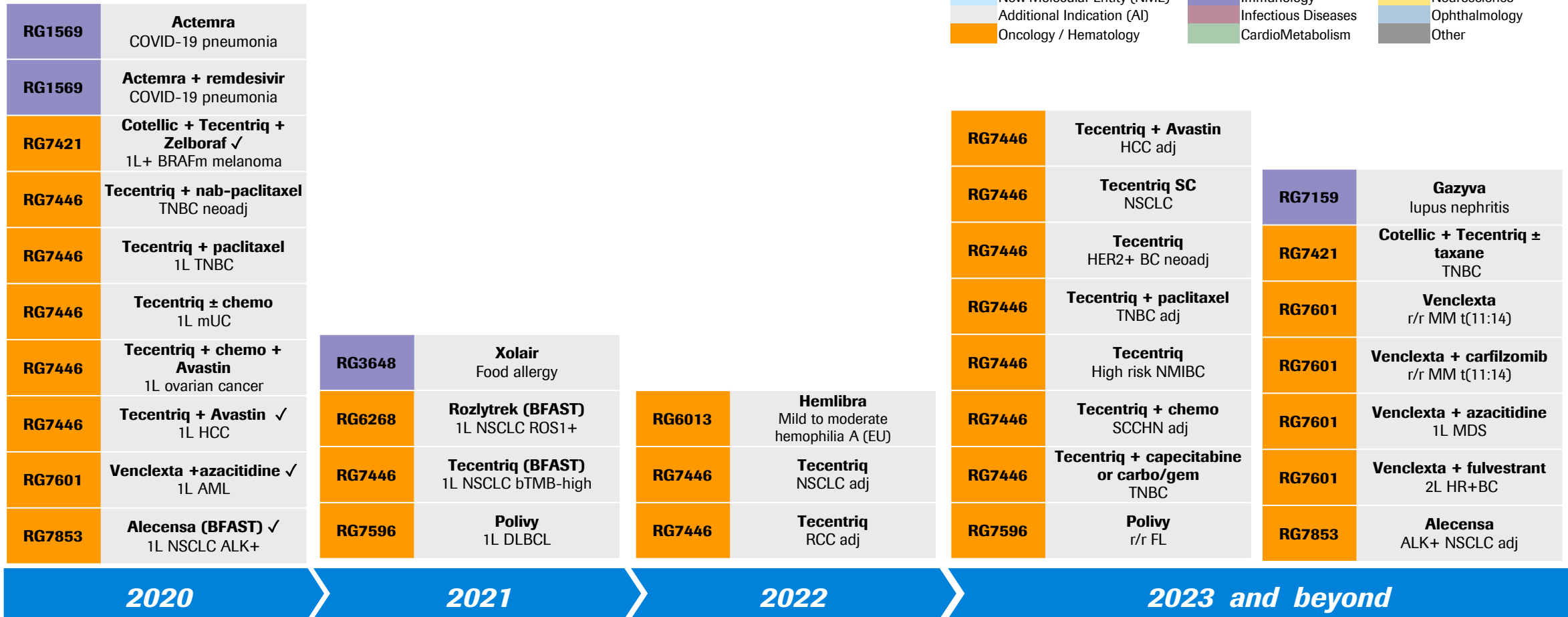
✓ Indicates submission to health authorities has occurred  
Unless stated otherwise submissions are planned to occur in US and EU



\*Individualized NeoAntigen Specific Immunotherapy

# AI submissions for existing products

## Projects in phase II and III



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<span style="background-color: #D3D3D3; border: 1px solid black; display: inline-block; width: 15px; height: 10px;"></span> Additional Indication (AI)	<span style="background-color: #C08080; border: 1px solid black; display: inline-block; width: 15px; height: 10px;"></span> Infectious Diseases	<span style="background-color: #ADD8E6; border: 1px solid black; display: inline-block; width: 15px; height: 10px;"></span> Ophthalmology
<span style="background-color: #FFA500; border: 1px solid black; display: inline-block; width: 15px; height: 10px;"></span> Oncology / Hematology	<span style="background-color: #90EE90; border: 1px solid black; display: inline-block; width: 15px; height: 10px;"></span> CardioMetabolism	<span style="background-color: #808080; border: 1px solid black; display: inline-block; width: 15px; height: 10px;"></span> Other

# Major pending approvals 2020

US		EU		China		Japan-Chugai	
RG6168	<b>satralizumab</b> NMOSD Filed Aug 2019	RG6268	<b>Rozlytrek (entrectinib)</b> ROS1+ NSCLC Filed Jan 2019	RG99	<b>CellCept</b> lupus nephritis Filed Aug 2018	RG3502	<b>Kadcyla</b> HER2+ eBC adj Filed Aug 2019
RG3648	<b>Xolair</b> nasal polyps Filed Sept 2019	RG6268	<b>Rozlytrek (entrectinib)</b> NTRK+ tumor-agnostic Filed Jan 2019	RG405	<b>Avastin</b> 1L/2L glioblastoma Filed Jan 2019	RG7446	<b>Tecentriq +Avastin</b> HCC Filed Feb 2020
RG7916	<b>risdiplam</b> SMA Filed Nov 2019	RG6168	<b>satralizumab</b> NMOSD Filed Aug 2019	RG105	<b>MabThera</b> CLL Filed Apr 2019	RG7596	<b>Polivy</b> r/r DLBCL Filed June 2020
RG7853	<b>Alecensa (BFAST)</b> 1L NSCLC ALK+ Filed Jan 2020	RG7446	<b>Tecentriq</b> 1L non-sq + sq NSCLC Dx+ Filed Nov 2019	RG105	<b>MabThera</b> FL Filed Apr 2019		
RG1594	<b>Ocrevus</b> Short infusion RMS & PPMS Filed Feb 2020	RG6152	<b>Xofluza</b> influenza Filed Nov 2019	RG7159	<b>Gazyva</b> 1L FL Filed Sept 2019		
RG6152	<b>Xofluza</b> post exposure prophylaxis Filed March 2020	RG6152	<b>Xofluza</b> influenza, high risk Filed Nov 2019	RG7159	<b>Gazyva</b> r/r FL Filed Sept 2019		
RG6152	<b>Xofluza</b> influenza, pediatric (1-12 yrs) Filed March 2020	RG7446	<b>Tecentriq +Avastin</b> 1L HCC Filed Jan 2020	RG7446	<b>Tecentriq +Avastin</b> 1L HCC Filed Jan 2020		
RG7421	<b>Cotellic + Zelboraf+ Tecentriq</b> 1L+ BRAFm melanoma Filed May 2020	RG6264	<b>Perjeta+Herceptin FDC SC</b> Her2+BC Filed Jan 2020	RG6168	<b>satralizumab</b> NMOSD Filed April 2020		
RG7601	<b>Venclexta+ azacitidine</b> 1L AML Filed May 2020	RG7601	<b>Venclexta+ azacitidine</b> 1L AML Filed May 2020	RG7916	<b>risdiplam</b> SMA Filed March 2020		
				RG6152	<b>Xofluza</b> influenza Filed May 2020		
				RG6152	<b>Xofluza</b> influenza, high risk Filed May 2020		
				RG6013	<b>Hemlibra</b> Hemophilia A Filed June 2020		

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

FDC = fixed-dose combination

# Major granted approvals 2020

US		EU		China		Japan-Chugai	
<b>RG7601</b>	<b>Venclexta+Gazyva</b> 1L CLL Mar 2020	<b>RG7596</b>	<b>Polivy</b> r/r DLBCL January 2020	<b>RG3502</b>	<b>Kadcyla</b> HER2+ eBC Jan 2020	<b>RG6268</b>	<b>Rozlytrek (entrectinib)</b> ROS1+ NSCLC Feb 2020
<b>RG7446</b>	<b>Tecentriq + Avastin</b> 1L HCC May 2020	<b>RG7601</b>	<b>Venclexta+Gazyva</b> 1L CLL Mar 2020	<b>RG7446</b>	<b>Tecentriq + chemo</b> 1L extensive stage SCLC Feb 2020	<b>RG7853</b>	<b>Alecensa</b> r/r ALK+ ALCL Feb 2020
<b>RG7446</b>	<b>Tecentriq</b> 1L non-sq + sq NSCLC Dx+ May 2020	<b>RG1594</b>	<b>Ocrevus</b> Short infusion RMS & PPMS May 2020			<b>RG105</b>	<b>Rituxan</b> thrombocytopenic purpura Feb 2020
<b>RG6264</b>	<b>Phesgo (Perjeta+Herceptin FDC) SC</b> Her2+BC June 2020					<b>RG6168</b>	<b>Enspryng (satralizumab)</b> NMOSD June 2020

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

*Doing now what patients need next*