

New Active Substances (NASs) approved by six major authorities in 2021

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EMA NAS approvals in 2021



Brand Name	Generic Name	Sponsor	Approval Date	Expedited Review*	Orphan	Exceptional Circumstances	Conditional Approval	PRIME designation
Abecma	idecabtagene vicleuceel	Bristol-Myers Squibb Pharma EEIG	18/08/2021					
Adtralza	tralokinumab	LEO Pharma A/S	17/06/2021					
Artesunate Amivas	artesianate	Amivas Ireland Ltd	22/11/2021					
Aspaveli	pegcetacoplan	Swedish Orphan Biovitrum AB (publ)	13/12/2021					
Bimzelx	bimekizumab	UCB Pharma S.A.	20/08/2021					
Brukinsa	zanubrutinib	BeiGene Ireland Ltd	22/11/2021					
Byfavo	remimazolam	PAION Netherlands B.V.	26/03/2021					
Bylvay	odevixibat	Albireo	16/07/2021					
Cibinqo	abrocitinib	Pfizer Europe MA EEIG	09/12/2021					
Copiktra	duvelisib	Secura Bio Limited	19/05/2021					
Drovelis/ Lydisilka	estetrol, drospirenone	Gedeon Richter Plc./ Estetra SPRL	19/05/2021					
Elzonris	tagraxofusp	Stemline Therapeutics B.V.	07/01/2021					
Enhertu	trastuzumab deruxtecan	Daiichi Sankyo Europe GmbH	18/01/2021					
Enspryng	satralizumab	Roche Registration GmbH	24/06/2021					

*Expedited review refers to EMA Accelerated Assessment

EMA NAS approvals in 2021



Brand Name	Generic Name	Sponsor	Approval Date	Expedited Review*	Orphan	Exceptional Circumstances	Conditional Approval	PRIME designation
Evkeeza	evinacumab	Regeneron Ireland Designated Activity Company (DAC)	17/06/2021					
Evrenzo	roxadustat	Astellas Pharma Europe B.V.	18/08/2021					
Evrysdi	risdiplam	Roche Registration GmbH	26/03/2021					
Gavreto	pralsetinib	Roche Registration GmbH	18/11/2021					
Imcivree	setmelanotide	Rhythm Pharmaceuticals Netherlands B.V.	16/07/2021					
Inrebic	fedratinib	Bristol Myers Squibb Pharma EEIG	08/02/2021					
Jemperli	dostarlimab	GlaxoSmithKline (Ireland) Limited	21/04/2021					
Klisyri	tirbanibulin	Almirall, S.A.	16/07/2021					
Koselugo	selumetinib	AstraZeneca AB	17/06/2021					
Minjuvi	tafasitamab	Incyte Biosciences Distribution B.V.	26/08/2021					
Nexpovio	selinexor	Karyopharm Europe GmbH	26/03/2021					
Ontozry	cenobamate	Angelini Pharma S.p.A	26/03/2021					
Orladeyo	berotralstat	BioCryst Ireland Limited	30/04/2021					
Pemazyre	pemigatinib	Incyte Biosciences Distribution B.V.	26/03/2021					

*Expedited review refers to EMA Accelerated Assessment

EMA NAS approvals in 2021



Brand Name	Generic Name	Sponsor	Approval Date	Expedited Review*	Orphan	Exceptional Circumstances	Conditional Approval	PRIME designation
Ponvory	ponesimod	Janssen-Cilag International N.V.	19/05/2021					
Qinlock	ripretinib	Deciphera Pharmaceuticals (Netherlands) B.V.	18/11/2021					
Regkirona	regdanvimab	Celltrion Healthcare Hungary Kft.	12/11/2021					
Retsevmo	selpercatinib	Eli Lilly Nederland B.V.	11/02/2021					
Ronapreve	casirivimab, imdevimab	Roche Registration GmbH	12/11/2021					
Rukobia	fostemsavir	ViiV Healthcare B.V.	04/02/2021					
Rybrevant	amivantamab	Janssen-Cilag International N.V.	09/12/2021					
Ryeqo	relugolix, estradiol, norethisterone acetate	Gedeon Richter Plc.	16/07/2021					
Skysona	elivaldogene autotemcel	bluebird bio (Netherlands) B.V.	16/07/2021					
Sogroya	somapacitan	Novo Nordisk A/S	31/03/2021					
Trodelyv	sacituzumab govitecan	Gilead Sciences Ireland UC	22/11/2021					
Tukysa	tucatinib	Seagen B.V.	11/02/2021					
Vazkepa	icosapent ethyl	Amarin Pharmaceuticals Ireland Limited	26/03/2021					
Verquvo	vericiguat	Bayer AG	16/07/2021					
Voxzogo	vosoritide	BIOMARIN INTERNATIONAL LIMITED	26/08/2021					

*Expedited review refers to EMA Accelerated Assessment

EMA NAS approvals in 2021



Brand Name	Generic Name	Sponsor	Approval Date	Expedited Review*	Orphan	Exceptional Circumstances	Conditional Approval	PRIME designation
Xevudy	sotrovimab	GlaxoSmithKline Trading Services Limited	17/12/2021					
Xofluza	baloxavir marboxil	Roche Registration GmbH	07/01/2021					

*Expedited review refers to EMA Accelerated Assessment

FDA NAS approvals in 2021



Brand Name	Generic Name	Sponsor	Approval Date	Expedited Review*	Orphan	Fast Track	Break-through	Accelerated Approval	RTOR	Project Orbis
Abecma	idecabtagene vicleucel	Celgene Corporation	26/03/2021							
Adbry	tralokinumab	LEO PHARMA AS	27/12/2021							
Aduhelm	aducanumab-avwa	Biogen Inc	07/06/2021							
Amondys 45	casimersen	SAREPTA THERAPS INC	25/02/2021							
Azstarys	dexamethylphenidate hydrochloride; serdexmethylphenidate chloride	Commave Therap	02/03/2021							
Besremi	ropeginterferon alfa-2b-njft	Pharmaessentia Corp	12/11/2021							
Brexafemme	ibrexafungerp citrate	Scynexis	01/06/2021							
Breyanzi	lisocabtagene maraleucel	Juno Therapeutics, Inc.	05/02/2021							
Bylvay	odevixibat	Albireo	20/07/2021							
Cabenuva	cabotegravir; rilpivirine	ViiV Healthcare	21/01/2021							
Cosela	trilaciclib dihydrochloride	G1 Therap	12/02/2021							
Cytalux	pafolacianine sodium	On Target Labs	29/11/2021							
Empaveli	pegcetacoplan	Apellis Pharms	14/05/2021							
Evkeeza	evinacumab-dgnb	REGENERON PHARMACEUTICALS	11/02/2021							
Exkivity	mobocertinib succinate	TAKEDA PHARMS USA	15/09/2021							

* Expedited review refers to FDA Priority Review

FDA NAS approvals in 2021



Brand Name	Generic Name	Sponsor	Approval Date	Expedited Review*	Orphan	Fast Track	Break-through	Accelerated Approval	RTOR	Project Orbis
Fexinidazole	fexinidazole	Sanofi	16/07/2021							
Fotivda	tivozanib hydrochloride	Aveo Pharms	10/03/2021							
Jemperli	dostarlimab-gxly	glaxosmithkline	22/04/2021							
Kerendia	finerenone	BAYER HLTHCARE	09/07/2021							
Korsuva	difelikefalin acetate	Cara Therap	23/08/2021							
Leqvio	inclisiran sodium	Novartis	22/12/2021							
Livmarli	maralixibat chloride	Mirum Pharmaceuticals, Inc	29/09/2021							
Livtency	maribavir	TAKEDA PHARMS USA	23/11/2021							
Lumakras	sotorasib	Amgen Inc	28/05/2021							
Lupkynis	voclosporin	Aurinia	22/01/2021							
Lybalvi	olanzapine; samidorphan l-malate	ALKERMES INC	28/05/2021							
Nextstellis	drospirenone; estetrol	Mayne Pharma	15/04/2021							
Nexviazyme	avalglucosidase alfa-ngpt	GENZYME CORP	06/08/2021							
Nulibry	fosdenopterin hydrobromide	Origin	26/02/2021							
Pepaxto	melpalan flufenamide hydrochloride	Oncopeptides Ab	26/02/2021							

* Expedited review refers to FDA Priority Review

FDA NAS approvals in 2021



Brand Name	Generic Name	Sponsor	Approval Date	Expedited Review*	Orphan	Fast Track	Break-through	Accelerated Approval	RTOR	Project Orbis
Ponvory	ponesimod	Janssen Pharms	18/03/2021							
Pylarify	piflufolastat f-18	Progenics Pharms Inc	26/05/2021							
Qelbree	viloxazine hydrochloride	Supernus Pharms	02/04/2021							
Qulipta	atogepant	ABBVIE INC	28/09/2021							
Rezurock	belumosudil mesylate	Kadmon Pharms Llc	16/07/2021							
Rybrevent	amivantamab-vmjw	Janssen Biotech	21/05/2021							
Rylaze	asparaginase erwinia chrysanthemi (recombinant)-rywn	Jazz Pharms	30/06/2021							
Saphnelo	anifrolumab-fnia	AstraZeneca AB	30/07/2021							
Scemblix	asciminib hydrochloride	Novartis	29/10/2021							
Skytrofa	lonapegsomatropin-tcgd	Ascendis Pharma Encocrinology Div A/S	25/08/2021							
Tavneos	avacopan	Chemocentryx	07/10/2021							
Tepmetko	tepotinib hydrochloride	EMD SERONO INC	03/02/2021							
Tezspire	tezepelumab-ekko	AstraZeneca AB	17/12/2021							
Tivdak	tisotumab vedotin-tftv	Seagen	20/09/2021							
Truseltiq	infigratinib phosphate	HELSINN HLTHCARE	28/05/2021							

* Expedited review refers to FDA Priority Review

FDA NAS approvals in 2021



Brand Name	Generic Name	Sponsor	Approval Date	Expedited Review*	Orphan	Fast Track	Break-through	Accelerated Approval	RTOR	Project Orbis
Ukoniq	umbralisib tosylate	Tg Theraps	05/02/2021							
Verquvo	vericiguat	MERCK SHARP DOHME	19/01/2021							
Voxzogo	vosoritide	Biomarin Pharm	19/11/2021							
Vyvgart	efgartigimod alfa	Argenx Bv	17/12/2021							
Welireg	belzutifan	MERCK SHARP DOHME	13/08/2021							
Zegalogue	dasiglucagon hydrochloride	Zealand Pharma	22/03/2021							
Zynlonta	loncastuximab tesirine-lpyl	Adc Therapeutics Sa	23/04/2021							

* Expedited review refers to FDA Priority Review

PMDA NAS approvals in 2021



Brand Name	Generic Name	Sponsor	Approval Date	Expedited Review*	Orphan	Sakigake	Conditional Early Approval
Adlumiz	anamorelin hydrochloride	Ono Pharmaceutical Co., Ltd.	22/01/2021				
Aimovig	ereunumab (genetical recombination)	Amgen K.K.	23/06/2021				
Ajovy	fremanezumab (genetical recombination)	Otsuka Pharmaceutical Co., Ltd.	23/06/2021				
Alunbrig	brigatinib	Takeda Pharmaceutical Company Limited	22/01/2021				
Axumin	fluciclovine (18f)	Nihon Medi-Physics Co., Ltd.	23/03/2021				
Calquence	acalabrutinib	AstraZeneca K.K.	22/01/2021				
Cibinqo	abrocitinib	Pfizer Japan Inc.	27/09/2021				
Emgality	galcanezumab (genetical recombination)	Eli Lilly Japan K.K.	22/01/2021				
Evrysdi Dry Syrup	risdiplam	Chugai Pharmaceutical Co., Ltd.	23/06/2021				
Givlaari	givosiran sodium	Alnylam Japan K.K.	23/06/2021				
Hiyasta	tucidinostat	Huya Japan G.K.	23/06/2021				
Isturisa	osilodrostat phosphate	Recordati Rare Diseases Japan K.K.	23/03/2021				
Izcargo	pabinafusp alfa (genetical recombination)	JCR Pharmaceuticals Co., Ltd.	23/03/2021				
Lutathera	lutetium (177lu) oxodotreotide	Fujifilm Toyama Chemical Co., Ltd.	23/06/2021				
Megludase	glucarpidase (genetical recombination)	Ohara Pharmaceutical Co., Ltd.	27/09/2021				
Moizerto	difamilast	Otsuka Pharmaceutical Co., Ltd.	27/09/2021				

* Expedited review refers to PMDA Priority Review

PMDA NAS approvals in 2021



Brand Name	Generic Name	Sponsor	Approval Date	Expedited Review*	Orphan	Sakigake	Conditional Early Approval
Musredo	molidustat sodium	Bayer Yakuhin, Ltd.	22/01/2021				
Nexvazyme	avalglucosidase alfa (genetical recombination)	Sanofi K.K.	27/09/2021				
Nuwiq	simoctocog alfa (genetical recombination)	Fujimoto Pharmaceutical Corporation	22/01/2021				
Orladeyo	berotralstat hydrochloride	OrphanPacific, Inc.	22/01/2021				
Ostabalo	abaloparatide acetate	Teijin Pharma Limited	23/03/2021				
Padcev	enfortumab vedotin (genetical recombination)	Astellas Pharma Inc.	27/09/2021				
Pemazyre	pemigatinib	Incyte Biosciences Japan GK	23/03/2021				
Polivy	polatuzumab vedotin (genetical recombination)	Chugai Pharmaceutical Co., Ltd.	23/03/2021				
Recarbrio	relebactam hydrate/imipenem hydrate/cilastatin sodium	MSD K.K.	23/06/2021				
Remitoro	denileukin diftitox (genetical recombination)	Eisai co., Ltd.	23/03/2021				
Retevmo	selpercatinib	Eli Lilly Japan K.K.	27/09/2021				
Revestive	teduglutide (genetical recombination)	Takeda Pharmaceutical Company Limited	23/06/2021				
Saphnelo	anifrolumab (genetical recombination)	AstraZeneca K.K.	27/09/2021				
Sogroya	somapacitan (genetical recombination)	Novo Nordisk Pharma Ltd.	22/01/2021				
Tavneos	avacopan	Kissei Pharmaceutical Co., Ltd.	27/09/2021				
Tazverik	tazemetostat hydrobromide	Eisai co., Ltd.	23/06/2021				

* Expedited review refers to PMDA Priority Review

PMDA NAS approvals in 2021



Brand Name	Generic Name	Sponsor	Approval Date	Expedited Review*	Orphan	Sakigake	Conditional Early Approval
Twymeeg	imeglimin hydrochloride	Sumitomo Dainippon Pharma Co., Ltd.	23/06/2021				
Unituxin	dinutuximab (genetical recombination)	Ohara Pharmaceutical Co.,Ltd.	23/06/2021				
Upasita Iv Injection	upacicalcet sodium hydrate	Sanwa Kagaku Kenkyusho Co., Ltd.	23/06/2021				
Uplizna	inebilizumab (genetical recombination)	mitsubishi tanabe pharma corporation	23/03/2021				
Verquvo	vericiguat	Bayer Yakuhin, Ltd.	23/06/2021				
Vitrakvi	larotrectinib sulfate	Bayer Yakuhin, Ltd.	23/03/2021				

* Expedited review refers to PMDA Priority Review

Health Canada NAS approvals in 2021



Brand Name	Generic Name	Sponsor	Approval Date	Expedited Review*	Conditional - Notice of Compliance with conditions	Access Consortium worksharing	Project Orbis
Abecma	idecabtagene vicleucel	CELGENE INC	26/05/2021				
Adtralza	tralokinumab	leo pharma inc	13/10/2021				
Braftovi	encorafenib	PFIZER CANADA ULC	02/03/2021				
Brukinsa	zanubrutinib	Beigene Switzerland GmbH	01/03/2021				
Dojolvi	trihaptanoïn	Ultragenyx Pharmaceutical Inc	15/02/2021				
Enhertu	trastuzumab deruxtecan	astrazeneca canada inc	15/04/2021				
Evrysdi	risdiplam	HOFFMANN LA ROCHE LIMITED	14/04/2021				
Gavreto	pralsetinib	Hoffmann-La Roche Limited	30/06/2021				
Ilumya	tildrakizumab	Sun Pharma Global Fze	19/05/2021				
Jemperli	dostarlimab	GlaxoSmithKline Inc	23/12/2021				
Leqvio	inclisiran sodium	Novartis Pharmaceuticals Canada Inc	26/07/2021				
Lumakras	sotorasib	AMGEN CANADA INC	10/09/2021				
Mektovi	binimetinib	PFIZER CANADA ULC	02/03/2021				
Minjuvi	tafasitamab	Incyte Corporation	19/08/2021				
Nextstellis	drospirenone, estetrol monohydrate	Searchlight Pharma Inc	05/03/2021				
Nexvazyme	avalglucosidase alfa	Sanofi-Aventis Canada Inc	12/11/2021				
Ngenla	somatrogon	PFIZER CANADA ULC	26/10/2021				
Osphena	ospemifene	DUCHESNAY INC	16/07/2021				
Padcev	enfortumab vedotin	Seagen Inc.	29/10/2021				
Pemazyre	pemigatinib	Incyte Corporation	17/09/2021				

*Expedited review refers to Health Canada Priority Review

Health Canada NAS approvals in 2021



Brand Name	Generic Name	Sponsor	Approval Date	Expedited Review*	Conditional - Notice of Compliance with conditions	Access Consortium worksharing	Project Orbis
Ponvory	ponesimod	JANSSEN INC	28/04/2021				
Retevmo	selpercatinib	Loxo Oncology Inc	15/06/2021				
Rukobia	fostemsavir tromethamine	viiv healthcare ulc	01/10/2021				
Saphnelo	anifrolumab	astrazeneca canada inc	30/11/2021				
Sunosi	solriamfetol hydrochloride	JAZZ PHARMACEUTICALS IRELAND LIMITED	13/05/2021				
Tecartus	brexucabtagene autoleucel	gilead sciences canada inc	08/06/2021				
Tepmetko	tepotinib hydrochloride	EMD SERONO A DIVISION OF EMD INC CANADA	27/05/2021				
Tpoxx	tecovirimat monohydrate	Siga Technologies, Inc.	29/11/2021				
Trikafta	elexacaftor, ivacaftor, tezacaftor	vertex pharmaceuticals (canada) incorporated	18/06/2021				
Trodelvy	sacituzumab govitecan	gilead sciences canada inc	24/09/2021				
Truseltiq	infigratinib phosphate	Qed Therapeutics, Inc.	27/09/2021				
Vyepti	eptinezumab	lundbeck canada inc	11/01/2021				
Wakix	pitolisant	Endo Ventures Ltd	25/05/2021				
Zepzelca	lurbinectedin	JAZZ PHARMACEUTICALS IRELAND LIMITED	29/09/2021				

*Expedited review refers to Health Canada Priority Review

Swissmedic NAS approvals in 2021



Brand Name	Generic Name	Sponsor	Approval Date	Expedited Review*	Orphan	Procedure with prior notification (VmVA)	Conditional approval	Art.13 TPA	Art.14 TPA	Access Consortium worksharing	Project Orbis
Abecma	idecabtagenum vicleucelum	Celgene GmbH	20/08/2021								
Alunbrig	brigatinibum	Takeda Pharma AG	04/05/2021								
Calquence	acalabrutinibum	AstraZeneca AG	04/03/2021								
Clofara	clofarabinum	IDEOGEN AG	15/07/2021								
Doptelet	avatrombopagum	Swedish Orphan Biovitrum AG	23/11/2021								
Enhertu	trastuzumabum deruxtecanum	Daiichi Sankyo (Schweiz) AG	29/11/2021								
Epidyolex	cannabidiolum	Drac AG	10/02/2021								
Evryssi	risdiplamum	Roche Pharma (Schweiz) AG	06/05/2021								
Gavreto	pralsetinibum	Roche Pharma (Schweiz) AG	12/08/2021								
Givlaari	givosiranum	Alnylam Switzerland GmbH	29/03/2021								
Inrebic	fedratinibum	Celgene GmbH	01/07/2021								
Kerendia	finerenonum	Bayer (Schweiz) AG	26/11/2021								
Leqvio	inclisiranum	Novartis Pharma Schweiz AG	09/09/2021								
Lokelma	natriumzirconium cyclosilicat	AstraZeneca AG	16/04/2021								
Lumykras	sotorasibum	Amgen Switzerland AG	16/12/2021								

*Expedited review refers to Swissmedic Fast-Track

Swissmedic NAS approvals in 2021



Brand Name	Generic Name	Sponsor	Approval Date	Expedited Review*	Orphan	Procedure with prior notification (VmVA)	Conditional approval	Art.13 TPA	Art.14 TPA	Access Consortium worksharing	Project Orbis
Nexviadyme	avalglucosidase alfa	Sanofi-Aventis (Suisse) SA	17/11/2021								
Nicardipin Labatec	nicardipini hydrochloridum	Labatec Pharma SA	22/03/2021								
Oxlumo	lumasiranum	Alnylam Switzerland GmbH	01/12/2021								
Padcev	enfortumab vedotin	Astellas Pharma AG	09/11/2021								
Pemazyre	pemigatinibum	Incyte Biosciences International	13/07/2021								
Polivy	polatuzumabum vedotinum	Roche Pharma (Schweiz) AG	15/06/2021								
Ponvory	ponesimodum	Janssen-Cilag AG	16/11/2021								
Poteligeo	mogamulizumabum	Kyowa Kirin Sàrl	01/09/2021								
Qinlock	ripretinibum	Deciphera Pharmaceuticals	07/10/2021								
Retsevmo	selpercatinibum	Eli Lilly (Suisse) SA	08/02/2021								
Ronapreve	casirivimabum / imdevimabum	Roche Pharma (Schweiz) AG	23/12/2021								
Rukobia	fostemsavirum	ViiV Healthcare GmbH	28/09/2021								
Tabrecta	capmatinibum	Novartis Pharma Schweiz AG	26/04/2021								
Tecartus	autologe anti-cd19-transduzierte cd3+ zellen	Gilead Sciences Switzerland Sàrl	25/08/2021								
Tegsedi	inotersen	SFL Pharma GmbH	31/05/2021								

*Expedited review refers to Swissmedic Fast-Track

Swissmedic NAS approvals in 2021



Brand Name	Generic Name	Sponsor	Approval Date	Expedited Review*	Orphan	Procedure with prior notification (VmVA)	Conditional approval	Art.13 TPA	Art.14 TPA	Access Consortium worksharing	Project Orbis
Tepmetko	tepotinibum	Merck (Schweiz) AG	22/06/2021								
Trodelyv	sacituzumab govitecan	Gilead Sciences Switzerland Sàrl	09/09/2021								
Vaborem	meropenemum / vaborbactamum	A. Menarini GmbH	01/07/2021								
Verquvo	vericiguatum	Bayer (Schweiz) AG	22/09/2021								
Vocabria	cabotegravirum	ViiV Healthcare GmbH	08/10/2021								
Vyepti	eptinezumabum	Lundbeck (Schweiz) AG	11/10/2021								
Zolgensma	onasemnogen-abeparvovec	Novartis Pharma Schweiz AG	28/06/2021								

*Expedited review refers to Swissmedic Fast-Track

TGA NAS approvals in 2021



Brand Name	Generic Name	Sponsor	Approval Date	Expedited Review*	Orphan	Conditional - Provisional Approval	Access Consortium worksharing	Project Orbis	Comparable overseas regulators (COR) review
Adakveo	crizanlizumab	Novartis Pharmaceuticals Australia Pty Ltd	06/04/2021						
Aklief	trifarotene	Galderma Australia Pty Ltd	11/01/2021						
Austedo	deutetrabenazine	Teva Pharma Australia Pty Ltd	26/05/2021						
Brukinsa	zanubrutinib	Beigene Aus Pty Ltd	08/10/2021						
Crysvita	burosumab	Kyowa Kirin Australia Pty Ltd	03/09/2021						
Dayvigo	lemborexant	Eisai Australia Pty Ltd	15/07/2021						
Enhertu	trastuzumab deruxtecan	ASTRAZENECA PTY LTD	05/10/2021						
Evryssi	risdiplam	ROCHE PRODUCTS PTY LTD	02/06/2021						
Illuccix	glu-urea-lys(ahx)-hbed-cc	Telix Pharmaceuticals (ANZ) Pty Ltd	01/11/2021						
Kerendia	finerenone	Bayer Australia Ltd	18/11/2021						
Koselugo	selumetinib	ASTRAZENECA PTY LTD	29/11/2021						
Leqvio	inclisiran	Novartis Pharmaceuticals Australia Pty Ltd	14/09/2021						
Nextstellis	estetrol monohydrate; drospirenone	Mayne Pharma International Pty Ltd	11/11/2021						
Nexviazyme	avalglucosidase alfa	Sanofi-Aventis Australia Pty Ltd	15/11/2021						
Ngenla	somatrogon	Pfizer Australia Pty Ltd	23/11/2021						
Palynziq	pegvaliase	BioMarin Pharmaceutical Australia Pty Ltd	06/07/2021						
Poteligeo	mogamulizumab	Kyowa Kirin Australia Pty Ltd	06/01/2021						
Reblozyl	luspatercept	Celgene Pty Ltd	27/08/2021						
Regkirona	regdanvimab	Celltrion Healthcare Australia Pty Ltd	06/12/2021						
Rholistiq	belumosudil mesylate	Kadmon Oceania Pty Ltd	11/11/2021						
Ronapreve	casirivimab; imdevimab	ROCHE PRODUCTS PTY LTD	15/10/2021						

* Expedited review refers to TGA priority review

TGA NAS approvals in 2021



Brand Name	Generic Name	Sponsor	Approval Date	Expedited Review*	Orphan	Conditional - Provisional Approval	Access Consortium worksharing	Project Orbis	Comparable overseas regulators (COR) review
Rukobia	fostemsavir trometamol	ViiV Healthcare Pty Ltd	09/07/2021						
Ruzurgi	amifampridine	ORSPEC Pharma Pty Ltd	10/09/2021						
Spravato	esketamine hydrochloride	Janssen-Cilag Pty Ltd	05/03/2021						
Trikafta	elexacaftor; ivacaftor; tezacaftor	Vertex Pharmaceuticals Australia Pty Ltd	17/03/2021						
Trodelyv	sacituzumab govitecan	Gilead Sciences Pty Ltd	03/09/2021						
Truseltiq	infigratinib	Adjutor Healthcare Pty Ltd	03/11/2021						
Verquvo	vericiguat	Bayer Australia Ltd	10/11/2021						
Vocabria	cabotegravir	ViiV Healthcare Pty Ltd	10/02/2021						
Vyepti	eptinezumab	LUNDBECK AUSTRALIA PTY LTD	09/06/2021						
Xevudy	sotrovimab	GlaxoSmithKline Australia Pty Ltd	20/08/2021						
Yondelis	trabectedin	Specialised Therapeutics Pharma Pty Ltd	21/04/2021						
Zebinix	eslicarbazepine acetate	Maxx Pharma Pty Ltd	10/05/2021						
Zepzelca	lurbinctedin	Specialised Therapeutics Pharma Pty Ltd	10/09/2021						
Zolgensma	onasemnogene abeparvovec	Novartis Pharmaceuticals Australia Pty Ltd	24/02/2021						

* Expedited review refers to TGA priority review

Approval time

Time calculated from the date of submission to the date of approval by the agency. This time includes agency and company time.

New active substances (NASs)*

A chemical, biological, biotechnology or radiopharmaceutical substance that has not been previously available for therapeutic use in humans and is destined to be made available as a 'prescription only medicine', to be used for the cure, alleviation, treatment, prevention or in vivo diagnosis of diseases in humans. The term NAS also includes:

- An isomer, mixture of isomers, a complex or derivative or salt of a chemical substance previously available as a medicinal product but differing in properties with regard to safety and efficacy from that substance previously available
- A biological or biotech substance previously available as a medicinal product, but differing in molecular structure through changes to the nature of source material or manufacturing process and which will require clinical investigation
- A radiopharmaceutical substance that is a radionuclide or a ligand not previously available as a medicinal product.

Alternatively, the coupling mechanism linking the molecule and the radionuclide has not been previously available.

Applications that are excluded from the study:

- Vaccines
- Biosimilars
- Any other application, where new clinical data were submitted
- Generic applications
- Those applications where a completely new dossier was submitted from a new company for the same indications as already approved for another company
- Applications for a new or additional name, or a change of name, for an existing compound (i.e., a 'cloned' application).
- Emergency use or Special authorisations derived from an emergency (e.g. COVID-19 pandemic)

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The Centre for Innovation in Regulatory Science (CIRS) is a neutral, independent UK-based subsidiary of Clarivate plc. CIRS provides an international forum for industry, regulators, HTA and other healthcare stakeholders to meet, debate and develop regulatory and reimbursement policy through the innovative application of regulatory science and to facilitate access to pharmaceutical products. It is governed and operated by Clarivate for the sole support of its members' activities. The organisation has its own dedicated management and advisory boards, and its funding is derived from membership dues, related activities, special projects and grants.

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