



R&D Briefing 101: New drug approvals in six major authorities 2015– 2024

*Trends in an evolving regulatory
landscape.*

List of NASs approved by the six regulatory authorities

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NASs approved by EMA in 2024



Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Expedited Review*	Conditional Approval	Exceptional Circumstances	PRIME designation	Rolling review
Adzynma	apadamtase alfa;cinaxadamtase alfa (radamts13)	Takeda Manufacturing Austria AG	01/08/2024	✓			✓		
Altuvect	efanesoctocog alfa	SWEDISH ORPHAN BIOVITRUM AB (PUBL)	17/06/2024	✓					
Anzupgo	delgocitinib	LEO Pharma A/S	19/09/2024						
Awikli	insulin icodec	Novo Nordisk A/S	17/05/2024						
Balversa	erdafitinib	Janssen-Cilag International N.V.	22/08/2024						
Beqvez (Previously Durveqtix)	fidanacogene elaparovvec	Pfizer Europe MA EEIG	24/07/2024			✓		✓	
Casgevvy	exagamglogene autotemcel	Vertex Pharmaceuticals (Ireland) Limited	09/02/2024	✓		✓		✓	
Cejemly	sugemalimab	SFL Pharmaceuticals Deutschland GmbH	24/07/2024						
Elahere	mirvetuximab soravtansine	AbbVie Deutschland GmbH & Co. KG	14/11/2024	✓					
Exblifep	cefepime;enmetazobactam	ADVANZ PHARMA Limited	21/03/2024						
Fabhalta	iptacopan	Novartis Europharm Limited	17/05/2024	✓				✓	
Filspari	sparsentan	Vifor France	19/04/2024	✓		✓			
Fruzaqla	fruquintinib	Takeda Pharmaceuticals International AG Ireland	20/06/2024						
Hympavzi	marstacimab	Pfizer Europe MA EEIG	18/11/2024						
Iqirvo	elafibranor	Ipsen Pharma	19/09/2024	✓		✓			
Jeraygo	aprocitentan	Idorsia Pharmaceuticals Deutschland GmbH	25/04/2024						
Krazati	adagrasib	Bristol-Myers Squibb Pharma EEIG	05/01/2024			✓			
Loqtorzi	toripalimab	TMC Pharma (EU) Limited	19/09/2024						
Obgemsa	vibegron	Pierre Fabre Medicament	27/06/2024						
Omjjara	momelotinib	GlaxoSmithKline Trading Services Limited	25/01/2024	✓					

*: 'Expedited review' refers to EMA 'Accelerated Assessment'.

NASs approved by EMA in 2024



Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Expedited Review*	Conditional Approval	Exceptional Circumstances	PRIME designation	Rolling review
Ordspono	odronextamab	Regeneron Ireland Designated Activity Company (DAC)	22/08/2024	✓		✓			
Piasky	crovalimab	Roche Registration GmbH	22/08/2024						
Qalsody	tofersen	Biogen Netherlands B.V.	29/05/2024	✓			✓		
Rystiggo	rozanolixizumab	UCB Pharma	05/01/2024	✓					
Ryzneuta	efbemalenogras tim alfa	Evive Biotechnology Ireland Limited	21/03/2024						
Skyclarys	omaveloxolone	Biogen Netherlands B.V.	09/02/2024	✓					
Tauvid	flortaucipir (18f)	Eli Lilly Nederland B.V.	22/08/2024						
Truqap	capivasertib	AstraZeneca AB	17/06/2024						
Velsipity	etrasimod	Pfizer Europe MA EEIG	16/02/2024						
Voydeya	danicopan	Alexion Europe SAS	19/04/2024	✓				✓	
Vyloy	zolbetuximab	Astellas Pharma Europe B.V.	19/09/2024	✓					
Winrevair	sotatercept	Merck Sharp & Dohme B.V.	22/08/2024	✓				✓	
Zegalogue	dasiglucagon	Novo Nordisk A/S	24/07/2024						
Zynyz	retifanlimab	Incyte Biosciences Distribution B.V.	19/04/2024	✓					

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NASs approved by FDA in 2024



Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Exp. rev.*	Accel. App.**	Break. design.†	Fast track	Project Orbis	RTOR‡	Rolling review
Alhemo	concizumab-mtci	NOVO NORDISK INC	20/12/2024	✓	✓		✓				✓
Alyftrek	deutivacaftor; tezacaftor; vanzacaftor calcium	VERTEX PHARMS INC	20/12/2024	✓				✓			
Amtagvi	lifileucel	Iovance Biotherapeutics, Inc.	16/02/2024	✓	✓	✓		✓			✓
Anktiva	nogapendekin alfa inbakicept-pmIn	ALTOR BIOSCIENCE, LLC, AN INDIRECT WHOLLY- OWNED SU	22/04/2024				✓	✓			
Aqneursa	levacetylleucine	INTRABIO	24/09/2024	✓	✓			✓			
Attruby	acoramidis hydrochloride	BRIDGEBIO PHARMA	22/11/2024	✓							
Aucatzyl	obecabtagene autoleucel	Autolus Inc.	08/11/2024	✓							
Beqvez	fidanacogene elaparovec-dzkt	Pfizer, Inc.	25/04/2024	✓			✓				
Bizengri	zenocutuzumab-zbco	MERUS N.V.	04/12/2024	✓	✓	✓	✓	✓			✓
Casgevvy	exagamglogene autotemcel	Vertex Pharmaceuticals Incorporated	16/01/2024	✓	✓			✓			
Cobenfy	tropium chloride; xanomeline tartrate	BRISTOL-MYERS	26/09/2024								
Crenessity	crinecerfont	NEUROCRINE	13/12/2024	✓	✓		✓	✓			
Duvyzat	givinostat hydrochloride	ITALFARMACO SPA	21/03/2024	✓	✓			✓			
Ebglyss	lebrikizumab-lbkz	ELI LILLY AND CO	13/09/2024					✓			
Ensacove	ensartinib hydrochloride	XCOVERY	18/12/2024								
Exblifep	cefepime hydrochloride; enmetazobactam	ALLECRA THERAPS	22/02/2024		✓			✓			
Flyrcado	flurpiridaz f-18	GE HLTHCARE	27/09/2024								
Hypavzi	marstacimab-hncq	Pfizer Inc	11/10/2024	✓				✓			
Imdeltra	tarlatamab-dlle	AMGEN INC	16/05/2024	✓	✓	✓	✓		✓	✓	
Iomervu	iomeprol	Bracco	27/11/2024								
Iqirvo	elafibranor	IPSEN	10/06/2024	✓	✓	✓	✓				
Itovebi	inavalisib	GENENTECH INC	10/10/2024		✓		✓		✓		
Kebilidi	eladocogene exuparovec-tneq	PTC Therapeutics	13/11/2024	✓	✓	✓					
Kisunla	donanemab-azbt	ELI LILLY CO	02/07/2024		✓		✓	✓			✓

*: 'Expedited review' refers to FDA/PMDA/Health Canada/TGA 'Priority Review' and Swissmedic 'Fast-track'.

** : Accelerated approval.

†: Breakthrough designation.

‡: Real-time oncology review.

NASs approved by FDA in 2024



Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Exp. rev.*	Accel. App.**	Break. desig.†	Fast track	Project Orbis	RTOR‡	Rolling review
Lazcluze	lazertinib mesylate	Janssen Biotech	19/08/2024		✓				✓		✓
Lenmeldy	atidarsagene autotemcel	Orchard Therapeutics (Europe) Limited	18/03/2024	✓	✓						✓
Leqselvi	deuruxolitinib phosphate	SUN PHARM INDS INC	25/07/2024					✓			
Livdelzi	seladelpar lysine	GILEAD SCIENCES INC	14/08/2024	✓	✓	✓	✓				✓
Lumisight	pegulicianine acetate	LUMICELL	17/04/2024		✓			✓			✓
Miplyffa	arimoclomol citrate	ZEVRA DENMARK	20/09/2024	✓	✓		✓	✓			✓
Nemluvio	nemolizumab-ilto	GALDERMA LABS LP	12/08/2024		✓		✓				
Niktimvo	axatilimab-csfr	INCYTE CORP	14/08/2024	✓	✓			✓			
Ohtuvayre	ensifentrine	VERONA PHARMA	26/06/2024								
Ojemda	tovorafenib	DAY ONE BIOPHARMS	23/04/2024	✓	✓	✓	✓				✓
Orlynvah	probenecid; sulopenem etzadroxil	ITERUM THERAP	25/10/2024		✓			✓			
Piasky	crovalimab-akkz	GENENTECH INC	20/06/2024	✓							
Rapiblyk	landiolol hydrochloride	AOP ORPHAN	22/11/2024								
Revuforj	revumenib citrate	SYNDAX	15/11/2024	✓	✓		✓	✓		✓	
Rezdiffra	resmetirom	MADRIGAL	14/03/2024		✓	✓	✓	✓			✓
Rytelo	imetelstat sodium	GERON	06/06/2024	✓				✓			✓
Sofdra	sofpironium bromide	BOTANIX SB	18/06/2024								
Tecelra	afamitresgene autoleucel	Adaptimmune LLC	01/08/2024	✓	✓	✓					✓
Tevimbra	tislelizumab-jsgr	BEIGENE	13/03/2024	✓							
Tryngolza	olezarsen sodium	IONIS PHARMS INC	19/12/2024	✓	✓		✓	✓			
Tryvio	aprocintentan	IDORSIA	19/03/2024								
Unloxcyt	cosibelimab-ipdl	CHECKPOINT THERAPEUTICS INC	13/12/2024								
Vafseo	vadadustat	AKEBIA	27/03/2024								
Voranigo	vorasidenib	SERVIER	06/08/2024	✓	✓		✓	✓	✓		
Voydeya	danicopan	ALEXION PHARMS INC	29/03/2024	✓			✓				✓
Vyloy	zolbetuximab-clzb	Astellas	18/10/2024	✓	✓			✓		✓	

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NASs approved by FDA in 2024



Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Exp. rev.*	Accel. App.**	Break. desig.†	Fast track	Project Orbis	RTOR‡	Rolling review
Winrevair	sotatercept-csrk	MERCK SHARP DOHME	26/03/2024	✓	✓		✓				✓
Xolremdi	mavorixafor	X4 PHARMS	26/04/2024	✓	✓		✓	✓			
Yorvipath	palopegteriparatide	ASCENDIS PHARMA BONE	09/08/2024	✓	✓						
Zelsuvmi	berdazimer sodium	LNHC	05/01/2024								
Zevtera	ceftobiprole medocaril sodium	BASILEA PHARM ALLSCH	03/04/2024		✓			✓			
Ziihera	zanidatamab-hrii	Jazz Pharms	20/11/2024	✓	✓	✓	✓	✓			✓

*: 'Expedited review' refers to FDA/PMDA/Health Canada/TGA 'Priority Review' and Swissmedic 'Fast-track'.

** : Accelerated approval.

† : Breakthrough designation.

‡ : Real-time oncology review.

NASs approved by PMDA in 2024



Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Expedited review*	Sakigake	Conditional early approval
(1) Briviact Tablets 25 Mg	brivaracetam	UCB Japan Co., Ltd.	24/06/2024				
(1) Talzenna Capsules 0.1 Mg	talazoparib tosilate	Pfizer Japan Inc.	18/01/2024				
Acenobel Extended Release Tablets 500 Mg	aceneuramic acid	Nobelpharma Co., Ltd.	26/03/2024	✓	✓		
Adzynma Intravenous 1500	apadamtase alfa (genetical recombination)/ cinaxadamtase alfa (genetical recombination)	Takeda Pharmaceutical Company Limited	26/03/2024	✓	✓		
Alyssa Combination Tablets	estetrol hydrate/drospire none	Fuji Pharma Co., Ltd.	24/09/2024				
Augtyro Capsules 40 Mg	repotrectinib	Bristol-Myers Squibb K.K.	24/09/2024				
Awikli Flextouch 300 Units	insulin icodec (genetical recombination)	Novo Nordisk Pharma Ltd.	24/06/2024				
Balversa Tablets 3 Mg	erdafitinib	Janssen Pharmaceutical K.K.	27/12/2024				
Beyfortus 50 Mg Solution Intramuscular	nirsevimab (genetical recombination)	AstraZeneca K.K.	26/03/2024				
Brukinsa Capsules 80 Mg	zanubrutinib	BeiGene Japan GK.	27/12/2024				
Ceprotrin Intravenous 1000 lu	human protein c	Takeda Pharmaceutical Company Limited	26/03/2024				
Datroway Intravenous Drip 100 Mg	datopotamab deruxtecan (genetical recombination)	Daiichi Sankyo Company, Limited	27/12/2024				
Ebglyss Subcutaneous 250 Mg	lebrikizumab (genetical recombination)	Eli Lilly Japan K.K.	18/01/2024				
Elrexio S.C. 44 Mg	elranatamab (genetical recombination)	Pfizer Japan Inc.	26/03/2024	✓	✓		
Evkeeza Intravenous 345 Mg	evinacumab (genetical recombination)	Ultragenyx Japan K.K.	18/01/2024	✓	✓		
Fabhalta Capsules 200 Mg	iptacopan hydrochloride hydrate	Novartis Pharma K.K.	24/06/2024				
Firdapse Tablets 10 Mg	amifampridine phosphate	DyDo Pharma, Inc.	24/09/2024	✓	✓		
Fruzaqla Capsules 1 Mg	fruquintinib	Takeda Pharmaceutical Company Limited	24/09/2024				
Haiyitan Tablets 50 Mg	gumarontinib hydrate	Haihe Biopharma K. K.	24/06/2024				

*: 'Expedited review' refers to FDA/PMDA/Health Canada/TGA 'Priority Review' and Swissmedic 'Fast-track'.

NASs approved by PMDA in 2024



Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Expedited review*	Sakigake	Conditional early approval
Hympavzi S.C. 150 Mg Pen	marstacimab (genetical recombination)	Pfizer Japan Inc.	27/12/2024				
Imdelltra I.V. 1 Mg	tarlatamab (genetical recombination)	Amgen K.K.	27/12/2024	✓	✓		
Jaypirca Tablets 50 Mg	pirtobrutinib	Eli Lilly Japan K.K.	24/06/2024				
Kavigale Solution 300 Mg	sipavibart (genetical recombination)	AstraZeneca K.K.	27/12/2024				
Kisunla Intravenous 350 Mg	donanemab (genetical recombination)	Eli Lilly Japan K.K.	24/09/2024				
Livtency Tablets 200 Mg	maribavir	Takeda Pharmaceutical Company Limited	24/06/2024	✓	✓		
Lunsumio Intravenous 1 Mg	mosunetuzumab (genetical recombination)	Chugai Pharmaceutical Co., Ltd.	27/12/2024				
Lupkynis Capsules 7.9 Mg	voclosporin	Otsuka Pharmaceutical Co., Ltd.	24/09/2024				
Obizur Intravenous 500	susoctocog alfa (genetical recombination)	Takeda Pharmaceutical Company Limited	26/03/2024	✓	✓		
Omijara Tablets 100 Mg	momelotinib hydrochloride hydrate	GlaxoSmithKline K.K.	24/06/2024				
Piasky 340 Mg	crovalimab (genetical recombination)	Chugai Pharmaceutical Co., Ltd.	26/03/2024				
Qalsody Intrathecal 100 Mg	tofersen	Biogen Japan Ltd.	27/12/2024	✓	✓		
Quviviq Tablets 25 Mg	daridorexant hydrochloride	Nexera Pharma Co., Ltd.	24/09/2024				
Reblozyl S.C. 25 Mg	luspatercept (genetical recombination)	Bristol-Myers Squibb K.K.	18/01/2024	✓	✓		
Rezurock Tablets 200 Mg	belumosudil mesilate	Meiji Seika Pharma Co., Ltd.	26/03/2024	✓	✓		
Rybrevant Intravenous 350 Mg	amivantamab (genetical recombination)	Janssen Pharmaceutical K.K.	24/09/2024				
Sargmalin Inhalation 250 Mg	sargramostim (genetical recombination)	Nobelpharma Co., Ltd.	26/03/2024	✓	✓		
Septocaine Combination Cartridge	articaine hydrochloride/ adrenaline bitartrate	GC Showayakuhin Corporation	24/09/2024				
Tasfygo Tablets 35 Mg	tasurgratinib succinate	Eisai co., Ltd.	24/09/2024	✓	✓		
Tauvid	flortaucipir (^{18}f)	PDRadiopharma Inc.	27/12/2024				

*: 'Expedited review' refers to FDA/PMDA/Health Canada/TGA 'Priority Review' and Swissmedic 'Fast-track'.

NASs approved by PMDA in 2024



Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Expedited review*	Sakigake	Conditional early approval
Tecvayli Subcutaneous 153 Mg	teclistamab (genetical recombination)	Janssen Pharmaceutical K.K.	27/12/2024	✓	✓		
Tepezza Intravenous 500 Mg	teprotumumab (genetical recombination)	Amgen K.K.	24/09/2024	✓	✓		
Tepoxx Capsules 200 Mg	tecovirimat hydrate	Japan Biotechno Pharma Co., Ltd.	27/12/2024				
Trodelvy 200 Mg	sacituzumab govitecan (genetical recombination)	Gilead Sciences, Inc.	24/09/2024		✓		
Truqap Tablets 160 Mg	capivasertib	AstraZeneca K.K.	26/03/2024				
Veltassa 8.4 G Powder Suspension (Single-Dose Package)	patiromer sorbitex calcium	Zeria Pharmaceutical Co., Ltd.	24/09/2024				
Voydeya Tablets 50 Mg	danicopan	Alexion Pharma GK	18/01/2024	✓	✓		
Vtama Cream 1%	tapinarof	Japan Tobacco Inc.	24/06/2024				
Vyloy I.V. 100 Mg	zolbetuximab (genetical recombination)	Astellas Pharma Inc.	26/03/2024				
Vyvdua Combination Subcutaneous	efgartigimod alfa (genetical recombination) and vorhyaluronidase alfa (genetical recombination)	Argenx Japan K.K.	18/01/2024				
Xocova Tablets 125 Mg	ensitrelvir fumaric acid	Shionogi & Co., Ltd.	05/03/2024				
Zavicefta Combination Intravenous	avibactam sodium/ceftazidime hydrate	Pfizer Japan Inc.	24/06/2024				
Zeposia Capsules 0.92 Mg	ozanimod hydrochloride	Bristol-Myers Squibb K.K.	27/12/2024				
Zokinvy Capsules 50 Mg	lonafarnib	AnGes, Inc.	18/01/2024	✓	✓		

*: 'Expedited review' refers to FDA/PMDA/Health Canada/TGA 'Priority Review' and Swissmedic 'Fast-track'.

NASs approved by Health Canada in 2024



Brand Name	Generic Name	Sponsor	Approval Date	Expedited review.*	Conditional approval	Access Consortium	Project Orbis	Rolling review
Awikli	insulin icodec	novo nordisk canada inc	12/03/2024			✓		
Ayvakyt	avapritinib	Blueprint Medicines Corporation	18/09/2024					
Casgevvy	exagamglogene autotemcel	vertex pharmaceuticals (canada) incorporated	23/09/2024	✓				
Daybue	trofinetide	ACADIA PHARMACEUTICALS INC	11/10/2024	✓				
Ebglyss	lebrikizumab	ELI LILLY CANADA INC	24/06/2024					
Fruzaqla	fruquintinib	TAKEDA CANADA INC	10/09/2024			✓	✓	
Imdelltra	tarlatamab	AMGEN CANADA INC	11/09/2024		✓		✓	
Miebo	perfluorohexyloctane	BAUSCH & LOMB INC	04/09/2024					
Myalepta	metreleptin	AMRYT PHARMACEUTICALS DAC	17/01/2024	✓				
Ojjaara	momelotinib dihydrochloride	GLAXOSMITHKLINE INC	08/11/2024					
Ringza	segesteron acetate, ethinyl estradiol	DUCHESNAY INC	18/12/2024					
Talvey	talquetamab	JANSSEN INC	30/04/2024		✓		✓	
Tibsovo	ivosidenib	SERVIER CANADA INC	19/07/2024					
Truqap	capivasertib	ASTRAZENECA CANADA INC	26/01/2024				✓	
Vabomere	vaborbactam, meropenem trihydrate	XEDITON PHARMACEUTICALS INC	20/12/2024	✓				
Velsipity	etrasimod l-arginine	PFIZER CANADA ULC	31/01/2024					
Veozah	fezolinetant	astellas pharma canada inc	02/12/2024					
Voranigo	vorasidenib	SERVIER CANADA INC	27/08/2024	✓			✓	
Voydeya	danicopan	Alexion Pharma GmbH	19/07/2024					
Vyloy	zolbetuximab	astellas pharma canada inc	13/12/2024					
Wainua	eplontersen sodium	ASTRAZENECA CANADA INC	19/06/2024					
Winrevair	sotatercept	MERCK CANADA INC	28/08/2024	✓		✓		
Xenpozyme	olipudase alfa	SANOFI-AVENTIS CANADA INC	28/02/2024	✓				
Zilbrysq	zilucoplan sodium	UCB CANADA INC	11/07/2024					

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NASs approved by Swissmedic in 2024



Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Exp. rev.*	Prior not.**	Temp. Auth.†	Art. 13 TPA	Art.14 TPA	Access Cons.‡	Project Orbis	Rolling review
18F-Psma-1007 Zrp	[18f]psma-1007	Universitätsspital Zürich	11/06/2024									
Altuvoc	efanesoctocog alfa	Swedish Orphan Biovitrum AG	02/09/2024	✓								
Anzupgo	delgocitinib	Leo Pharmaceutical Products Sarath Ltd.	13/11/2024			✓						
Aquipta	atogepant	AbbVie AG	06/03/2024									
Awikli Flextouch	insulin icodec	Novo Nordisk Pharma AG	07/03/2024							✓		
Casgev	exagamglogen autotemcel	Vertex Pharmaceuticals (CH) GmbH	06/09/2024	✓	✓		✓	✓				
Desveneurax	desvenlafaxin	Neuraxpharm Switzerland AG	22/11/2024						✓			
Ebglyss	lebrikizumab	Almirall AG	30/08/2024									
Ebvallo	tabelecleucel	Pierre Fabre Pharma SA	03/05/2024	✓				✓				
Enrylaze	crisantaspase	Jazz Pharmaceuticals	18/04/2024	✓								
Fabhalta	iptacopan	Novartis Pharma Schweiz AG	29/08/2024	✓		✓						
Filspari	sparsentan	Vifor (International) Inc.	14/10/2024	✓	✓		✓	✓				
Fruzaqla	fruquintinib	Takeda Pharma AG	27/08/2024							✓		
Hepcludex	bulevirtid	Gilead Sciences Switzerland Sàrl	05/02/2024	✓	✓							
Hympavzi	marstacimab	Pfizer AG	23/12/2024	✓						✓		
Levocalm	levodropropizin	Gebro Pharma AG	18/07/2024						✓			
Livmarli	maralixibat	Mirum Pharmaceuticals AG	18/07/2024	✓				✓				
Lytgobi	futibatinib	Taiho Oncology Europe GmbH	08/10/2024	✓	✓		✓	✓				
Omjjara	momelotinib	GlaxoSmithKline AG	25/09/2024	✓								
Orserdu	elacestrant	Stemline Therapeutics Switzerland GmbH	04/06/2024									
Pombiliti	cipaglucosidase alfa	Amicus Therapeutics Switzerland GmbH	04/07/2024	✓				✓				
Qarziba	dinutuximab beta	Medius AG	18/04/2024	✓								
Raxone	idebenon	Chiesi SA	01/03/2024	✓								
Sogroya	somapacitan	Novo Nordisk Pharma AG	26/04/2024	✓								

*: 'Expedited review' refers to FDA/PMDA/Health Canada/TGA 'Priority Review' and Swissmedic 'Fast-track'.

** : Prior notification.

†: Temporary authorisation.

‡: Access Consortium.

NASs approved by Swissmedic in 2024



Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Exp. rev.*	Prior not.**	Temp. Auth.†	Art. 13 TPA	Art.14 TPA	Access Cons.‡	Project Orbis	Rolling review
Tepkinly	epcoritamab	AbbVie AG	15/02/2024	✓	✓		✓					
Tevimbra	tislelizumab	Beigene Switzerland GmbH	11/04/2024									
Tibsovo	ivosidenib	Servier (Suisse) SA	13/06/2024	✓								
Truqap	capivasertib	AstraZeneca AG	19/03/2024									
Tymlos	abaloparatid	Labatec Pharma SA	07/03/2024									
Uplizna	inebilizumab	Horizon Therapeutics	04/03/2024	✓				✓				
Velsipity	etrasimod	Pfizer AG	10/09/2024							✓		
Voranigo	vorasidenib	Servier (Suisse) SA	15/11/2024	✓								
Voydeya	danicopan	Alexion Pharma GmbH	30/04/2024	✓	✓							
Vyvgart	efgartigimod alfa	argenx Switzerland SA	03/10/2024	✓				✓				
Welireg	belzutifan	MSD Merck Sharp & Dohme AG	21/03/2024	✓			✓	✓				
Winrevair	sotatercept	MSD Merck Sharp & Dohme AG	13/09/2024	✓	✓					✓		
Zilbrysq	zilucoplan	UCB-Pharma SA	30/08/2024	✓	✓							

*: 'Expedited review' refers to FDA/PMDA/Health Canada/TGA 'Priority Review' and Swissmedic 'Fast-track'.

**.: Prior notification.

†.: Temporary authorisation.

‡.: Access Consortium.

NASs approved by TGA in 2024



Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Exp. rev.*	Prov. App.†	COR-A	COR-B	Access Cons.‡	Project Orbis
Amvuttra	vutrisiran sodium	Medison Pharma Australia Pty Ltd	18/06/2024	✓						
Awikli	insulin icodec	Novo Nordisk Pharmaceuticals Pty Ltd	17/05/2024						✓	
Cibinqo	abrocitinib	Pfizer Australia Pty Ltd	12/04/2024							
Daxxify	daxibotulinumto xina	Revance Australia Pty Ltd	03/12/2024							
Ebglyss	lebrikizumab	Eli Lilly Australia Pty Ltd	16/05/2024							
Eladynos	abaloparatide	Theramex Australia Pty Ltd	06/11/2024							
Elrexio	elranatamab	Pfizer Australia Pty Ltd	26/06/2024			✓				✓
Epkinly	epcoritamab	AbbVie Pty Ltd	19/02/2024	✓		✓				
Erwinase	crisantaspase	PPD Australia Pty Ltd	06/02/2024	✓						✓
Fabhalta	iptacopan	Novartis Pharmaceuticals Australia Pty Ltd	07/08/2024	✓						
Fruzaqla	fruquintinib	Takeda Pharmaceuticals Australia Pty Ltd	01/10/2024						✓	✓
Hemgenix	etranacogene dezaparvovec	CSL Behring Australia Pty Ltd	15/03/2024	✓		✓				
Hepcludex	bulevirtide acetate	Gilead Sciences Pty Ltd	22/07/2024	✓	✓					
Litfulo	ritlecitinib tosylate	Pfizer Australia Pty Ltd	26/06/2024				✓			
Lokelma	sodium zirconium cyclosilicate hydrate	ASTRAZENECA PTY LTD	04/04/2024							
Nelarabine-Reach	nelarabine	Reach Pharmaceuticals Pty Ltd	25/03/2024	✓						
Omjjara	mometotinib dihydrochloride monohydrate	GlaxoSmithKline Australia Pty Ltd	17/12/2024	✓			✓			
Orserdu	elacestrant dihydrochloride	A Menarini Australia Pty Ltd	11/12/2024				✓			
Oxlumo	lumasiran sodium	Medison Pharma Australia Pty Ltd	20/06/2024	✓						
Pluvicto	lutetium (177lu) vipivotide tetraxetan	Novartis Pharmaceuticals Australia Pty Ltd	16/07/2024							✓
Relfydess	relabotulinumto xina	Ipsen Pty Ltd	07/06/2024							
Talvey	talquetamab	Janssen-Cilag Pty Ltd	24/09/2024			✓				✓

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†: Provisional approval.

‡: Access Consortium.

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Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Exp. rev.*	Prov. App.†	COR-A	COR-B	Access Cons.‡	Project Orbis
Tevimbra	tislelizumab	Beigene Aus Pty Ltd	24/05/2024							
Truqap	capivasertib	ASTRAZENECA PTY LTD	07/05/2024							✓
Velsipity	etrasimod arginine	Pfizer Australia Pty Ltd	17/05/2024							
Veoza	fezolinetant	Astellas Pharma Australia Pty Ltd	22/02/2024						✓	
Voranigo	vorasidenib	Servier Laboratories (Aust) Pty Ltd	10/09/2024	✓	✓					✓
Voydeya	danicopan	Alexion Pharmaceuticals Australasia Pty Ltd	11/11/2024							
Vyalev	foscarbidopa, foslevodopa	AbbVie Pty Ltd	04/03/2024							
Winlevi	clascoterone	Sun Pharma ANZ Pty Ltd	08/03/2024							
Winrevair	sotatercept	MERCK SHARP & DOHME (AUSTRALIA) PTY LTD	07/11/2024	✓	✓				✓	
Yselyt	linzagolix choline	Theramex Australia Pty Ltd	05/09/2024							
Zilbrysq	zilucoplan tetrasodium	UCB Australia Pty Ltd T/A UCB Pharma Division of UCB Australia	31/07/2024							

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†: Provisional approval.

‡: Access Consortium.