R&D Briefing 106: New drug approvals in six major authorities 2016–2025

Trends in an evolving regulatory landscape.

List of NASs approved by the six regulatory authorities

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NASs approved by EMA in 2025

Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Expedited Review*	Conditional Approval	Exceptional Circumstances	PRIME designation	Rolling review
Alyftrek	deutivacaftor / tezacaftor / vanzacaftor	Vertex Pharmaceuticals (Ireland) Limited	30/06/2025	✓					
Andembry	garadacimab	CSL Behring GmbH	10/02/2025						
Aucatzyl	obecabtagene autoleucel	Autolus GmbH	17/07/2025			✓		✓	
Augtyro	repotrectinib	Bristol-Myers Squibb Pharma EEIG	13/01/2025			✓			
Beyonttra	acoramidis	Bayer AG	10/02/2025						
Brinsupri	brensocatib	Insmed Netherlands B.V.	18/11/2025		✓			✓	
Datroway	datopotamab deruxtecan	Daiichi Sankyo Europe GmbH	04/04/2025						
Duvyzat	givinostat	Italfarmaco S.p.A.	06/06/2025	✓		✓			
Ekterly	sebetralstat	Kalvista Pharmaceuticals (Ireland) Limited	17/09/2025	✓					
Ezmekly	mirdametinib	SpringWorks Therapeutics Ireland Limited	17/07/2025	✓		✓			
Gohibic	vilobelimab	InflaRx GmbH	13/01/2025				✓		
Hetronifly	serplulimab	Accord Healthcare S.L.U.	03/02/2025	✓					
Imaavy	nipocalimab	Janssen Cilag International NV	28/11/2025						
Itovebi	inavolisib	Roche Registration GmbH	18/07/2025						
Kavigale	sipavibart	AstraZeneca AB	20/01/2025		✓				
Kisunla	donanemab	Eli Lilly Nederland B.V.	24/09/2025						
Lazcluze	lazertinib	Janssen Cilag International NV	20/01/2025						
Leqembi	lecanemab	Eisai GmbH	15/04/2025						
Lynkuet	elinzanetant	Bayer AG	17/11/2025						
Lynozyfic	linvoseltamab	Regeneron Ireland Designated Activity Company (DAC)	23/04/2025			✓			
Lyvdelzi	seladelpar	Gilead Sciences Ireland Unlimited Company	16/05/2025	✓		✓		✓	
Nemluvio	nemolizumab	Galderma International	12/02/2025						
Ogsiveo	nirogacestat	SpringWorks Therapeutics Ireland Limited	14/08/2025	✓					

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

NASs approved by EMA in 2025

Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Expedited Review*	Conditional Approval	Exceptional Circumstances	PRIME designation	Rolling review
Rezdiffra	resmetirom	Madrigal Pharmaceuticals EU Limited	18/08/2025			✓			
Romvimza	vimseltinib	Deciphera Pharmaceuticals (Netherlands) B.V.	17/09/2025	✓					
Rytelo	imetelstat	Geron Netherlands B.V.	07/03/2025	✓					
Sephience	sepiapterin	PTC THERAPEUTICS INTERNATIONAL LIMITED	19/06/2025	✓					
Siiltibcy	mycobacterium tuberculosis derived antigens (rdesat-6 / rcfp-10)	Serum Life Science Europe GmbH	13/01/2025						
Tepezza	teprotumumab	Amgen Europe B.V.	19/06/2025						
Tivdak	tisotumab vedotin	Genmab A/S	28/03/2025						
Tryngolza	olezarsen	SWEDISH ORPHAN BIOVITRUM AB (PUBL)	17/09/2025	✓					
Voranigo	vorasidenib	Les Laboratoires Servier	17/09/2025	✓					
Vyjuvek	beremagene geperpavec	Krystal Biotech Netherlands B.V.	23/04/2025	✓				✓	
Wainzua	eplontersen	AstraZeneca AB	06/03/2025						
Wayrilz	rilzabrutinib	Sanofi B.V.	22/12/2025	✓					
Welireg	belzutifan	Merck Sharp & Dohme B.V.	12/02/2025			✓			
Winlevi	clascoterone	Cassiopea S.p.A.	17/10/2025						
Zemcelpro	allogeneic umbilical cord-derived cd34-cells, non-expanded;dorocubicel	Cordex Biologics International Limited	25/08/2025	✓		✓		✓	
Ziihera	zanidatamab	JAZZ PHARMACEUTICALS IRELAND LIMITED	27/06/2025	✓		✓			
Zurzuvae	zuranolone	Biogen Netherlands B.V.	30/10/2025						

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

NASs approved by FDA in 2025

Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Exp. rev.*	Accel. App.**	Break. desig.†	Fast track	Project Orbis	RTOR‡	Rolling review
Andembry	garadacimab-gxii	CSL Behring LLC	16/06/2025	✓				✓			
Anzupgo	delgocitinib	LEO PHARMA AS	23/07/2025					✓			
Avmapki Fakzynja Co-Pack (Copackaged)	avutometinib potassium; defactinib hydrochloride	VERASTEM INC	08/05/2025	✓	✓	✓	✓				
Blujepa	gepotidacin mesylate	glaxosmithkline	25/03/2025		✓						
Brinsupri	brensocatib	INSMED INC	12/08/2025		✓		✓				
Cardamyst	etripamil	MILESTONE PHARMS USA	12/12/2025								
Datroway	datopotamab deruxtecan-dlnk	DAIICHI SANKYO INC	17/01/2025								
Dawnzera (Autoinjector)	donidalorsen sodium	IONIS PHARMS INC	21/08/2025	✓							
Ekterly	sebetralstat	KALVISTA	03/07/2025	✓				✓			
Emrelis	telisotuzumab vedotin-tllv	Abbvie Inc	14/05/2025		✓	✓	✓			✓	
Encelto	revakinagene taroretcel-lwey	Neurotech Pharmaceuticals, Inc.	05/03/2025	✓	✓			✓			
Enflonsia	clesrovimab-cfor	Merck Sharp & Dohme LLC	09/06/2025		✓			✓			
Exdensur	depemokimab-ulaa	glaxosmithkline	16/12/2025								
Forzinity	elamipretide hydrochloride	STEALTH BIOTHERAPS	19/09/2025	✓	✓	✓					
Gomekli	mirdametinib	SPRINGWORKS	11/02/2025	✓	✓			✓			✓
Grafapex	treosulfan	MEDEXUS	21/01/2025	✓							
Hernexeos	zongertinib	Boehringer Ingelheim	08/08/2025		✓	✓	✓	✓		✓	
Hyrnuo	sevabertinib	BAYER HEALTHCARE	19/11/2025	✓	✓	✓	✓		✓		
Ibtrozi	taletrectinib adipate	NUVATION	11/06/2025	✓	✓		✓				
Imaavy	nipocalimab-aahu	Janssen Biotech	29/04/2025	✓	✓			✓			
Inluriyo	imlunestrant tosylate	ELI LILLY AND CO	25/09/2025					✓			
Jascayd	nerandomilast	Boehringer Ingelheim	07/10/2025	✓	✓		✓				
Journavx	suzetrigine	VERTEX PHARMS INC	30/01/2025		✓		✓	✓			✓
Keytruda Qlex	pembrolizumab and berahyaluronidase alfa-pmph	Merck Sharp & Dohme LLC	19/09/2025		✓	✓					
Komzifti	ziftomenib	KURA	13/11/2025	✓	✓		✓	✓			

*: *'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 2025

Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Exp. rev.*	Accel. App.**	Break. desig.†	Fast track	Project Orbis	RTOR‡	Rolling review
Kygevvi	doxecitine; doxribtimine	UCB INC	03/11/2025	✓	✓		✓				
Lerochol	lerodalcibep-liga	LIB Therapeutics	12/12/2025								
Lynkuet	elinzanetant	BAYER HLTHCARE	24/10/2025								
Lynozyfic	linvoseltamab-gcpt	Rengeneron Pharmaceuticals Inc	02/07/2025	✓	✓	✓		✓			
Modeyso	dordaviprone hydrochloride	CHIMERIX	06/08/2025	✓	✓	✓		✓			
Myqorzo	aficamten	CYTOKINETICS	19/12/2025	✓			✓				✓
Nereus	tradipitant	VANDA PHARMS INC	30/12/2025								
Nuzolvence	zoliflodacin	ENTASIS THERAP	12/12/2025		✓			✓			
Palsonify	paltusotine hydrochloride	CRINETICS	25/09/2025	✓							
Papzimeos	zopapogene imadenovec-drba	Precigen, Inc.	14/08/2025	✓	✓		✓				✓
Penpulimab-Kcqx	penpulimab-kcqx	Akeso Biopharma	23/04/2025	✓		✓	✓	✓		✓	
Qfitlia	fitusiran sodium	Genzyme Corp	28/03/2025	✓			✓	✓			
Redemplo	plozasiran sodium	ARROWHEAD	18/11/2025	✓			✓	✓			
Rhapsido	remibrutinib	Novartis	30/09/2025		✓						
Romvimza	vimseltinib	DECIPHERA PHARMS	14/02/2025		✓			✓			
Sephience	sepiapterin	PTC THERAP	28/07/2025	✓							
Tryptyr	acoltremon	ALCON LABS INC	28/05/2025								
Vanrafia	atrasentan hydrochloride	Novartis	02/04/2025			✓					
Vizz	aceclidine hydrochloride	LENZ THERAP	31/07/2025								
Voyxact	sibeprenlimab-szsi	OTSUKA PHARM CO LTD	25/11/2025		✓	✓	✓				
Waskyra	etuvetidigene autotemcel	Fondazione Telethon ETS	09/12/2025	✓	✓						
Wayrilz	rilzabrutinib	Genzyme Corp	29/08/2025	✓				✓			
Yartemlea	narsoplimab-wuug	Omeros Corp	23/12/2025	✓	✓		✓				✓
Zegfrovy	sunvozertinib	DIZAL JIANGSU	02/07/2025		✓	✓	✓				
Zevaskyn	prademagene zamikeracel	Abeona Therapeutics, Inc.	28/04/2025	✓	✓		✓				

*: *'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 2025

Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Expedited review*	Sakigake	Conditional early approval
Airwin	sotatercept (genetical recombination)	MSD K.K.	24/06/2025	✓	✓		
Andembry	garadacimab (genetical recombination)	CSL Behring K.K.	20/02/2025				
Avarept	motugivatrep	Senju Pharmaceutical Co., Ltd.	22/12/2025				
Beyonttra	acoramidis hydrochloride	Alexion Pharma GK	27/03/2025				
Blenrep	belantamab mafodotin (genetical recombination)	GlaxoSmithKline K.K.	19/05/2025	✓	✓		
Bylvay	odevixibat hydrate	IPSEN	19/09/2025	✓	✓		
Camzyos	mavacamten	Bristol-Myers Squibb K.K.	27/03/2025	✓	✓		
Ekterly	sebetralstat	KalVista Pharmaceuticals Ltd.	22/12/2025	✓	✓		
Elzonris	tagraxofusp	Nippon Shinyaku Co., Ltd.	22/12/2025	✓	✓		
Exdensur	depemokimab	GlaxoSmithKline K.K.	22/12/2025				
Hernexeos	zongertinib	Nippon Boehringer Ingelheim Co., Ltd.	19/09/2025	✓	✓		
Ibtrozi	taletrectinib adipate	Nippon Kayaku Co., Ltd.	19/09/2025	✓	✓		
Imaavy	nipocalimab	Janssen Pharmaceuticals K.K.	19/09/2025	✓	✓		
Inluriyo	imlunestrant tosylate	Eli Lilly Japan K.K.	22/12/2025				
Inrebic	fedratinib hydrochloride hydrate	Bristol-Myers Squibb K.K.	24/06/2025	✓	✓		
Izervay	avacincaptad pegol sodium	Astellas Pharma Inc.	19/09/2025				✓
Lazcluze	lazertinib mesilate hydrate	Janssen Pharmaceutical K.K.	27/03/2025				
Livmarli	maralixibat chloride	Takeda Pharmaceutical Company Limited	27/03/2025	✓	✓		
Locametz	gozetotide	Novartis Pharma K.K.	19/09/2025				
Minjuvi	tafasitamab	Insight Biosciences Japan (same company)	22/12/2025	✓	✓		

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NASs approved by PMDA in 2025

Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Expedited review*	Sakigake	Conditional early approval
Nexletol	bempedoic acid	Otsuka Pharmaceutical Co., Ltd.	19/09/2025				
Nurtec	rimegepant sulfate	Pfizer Inc.	19/09/2025				
Pluvicto	lutetium lu 177 vipivotide tetraxetan	Novartis Pharma K.K.	19/09/2025				
Pombiliti	cipaglucosidase alfa (genetical recombination)	Amicus Therapeutics, Inc.	24/06/2025	✓	✓		
Ravicti	glycerol phenylbutyrate	Orphan Pacific Co., Ltd.	22/12/2025	✓	✓		
Sephience	sepiapterin	PTC Therapeutics Inc.	22/12/2025	✓	✓		
Setaneo	sepetaprost	Santen Pharmaceutical Co., Ltd.	25/08/2025				
Talvey	talquetamab (genetical recombination)	Janssen Pharmaceutical K.K.	24/06/2025	✓	✓		
Tevimbra	tislelizumab (genetical recombination)	BeiGene Japan GK	27/03/2025				
Tibsovo	ivosidenib	Nihon Servier Co., Ltd.	27/03/2025	✓	✓		
Tivdak	tisotumab vedotin (genetical recombination)	Genmab K.K.	27/03/2025				
Velsipity	etrasimod l-arginine	Pfizer Japan Inc.	24/06/2025				
Voranigo	vorasidenib citrate	Japan Servier Co., Ltd.	19/09/2025	✓	✓		
Vorzzz	vornorexant hydrate	Taisho Pharmaceutical Co., Ltd.	25/08/2025				
Welireg	belzutifan	MSD K.K.	24/06/2025	✓	✓		
Ycanth	cantharidin	Torii Pharmaceutical Co., Ltd.	19/09/2025				
Yorvipath	palopegteriparatide	Teijin Pharma Limited	25/08/2025	✓	✓		
Yselty	linzagolix choline	Kissei Pharmaceutical Co., Ltd.	22/12/2025				
Zurzuvae	zuranolone	Shionogi & Co., Ltd.	22/12/2025				
Zynyz	retifanlimab	Insight Biosciences Japan (same company)	22/12/2025	✓	✓		

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NASs approved by Health Canada in 2025

Brand Name	Generic Name	Sponsor	Approval Date	Expedited review.*	Conditional approval	Access Consortium	Project Orbis	Rolling review
Agamree	vamorolone	Kye Pharmaceuticals Inc	29/09/2025	✓				
Altuviiio	*antihemophilic factor viii (recombinant, bdd), fc-vwf-xten fusion protein	SANOFI-AVENTIS CANADA INC	26/03/2025					
Alyftrek	vanzacaftor calcium, tezacaftor, deutivacaftor	vertex pharmaceuticals (canada) incorporated	21/07/2025					
Amivas-Artesunate	artesunate	AMIVAS IRELAND LTD.	04/07/2025	✓				
Amtagvi	lifileucel	IOVANCE BIOTHERAPEUTICS, INC	15/08/2025		✓			
Andembry	garadacimab	CSL BEHRING CANADA INC	06/08/2025			✓		
Anzupgo	delgocitinib	leo pharma inc	25/08/2025					
Augtyro	repotrectinib	BRISTOL-MYERS SQUIBB CANADA	07/05/2025				✓	
Baxdela	delafloxacin meglumine	XEDITON PHARMACEUTICALS INC	17/01/2025	✓				
Blenrep	belantamab mafodotin	GLAXOSMITHKLINE INC	18/07/2025					
Elahere	mirvetuximab soravtansine	ABBVIE CORPORATION	29/08/2025	✓				
Elfabrio	pegunigalsidase alfa	CHIESI FARMACEUTICI S.P.A.	09/12/2025					
Fabhalta	iptacopan hydrochloride	Novartis Pharmaceuticals Canada Inc	06/01/2025					
Hepcludex	bulevirtide acetate	GILEAD SCIENCES CANADA INC	08/08/2025	✓				
Imaavy	nipocalimab	JANSSEN INC	05/12/2025			✓		
Iqirvo	elafibranor	IPSEN BIOPHARMACEUTICALS CANADA INC	25/04/2025		✓			
Isturisa	osilodrostat phosphate	RECORDATI RARE DISEASES CANADA INC	03/07/2025					
Itovebi	inavolisib	Hoffmann-La Roche Limited	14/02/2025	✓			✓	
Jaypirca	pirtobrutinib	ELI LILLY CANADA INC	17/10/2025		✓			
Jeraygo	aprocitentan	IDORSIA PHARMACEUTICALS LTD	23/12/2025					
Kavigale	sipavibart	ASTRAZENECA CANADA INC	21/03/2025					✓

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NASs approved by Health Canada in 2025

Brand Name	Generic Name	Sponsor	Approval Date	Expedited review.*	Conditional approval	Access Consortium	Project Orbis	Rolling review
Lazcluze	lazertinib mesylate	JANSSEN INC	06/03/2025				✓	
Leqembi	lecanemab	Eisai Limited	24/10/2025		✓			
Loqtorzi	toripalimab	APOTEX INC	17/10/2025					
Lynkuet	elinzanetant	BAYER INC	23/07/2025			✓		
Lyvdelzi	seladelpar lysine	GILEAD SCIENCES CANADA INC	16/10/2025		✓			
Nduvra	tapinarof	DERMAVANT SCIENCES GMBH	04/04/2025					
Nemluvio	nemolizumab	GALDERMA CANADA INC	18/12/2025					
Nilemdo	bempedoic acid	HLS THERAPEUTICS INC	14/11/2025					
Oritiniv	oritavancin phosphate	XEDITON PHARMACEUTICALS INC	12/09/2025	✓				
Piasky	crovalimab	Hoffmann-La Roche Limited	04/06/2025					
Pombiliti	cipaglucosidase alfa	AMICUS THERAPEUTICS CANADA INC.	14/04/2025					
Qalsody	tofersen	BIOGEN CANADA INC	28/02/2025		✓			
Rystiggo	rozanolixizumab	UCB CANADA INC	28/03/2025			✓		
Sephience	sepiapterin	PTC THERAPEUTICS INTERNATIONAL LIMITED	07/10/2025	✓				
Skyclarys	omaveloxolone	BIOGEN CANADA INC	13/03/2025	✓				
Tepezza	teprotumumab	AMGEN CANADA INC	17/04/2025					
Tevimbra	tislelizumab	BEONE MEDICINES I GMBH	18/12/2025					
Tryngolza	olezarsen sodium	THERATECHNOLOGIES INC	16/12/2025	✓				
Tzield	teplizumab	SANOFI-AVENTIS CANADA INC	05/05/2025	✓				
Vanflyta	quizartinib hydrochloride	DAIICHI SANKYO PHARMA CANADA LIMITED	09/06/2025				✓	
Zurzuvae	zuranolone	BIOGEN CANADA INC	05/12/2025					
Zynlonta	loncastuximab tesirine	SWEDISH ORPHAN BIOVITRUM AB (PUBL)	07/03/2025		✓			

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NASs approved by Health Canada in 2025

Brand Name	Generic Name	Sponsor	Approval Date	Expedited review.*	Conditional approval	Access Consortium	Project Orbis	Rolling review
Zynyz	retifanlimab	Incyte Corporation	06/02/2025					

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NASs approved by Swissmedic in 2025

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
Alyftrek	vanzacaftor, tezacaftor, deutivacaftor	Vertex Pharmaceuticals (CH) GmbH	15/10/2025	✓		✓						
Andembry	garadacimab	CSL Behring AG	24/02/2025	✓						✓		
Balversa	erdafitinib	Janssen-Cilag AG	14/01/2025									
Beyonttra	acoramidis	Bayer (Schweiz) AG	18/12/2025	✓				✓				
Briumvi	ublituximab	Neuraxpharm Switzerland AG	06/02/2025									
Bylvay	odevixibat	IPSEN Pharma Schweiz GmbH	04/12/2025	✓								
Datroway	datopotamab deruxtecan	Daiichi Sankyo (Schweiz) AG	28/05/2025							✓		
Ekterly	sebetralstat	KalVista Pharmaceuticals	17/09/2025	✓						✓		
Elahere	mirvetuximab soravtansine	AbbVie AG	13/03/2025	✓	✓			✓				
Hetronifly	serplulimab	Accord Healthcare AG	27/11/2025	✓				✓				
Imaavy	nipocalimab	Janssen-Cilag AG	18/12/2025	✓						✓		
Imcivree	setmelanotide	pharma services Oehler GmbH	23/06/2025	✓				✓				
Itovebi	inavolisib	Roche Pharma (Schweiz) AG	31/01/2025									
Jeraygo	aprocitentan	IDORSIA PHARMACEUTICALS LTD	18/09/2025									
Lazcluze	lazertinib	Janssen-Cilag AG	07/02/2025									
Litfulo	ritlecitinib	Pfizer AG	03/02/2025									
Lynkuet	elinzanetant	Bayer (Schweiz) AG	05/08/2025							✓		
Lyvdelzi	seladelpar	Gilead Sciences Switzerland Sàrl	09/12/2025	✓	✓		✓					
Nemluvio	nemolizumab	Galderma SA	17/02/2025							✓		
Nexpovio	selinexor	Stemline Therapeutics Switzerland GmbH	29/04/2025	✓				✓				
Obgemsa	vibegron	Pierre Fabre Pharma SA	20/08/2025									
Piasky	crovalimab	Roche Pharma (Schweiz) AG	13/02/2025	✓								
Pylclari	piflufolastat (18-f)	b.e.imaging.ag	25/04/2025									
Qalsody	tofersen	Biogen Switzerland AG	19/12/2025	✓			✓					

*: *'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 2025

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
Rotecpsma	trofolastat	medeo AG	08/08/2025									
Rystiggo	rozanolixizumab	UCB-Pharma SA	12/02/2025	✓						✓		
Sephience	sepiapterin	PTC Therapeutics Switzerland GmbH	05/08/2025	✓	✓							
Tepezza	teprotumumab	Amgen Switzerland AG	30/04/2025		✓							
Vanflyta	quizartinib as quizartinib dihydrochloride	Daiichi Sankyo (Schweiz) AG	31/03/2025	✓				✓				
Voxzogo	vosoritide	Drac AG	30/01/2025	✓	✓							
Vyloy	zolbetuximab	Astellas Pharma AG	19/02/2025	✓						✓		
Wainzua	eplontersen	AstraZeneca AG	14/02/2025	✓								
Yorvipath	palopegteriparatide	Ascendis Pharma Switzerland GmbH	09/12/2025	✓				✓				
Zynyz	retifanlimab	Incyte Biosciences International	24/06/2025	✓	✓							

*: *'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 2025

Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Exp. rev.*	Prov. App.†	COR-A	COR-B	Access Cons.‡	Project Orbis
Alyftrek	deutivacaftor, tezacaftor, vanzacaftor calcium	Vertex Pharmaceuticals Australia Pty Ltd	14/11/2025	✓						
Andembry	garadacimab	CSL Behring Australia Pty Ltd	09/01/2025	✓					✓	
Anzupgo	delgocitinib	LEO Pharma Pty Ltd	27/08/2025							
Augtyro	repotrectinib	BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD	23/07/2025							✓
Blenrep	belantamab mafodotin	GlaxoSmithKline Australia Pty Ltd	12/11/2025							
Briumvi	ublituximab	Accelagen Pty Ltd	04/06/2025							
Bylvay	odevixibat, odevixibat sesquihydrate	Ipsen Pty Ltd	24/03/2025	✓						
Datroway	datopotamab deruxtecan	ASTRAZENECA PTY LTD	15/05/2025						✓	
Ekterly	sebetralstat	JACE Pharma Pty Ltd	09/10/2025	✓					✓	
Elahere	mirvetuximab soravtansine	AbbVie Pty Ltd	17/11/2025	✓				✓		
Elfabrio	pegunigalsidase alfa	Chiesi Australia Pty Ltd	12/05/2025							
Elucirem	gadopiclenol	Guerbet Australia Pty Ltd	15/04/2025							
Hympavzi	marstacimab	Pfizer Australia Pty Ltd	29/01/2025						✓	
Imdelltra	tarlatamab	Amgen Australia Pty Ltd	04/06/2025	✓		✓				✓
Inrebic	fedratinib hydrochloride	BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD	12/02/2025							
Iqirvo	elafibranor	Ipsen Pty Ltd	18/03/2025							
Itovebi	inavolisib	ROCHE PRODUCTS PTY LTD	24/03/2025							✓
Izervay	avacincaptad pegol	Astellas Pharma Australia Pty Ltd	08/10/2025							
Joenja	leniolisib phosphate	Ballia Holdings Pty Ltd	13/03/2025	✓	✓					
Kavigale	sipavibart	ASTRAZENECA PTY LTD	20/05/2025		✓					
Kisunla	donanemab	Eli Lilly Australia Pty Ltd	19/05/2025						✓	
Lamzede	velmanase alfa	Chiesi Australia Pty Ltd	13/03/2025	✓						
Lazcluze	lazertinib mesilate monohydrate	Janssen-Cilag Pty Ltd	09/04/2025							✓

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Leqembi	lecanemab	Eisai Australia Pty Ltd	23/09/2025							
Lutathera	lutetium (177lu) oxodotreotide	Novartis Pharmaceuticals Australia Pty Ltd	14/11/2025							✓
Lynkuet	elinzanetant	Bayer Australia Ltd	05/09/2025						✓	
Lytgobi	futibatinib	Taiho Pharma Oceania Pty Ltd	10/04/2025	✓		✓				✓
Nemluvio	nemolizumab	Galderma Australia Pty Ltd	12/05/2025						✓	
Nexobrid	anacaulase-bcdb	Nexo Pharmaceuticals Pty Ltd	08/09/2025	✓						
Pombiliti	cipaglucosidase alfa	Amicus Therapeutics Pty Ltd	10/02/2025							
Rapiblyk	landiolol hydrochloride	Phebra Pty Ltd	12/06/2025				✓			
Rystiggo	rozanolixizumab	UCB Australia Pty Ltd T/A UCB Pharma Division of UCB Australia	28/01/2025						✓	
Sephience	sepiapterin	PTC THERAPEUTICS AUSTRALIA PTY LIMITED	14/07/2025	✓						
Skyclarys	omaveloxolone	Biogen Australia Pty Ltd	23/05/2025	✓						
Skytrofa	lonapegsomatropin	Specialised Therapeutics Pharma Pty Ltd	20/05/2025							
Tepezza	teprotumumab	Amgen Australia Pty Ltd	14/03/2025		✓					
Tezspire	tezepelumab	ASTRAZENECA PTY LTD	21/03/2025							
Uplizna	inebilizumab	Amgen Australia Pty Ltd	11/03/2025					✓		
Vyloy	zolbetuximab	Astellas Pharma Australia Pty Ltd	12/03/2025	✓					✓	
Vyvgart	efgartigimod alfa	Argenx Australia Pty Ltd	17/02/2025							
Yorvipath	palopegteriparatide	Specialised Therapeutics Pharma Pty Ltd	17/02/2025	✓	✓					
Zytorvi	toripalimab	AA-Med Pty Ltd	16/01/2025	✓						✓

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