

R&D Briefing 93: New drug approvals in six major authorities 2014-2023

Changing regulatory landscape and facilitated regulatory pathways

List of NASs approved by the six regulatory authorities

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NASs approved by EMA in 2023



Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Expedited Review*	Conditional Approval	Exceptional Circumstances	PRIME designation	Rolling review
Agamree	Vamorolone	Santhera Pharmaceuticals (Deutschland) GmbH	14/12/2023	✓					
Aquipta	atogepant	AbbVie Deutschland GmbH & Co. KG	11/08/2023						
Briumvi	ublituximab	Neuraxpharm Pharmaceuticals S.L.	31/05/2023						
Camzyos	mavacamten	Bristol-Myers Squibb Pharma EEIG	26/06/2023						
COLUMVI	glofitamab	Roche Registration GmbH	07/07/2023	✓		✓			
Ebglyss	Lebrikizumab	Almirall, S.A.	16/11/2023						
ELREXFIO	ELRANATAM AB	Pfizer Europe MA EEIG	07/12/2023			✓			
Elucirem	Gadopiclenol	Guerbet	07/12/2023						
HEMGENIX	ETRANACOG ENE DEZAPARVO VEC	CSL Behring GmbH	20/02/2023	✓		✓			
Inaqovi	cedazuridine, decitabine	Otsuka Pharmaceutical Netherlands B.V.	15/09/2023						
Jaypirca	pirtobrutinib	Eli Lilly Nederland B.V.	30/10/2023			✓			
LITFULO	RITLECITINIB	Pfizer Europe MA EEIG	15/09/2023						
Loargys	Pegzilarginase	Immedica Pharma AB	15/12/2023	✓			✓		
Lyfnaa	gefapixant	Merck Sharp & Dohme B.V.	15/09/2023						
Lytgobi	futibatinib	Taiho Pharma Netherlands B.V.	04/07/2023			✓			
OmvoH	mirikizumab	Eli Lilly Nederland B.V.	26/05/2023						

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

NASs approved by EMA in 2023



Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Expedited Review*	Conditional Approval	Exceptional Circumstances	PRIME designation	Rolling review
Orserdu	elacestrant	Stemline Therapeutics B.V.	15/09/2023						
Pyclari	piflufolostat (18F)	Curium Pet France	24/07/2023						
Rezzayo	rezafungin	Mundipharma GmbH	22/12/2023	✓					
Sotyktu	deucravacitinib	Bristol-Myers Squibb Pharma EEIG	24/03/2023						
Talvey	talquetamab	Janssen-Cilag International N.V.	21/08/2023	✓	✓	✓			
Tepkinly	EPCORITAMA B	AbbVie Deutschland GmbH & Co. KG	22/09/2023	✓		✓			
Tevimbra	tislelizumab	Novartis Europharm Limited	15/09/2023	✓					
TIBSOVO	ivosidenib	Les Laboratoires Servier	04/05/2023	✓					
Tremelimumab AstraZeneca	tremelimumab	AstraZeneca AB	20/02/2023						
VAFSEO	vadadustat	Akebia Europe Limited	24/04/2023						
Vanflyta	quizartinib	Daiichi Sankyo Europe GmbH	06/11/2023						
Veozza	fezolinetant	Astellas Pharma Europe B.V	07/12/2023						
Yorvipath	palopegteriparatide	Ascendis Pharma Bone Diseases A/S	17/11/2023	✓					
Zilbrysq	zilucoplan	UCB Pharma S.A.	01/12/2023						
Ztalmy	ganaxolone	Marinus Pharmaceuticals Emerald Limited	26/07/2023	✓					

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NASs approved by FDA in 2023



Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Exp. rev.*	Accel. App.**	Break. desig.†	Fast track	Project Orbis	RTOR‡	Rolling review
Adzynma	ADAMTS13, recombinant-krhn	TAKEDA PHARMS USA	09/11/2023	✓	✓			✓			
Agamree	Vamorolone	CATALYST PHARMS	26/10/2023	✓				✓			✓
Altuviio	antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl	Bioerativ Therapeutics, Inc.	22/02/2023	✓	✓		✓	✓			
Aphexda	motixafortide	BIOLINERX LTD	08/09/2023	✓							
Augtyro	repotrectinib	BRISTOL	15/11/2023	✓	✓		✓		✓		
BEYFORTUS	nirsevimab-alip	AstraZeneca AB	17/07/2023				✓	✓			
Bimzelx	bimekizumab	UCB INC	17/10/2023								
Brenzavvy	bexagliflozin	THERACOSBIO	20/01/2023								
COLUMVI	glofitamab-gxbm	GENENTECH INC	15/06/2023		✓	✓		✓	✓		
Daybue	trofinetide	ACADIA PHARMS INC	10/03/2023	✓	✓			✓			
Defencath	taurolidine, heparin	CORMEDIX	15/11/2023		✓			✓			✓
Elevidys	delandistrogene moxeparvovec-rokl	Sarepta Therapeutics, Inc.	22/06/2023	✓	✓	✓		✓			
Elfabrio	pegunigalsidase alfa-iwxj	CHIESI FARMACEUTICI SPA	09/05/2023		✓			✓			
ELREXFIO	elranatamab-bcmm	Pfizer Inc	14/08/2023	✓	✓	✓	✓	✓	✓		✓
EPKINLY	epcoritamab-bysp	GENMAB US, INC.	19/05/2023		✓	✓					
Exxua	gepirone	FABRE KRAMER	22/09/2023								
Fabhalta	iptacopan	NOVARTIS PHARMS CORP	05/12/2023	✓	✓		✓				
Filspari	sparsentan	TRAVERE	17/02/2023	✓	✓	✓					
Fruzaqla	fruquintinib	TAKEDA PHARMS USA	08/11/2023		✓			✓	✓		✓
Inpefa	Sotagliflozin	LEXICON PHARMS INC	26/05/2023								
Izervay	avacincaptad pegol	IVERIC BIO	04/08/2023		✓		✓	✓			✓

*: '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 2023



Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Exp. rev.*	Accel. App.**	Break. desig.†	Fast track	Project Orbis	RTOR‡	Rolling review
Jaypirca	pirtobrutinib	LOXO ONCOL	27/01/2023	✓	✓	✓		✓			✓
Jesduvroq	Daprodustat	glaxosmithkline	01/02/2023								
Joenja	leniolisib	PHARMING	24/03/2023	✓	✓						
Lamzede	velmanase alfa-tycv	CHIESI FARMACEUTICI SPA	16/02/2023	✓	✓			✓			
Lantidra	donislecel-jujn	CellTrans Inc.	28/06/2023	✓							
Leqembi	lecanemab-irmb	Eisai Inc	06/01/2023		✓	✓	✓	✓			
LITFULO	RITLECITINIB	PFIZER	23/06/2023				✓				
Loqtorzi	toripalimab-tpzi	COHERUS BIOSCIENCES INC	27/10/2023		✓		✓		✓		✓
Miebo	perfluorohexyloctane	BAUSCH AND LOMB INC	18/05/2023								
Ngenla	somatrogon-ghla	PFIZER IRELAND PHARMACEUTICALS	27/06/2023	✓							
Ogsiveo	nirogacestat	SPRINGWORKS	27/11/2023	✓	✓		✓	✓		✓	
Ojjaara	momelotinib	glaxosmithkline	15/09/2023	✓				✓			
Omisirge	omidubicel-onlv	Gamida Cell Ltd.	17/04/2023	✓	✓		✓				
OmvoH	mirikizumab-mrkz	ELI LILLY AND CO	26/10/2023	✓							
Orserdu	elacestrant	STEMLINE THERAP	27/01/2023		✓			✓			
Paxlovid	nirmatrelvir, ritonavir	PFIZER	25/05/2023		✓			✓			
Pombiliti	cipaglucoSIdase alfa-atga	AMICUS THERAP US	28/09/2023	✓			✓				✓
Posluma	flotufolastat F 18	BLUE EARTH	25/05/2023								
Qalsody	tofersen	BIOGEN MA	25/04/2023	✓	✓	✓		✓			
Rezzayo	rezafungin	CIDARA THERAPS	22/03/2023	✓	✓			✓			
Rivfloza	nedosiran	NOVO	29/09/2023	✓			✓				
Roctavian	valoctocogene roxaparvovec-rvox	Biomarin Pharmaceutical Inc.	29/06/2023	✓	✓		✓	✓			

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NASs approved by FDA in 2023



Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Exp. rev.*	Accel. App.**	Break. desig.†	Fast track	Project Orbis	RTOR‡	Rolling review
Rystiggo	rozanolixizumab-noli	UCB INC	26/06/2023	✓	✓						
Ryzneuta	efbemalenograstim alfa-vuxw	EVIVE BIOTECHNOLOGY	16/11/2023								
Skyclarys	omaveloxolone	REATA PHARMS	28/02/2023	✓	✓			✓			
SOHONOS	palovarotene	IPSEN INC	16/08/2023	✓	✓		✓	✓			
Talvey	talquetamab-tgvs	Janssen Biotech	09/08/2023	✓	✓	✓	✓		✓		
Truqap	capivasertib	AstraZeneca	16/11/2023		✓			✓	✓	✓	✓
Vanflyta	quizartinib	DAIICHI SANKYO INC	20/07/2023	✓	✓			✓			
Velsipity	etrasimod	PFIZER	12/10/2023								
Veopoz	pozelimab-bbfg	REGENERON PHARMACEUTICALS	18/08/2023	✓	✓			✓			✓
Veozah	fezolinetant	Astellas	12/05/2023		✓						
Vyjuvek	beremagene geperpavec-svdt	Krystal Biotech, Inc.	19/05/2023	✓	✓			✓			
Wainua	eplontersen	IONIS PHARMA INC	21/12/2023	✓							
Xacduro	sulbactam, durlobactam	ENTASIS THERAP	23/05/2023		✓			✓			
Xdemvy	lotilaner	TARSUS	24/07/2023								
Zavzpret	zavegepant	PFIZER	09/03/2023								
Zilbrysq	zilucoplan	UCB INC	17/10/2023	✓							
Zurzuvae	zuranolone	Sage Therapeutics, Inc.	04/08/2023		✓			✓			✓
Zynyz	retifanlimab-dlwr	INCYTE CORP	22/03/2023	✓	✓	✓		✓			

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** : Accelerated approval.

† : Breakthrough designation.

‡ : Real-time oncology review.

NASs approved by PMDA in 2023



Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Expedited review*	Sakigake	Conditional early approval
Alemo	Consizumab (genetically modified)	Novo Nordisk Pharma	25/09/2023	✓	✓		
Besremi	Ropeginterferon alfa-2b (genetical recombination)	PharmaEssence Japan K.K.	27/03/2023				
Corsuba	diferriquefarin acetate	Maruishi	25/09/2023				
DOPTELET	avatrombopag maleate	Swedish Orphan Biovitrum Japan Co., Ltd.	27/03/2023				
Empaveli	pegcetacoplan	Swedish Orphan Biovitrum Japan Co., Ltd.	27/03/2023				
Epoquinli	Epicoritamab (genetically modified).	Gemmab Ltd	25/09/2023				
Fetroja	Cephedero cortosylate sulphate hydrate	Shionogi	30/11/2023	✓	✓		
Fozebel	tenapanol hydrochloride	Kyowa Kirin Co., Ltd.	25/09/2023				
Listigo	Rozanolixizumab (genetical recombination)	UCB Japan Ltd	25/09/2023	✓	✓		
LITFULO	Ritlecitinib tosilate	Pfizer Japan Inc.	26/06/2023				
Lytgobi	futibatinib	Taiho Pharmaceutical Co., Ltd.	26/06/2023				
Mefeego Pack	Mifepristone, Misoprostol	Linepharma K.K.	28/04/2023				
OmvoH	Mirikizumab (genetical recombination)	Eli Lilly Japan K.K.	27/03/2023				
ONCASPAR	pegaspargase	Nihon Servier Co., Ltd.	26/06/2023				
Orphacol	Cholic acid	ReqMed Company, Ltd.	27/03/2023	✓	✓		

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

NASs approved by PMDA in 2023



Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Expedited review*	Sakigake	Conditional early approval
Ortuvio	F Anesoctocog alpha (genetically modified)	Sanofi, Ltd.	25/09/2023				
Palyzinq	Pegvaliase (genetical recombination)	BioMarin Pharmaceutical Japan K.K.	27/03/2023	✓	✓		
RECUBIO	sodium increasirane	Novartis Pharma AG	25/09/2023				
Rekenbi	Recanemab (genetically modified).	Eisai co., Ltd.	25/09/2023		✓		
Sunlenca	lenacapavir sodium	Gilead Sciences, Inc.	01/08/2023	✓	✓		
Zilvisc	sodium zirkoplan	UCB Japan Co., Ltd.	25/09/2023				

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

NASs approved by Health Canada in 2023



Brand Name	Generic Name	Sponsor	Approval Date	Expedited review.*	Conditional approval	Access Consortium	Project Orbis	Rolling review
ALHEMO	concizumab	novo nordisk canada inc	10/03/2023	✓		✓		
AMVUTTRA	VUTRISIRAN	Alnylam Netherlands B.V.	18/10/2023					
ASPARLAS	CALASPARGASE PEGOL	SERVIER CANADA INC	08/11/2023					
BEQVEZ	FIDANACOGENE ELAPARVOVEC	PFIZER CANADA ULC	27/12/2023	✓				
BEYFORTUS	NIRSEVIMAB	astrazeneca canada inc	19/04/2023					
BYLVAY	ODEVIXIBAT	MEDISON PHARMA CANADA INC.	30/10/2023	✓				
CARVYKTI	CILTACABTAGENE AUTOLEUCEL	JANSSSEN INC	09/02/2023		✓			
COLUMVI	glofitamab	Hoffmann-La Roche Limited	24/03/2023		✓			
DOPTELET	avatrombopag maleate	SWEDISH ORPHAN BIOVITRUM AB (PUBL)	03/11/2023					
ELREXFIO	ELRANATAMAB	PFIZER CANADA ULC	06/12/2023		✓		✓	
EPKINLY	EPCORITAMAB	ABBVIE CORPORATION	13/10/2023		✓			
EVKEEZA	EVINACUMAB	Ultragenyx Pharmaceutical Inc	22/09/2023	✓				
HEMGENIX	ETRANACOGENE DEZAPARVOVEC	CSL BEHRING CANADA INC	23/10/2023	✓				
IMCIVREE	SETMELANOTIDE ACETATE	RHYTHM PHARMACEUTICALS, INC	05/05/2023	✓				
IMJUDO	tremelimumab	astrazeneca canada inc	31/08/2023					
KENGREXAL	CANGRELOR TETRASODIUM	CHIESI FARMACEUTICI S.P.A.	20/01/2023					
LITFULO	RITLECITINIB	PFIZER CANADA ULC	29/11/2023					
LIVMARLI	MARALIXIBAT CHLORIDE	MIRUM PHARMACEUTICALS, INC.	21/07/2023	✓				

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

NASs approved by Health Canada in 2023



Brand Name	Generic Name	Sponsor	Approval Date	Expedited review.*	Conditional approval	Access Consortium	Project Orbis	Rolling review
MYFEMBRE E	RELUGOLIX, NORETHINDRONE ACETATE, ESTRADIOL	SUMITOMO PHARMA SWITZERLAND GMBH	22/09/2023					
Nurtec ODT	RIMEGEPANT	PFIZER CANADA ULC	01/12/2023					
OmvoH	mirikizumab	Eli Lilly Canada Inc	20/07/2023					
ONAKTA	tirbanibulin	AVIR PHARMA INC	12/05/2023					
ONDEXXYA	andexanet alfa	astrazeneca canada inc	16/06/2023		✓			
Opdualag	nivolumab, relatlimab	BRISTOL-MYERS SQUIBB CANADA	13/09/2023					
QUVIVIQ	DARIDOREXANT HYDROCHLORIDE	IDORSIA PHARMACEUTICALS LTD	28/04/2023					
SIBBORAN	LANDIOLOL HYDROCHLORIDE	TRIMEDIC THERAPEUTICS INC.	20/11/2023					
Sogroya	somapacitan	novo nordisk canada inc	26/07/2023					
SPEVIGO	spesolimab	BOEHRINGER INGELHEIM (CANADA) LTD LTEE	22/03/2023	✓				
TECVAYLI	teclistamab	JANSSEN INC	26/07/2023		✓		✓	
UPLIZNA	INEBILIZUMAB	HORIZON THERAPEUTICS IRELAND DAC	15/12/2023					
Verquvo	vericiguat	bayer inc	28/04/2023					
VYVGART	EFGARTIGIMOD ALFA	ARGENX BV	19/09/2023					
WINLEVI	CLASCOTERONE	SUN PHARMACEUTICAL INDUSTRIES LIMITED	15/06/2023					
XCOPRI	CENOBAMATE	Endo Ventures Ltd	12/06/2023					

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NASs approved by Swissmedic in 2023



Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Exp. rev.*	Prior not.**	Cond. App.†	Art. 13 TPA	Art.14 TPA	Access Cons.‡	Project Orbis	Rolling review
ALHEMO	concizumab	Novo Nordisk Pharma AG	08/08/2023	✓	✓					✓		✓
AMVUTTRA	VUTRISIRAN	Alnylam Switzerland GmbH	23/06/2023	✓				✓				
Aspaveli	pegcetacoplan	Swedish Orphan Biovitrum AG	23/03/2023	✓								
Ayvakyt	avapritinib	Blueprint Medicines (Switzerland)	06/07/2023	✓				✓				
BEYFORTUS	NIRSEVIMAB	Sanofi-Aventis (Suisse) SA	22/12/2023									
Camzyos	mavacamten	Bristol-Myers Squibb SA	25/04/2023	✓								
COLUMVI	glofitamab	Roche Pharma (Schweiz) AG	07/11/2023	✓			✓				✓	✓
Elfabrio	Pegunigalsidase alfa	Chiesi SA	11/09/2023	✓				✓				
ELREXFIO	ELRANATAMAB	Pfizer AG	05/09/2023	✓			✓				✓	✓
Elucirem, Injektionslösung in einer Fertigspritze	Gadopicienol	Guerbet AG	21/12/2023									
Elzonris 1mg / ml	tagraxofusp	Stemline Therapeutics Switzerland GmbH	03/02/2023	✓	✓							
Enjaymo	sutimlimab	Sanofi-Aventis (Suisse) SA	21/06/2023	✓								
HEMGENIX	Etranacogen dezaparovec	CSL Behring AG	07/12/2023	✓	✓							
IMJUDO	tremelimumab	AstraZeneca AG	13/09/2023	✓								
Jaypirca	pirtobrutinib	Eli Lilly (Suisse) SA	30/11/2023	✓			✓	✓				
Kimmtrak	tebentafusp	Immunocore GmbH	09/05/2023	✓	✓			✓				
Libmeldy	Atidarsagen autotemcel	SFL Pharma GmbH	07/12/2023	✓				✓				
Livtency	maribavir	Takeda Pharma AG	19/07/2023	✓								
Locametz	Gozetotid	ADVANCED ACCELERATOR	03/03/2023								✓	
Lunsumio	mosunetuzumab	Roche Pharma (Schweiz) AG	09/02/2023	✓			✓	✓				
Lupkynis	Voclosporin	Otsuka Pharmaceutical	24/04/2023	✓								
milgamma	Benfotiamin	Maras AG	06/04/2023						✓			

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** : Prior notification.

† : Conditional approval.

‡ : Access Consortium.

NASs approved by Swissmedic in 2023



Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Exp. rev.*	Prior not.**	Cond. App.†	Art. 13 TPA	Art.14 TPA	Access Cons.‡	Project Orbis	Rolling review
OmvoH	mirikizumab	Eli Lilly (Suisse) SA	30/11/2023							✓		
Pluvicto	Lutetium(177Lu)-vipivotid-Tetraxetan	ADVANCED ACCELERATOR	24/02/2023								✓	
Roclanda	Lantanoprost und Netarsudil	Santen SA	03/10/2023									
Ryeqo	Relugolix, Estradiol, Norethisteron	Gedeon Richter (Schweiz) AG	02/02/2023			✓						
Spaverin	Drotaverin	Target BioScience AG	30/01/2023						✓			
SPEVIGO	spesolimab	Boehringer Ingelheim (Schweiz) GmbH	09/08/2023	✓			✓					
Sunlenca	Lenacapavir	Gilead Sciences Switzerland Sàrl	07/07/2023									
Talvey	talquetamab	Janssen-Cilag AG	30/10/2023	✓			✓				✓	✓
VAFSEO	vadadustat	Voisin Consulting CH Sàrl	19/06/2023							✓		
Veozza	fezolinetant	Astellas Pharma AG	04/12/2023							✓		
Vydura	RIMEGEPANT	Pfizer AG	18/10/2023									
Xenpozyme	olipudase alfa	Sanofi-Aventis (Suisse) SA	19/12/2023	✓	✓							
Zepzelca	lurbinectedin	PharmaMar AG	07/03/2023	✓			✓					

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** : Prior notification.

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‡ : Access Consortium.

NASs approved by TGA in 2023



Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Exp. rev.*	Prov. App.†	COR-A	COR-B	Access Cons.‡	Project Orbis
ALHEMO	concizumab	Novo Nordisk Pharmaceuticals Pty Ltd	03/07/2023	✓	✓				✓	
ANDEXXA	andexanet alfa	ASTRAZENECA PTY LTD	27/06/2023			✓				
COLUMVI	glofitamab	ROCHE PRODUCTS PTY LTD	03/08/2023	✓		✓				
DOPTELET	avatrombopag maleate	Swedish Orphan Biovitrum Pty Ltd	13/01/2023							
ELZONRIS	tagraxofusp	A Menarini Australia Pty Ltd	02/05/2023	✓						
Esperoct	turoctocog alfa pegol	Novo Nordisk Pharmaceuticals Pty Ltd	31/05/2023					✓		
Gavreto	pralsetinib	ROCHE PRODUCTS PTY LTD	29/03/2023			✓				✓
GIVLAARI	givosiran sodium	Alnylam Australia Pty Ltd	16/11/2023	✓				✓		
Idefirix	imlifidase	Hansa Biopharma (Australia) Pty Ltd	07/07/2023	✓		✓				
IMJUDO	tremelimumab	ASTRAZENECA PTY LTD	19/06/2023							
Intrarosa	prasterone	Theramex Australia Pty Ltd	15/06/2023					✓		
JIVI	damoctocog alfa pegol, water for injections	Bayer Australia Ltd	21/03/2023					✓		
KX-01	tirbanibulin	Seqirus Pty Ltd	19/09/2023							
MINJUVI	tafasitamab	Specialised Therapeutics Alim Pty Ltd	19/06/2023	✓		✓				✓
Nurtec ODT	rimegepant sulfate	Pfizer Australia Pty Ltd	17/07/2023					✓		
OmvoH	mirikizumab	Eli Lilly Australia Pty Ltd	26/09/2023						✓	
QULIPTA	atogepant	Allergan Australia Pty Ltd	14/11/2023							
Radicava	Edaravone	Teva Pharma Australia Pty Ltd	17/01/2023	✓						
Retevmo	selpercatinib	Eli Lilly Australia Pty Ltd	27/06/2023			✓				✓
SOHONOS	palovarotene	Ipsen Pty Ltd	27/11/2023	✓						
SPEVIGO	spesolimab	Boehringer Ingelheim Pty Ltd	05/09/2023	✓						
Sunlenca	lenacapavir sodium	Gilead Sciences Pty Ltd	23/03/2023		✓					
TAVNEOS	avacopan	Vifor Pharma Pty Ltd	17/01/2023	✓						

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

†: Provisional approval.

‡: Access Consortium.

NASs approved by TGA in 2023



Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Exp. rev.*	Prov. App.†	COR-A	COR-B	Access Cons.‡	Project Orbis
TECVAYLI	teclistamab	Janssen-Cilag Pty Ltd	02/06/2023			✓				✓
TIBSOVO	ivosidenib	Servier Laboratories (Aust) Pty Ltd	04/04/2023	✓	✓					
VAFSEO	vadadustat	Adjutor Healthcare Pty Ltd	25/09/2023						✓	
Xenpozyme	olipudase alfa	Sanofi-Aventis Australia Pty Ltd	21/08/2023	✓			✓			

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

†: Provisional approval.

‡: Access Consortium.