R&D Briefing 88:New drug approvals in six major authorities 2013-2022

Focus on orphan designation and facilitated regulatory pathways

List of NASs approved by the six regulatory authorities

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CIRS Centre for Innovation in Regulatory Science

NASs approved by EMA in 2022

Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Expedited Review*	Conditional Approval	Exceptional Circumstances	PRIME designation	Rolling review
Amvuttra	vutrisiran sodium	Alnylam Netherlands B.V.	15/09/2022	✓					
Beyfortus	nirsevimab	AstraZeneca AB	31/10/2022		✓			✓	
Breyanzi	CD19-directed genetically modified autologous cell-based product consisting of purified CD8+ T-cells (CD8+ cells), CD19-directed genetically modified autologous cell-based product consisting of purified CD4+ T cells (CD4+ cells)	Bristol-Myers Squibb Pharma EEIG	04/04/2022					✓	
Carvykti	ciltacabtagene autoleucel	Janssen-Cilag International NV	25/05/2022	✓		✓		✓	
Ebvallo	Tabelecleucel	Pierre Fabre Medicament	16/12/2022	✓			✓	✓	
Eladynos	abaloparatide	Radius Health Ireland Ltd	12/12/2022						
Enjaymo	sutimlimab	Genzyme Europe BV	15/11/2022	✓					
Evusheld	TIXAGEVIMAB, CILGAVIMAB	AstraZeneca AB	25/03/2022						✓
Kapruvia	difelikefalin	Vifor Fresenius Medical Care Renal Pharma France	25/04/2022						
Kerendia	finerenone	Bayer AG	16/02/2022						
Kimmtrak	tebentafusp	IMMUNOCORE IRELAND LIMITED	01/04/2022	✓	✓				
Livmarli	Maralixibat chloride	Mirum Pharmaceuticals International B.V.	09/12/2022	✓			✓		
Livtencity	maribavir	Takeda Pharmaceuticals International AG Ireland Branch	09/11/2022	✓					
Locametz	gozetotide	Novartis Europharm Limited	09/12/2022						
Lumykras	sotorasib	Amgen Europe BV	06/01/2022			✓			

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

NASs approved by EMA in 2022

Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Expedited Review*	Conditional Approval	Exceptional Circumstances	PRIME designation	Rolling review
Lunsumio	mosunetuzumab	Roche Registration GmbH	03/06/2022	✓	✓	✓			
Lupkynis	Voclosporin	Otsuka Pharmaceutical Netherlands B.V.	15/09/2022						
Mounjaro	tirzepatide	Eli Lilly Nederland B.V.	15/09/2022						
Nexviadyme	avalglucosidase alfa	Genzyme Europe BV	24/06/2022						
Ngenla	somatrogon	Pfizer Europe MA EEIG	14/02/2022	✓					
Nulibry	fosdenopterin hydrobromide dihydrate	Comharsa Life Sciences Ltd	15/09/2022	✓					
Opdualag	nivolumab, relatlimab	Bristol-Myers Squibb Pharma EEIG	15/09/2022						
Oxbryta	Voxelotor	Global Blood Therapeutics Netherlands B. V.	14/02/2022	✓				✓	
Padcev	enfortumab vedotin	Astellas Pharma Europe B.V.	13/04/2022						
Paxlovid	nirmatrelvir, ritonavir	Pfizer Europe MA EEIG	28/01/2022			✓			✓
Pluvicto	LUTETIUM (177LU) VIPIVOTIDE TETRAXETAN	Novartis Europharm Limited	09/12/2022						
Pyrukynd	mitapivat sulfate	Agios Netherlands B.V.	09/11/2022	✓					
Quviviq	daridorexant hydrochloride	Idorsia Pharmaceuticals Deutschland GmbH	29/04/2022						
Rayvow	lasmiditan succinate	Eli Lilly Nederland B.V.	17/08/2022						
Roctavian	valoctocogene roxaparvovec	BIOMARIN INTERNATIONAL LIMITED	24/08/2022	✓		✓		✓	
Saphnelo	anifrolumab	AstraZeneca AB	14/02/2022						
Scemblix	asciminib hydrochloride	Novartis Europharm Limited	25/08/2022	✓					
Skytrofa	Lonapegsomatropin	Ascendis Pharma Endocrinology Division A/S	11/01/2022	✓					
Spevigo	Spesolimab	Boehringer Ingelheim International GmbH	09/12/2022			✓			

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NASs approved by EMA in 2022

Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Expedited Review*	Conditional Approval	Exceptional Circumstances	PRIME designation	Rolling review
Sunlenca	Lenacapavir sodium	Gilead Sciences Ireland Unlimited Company	17/08/2022						
Tabrecta	capmatinib dihydrochloride monohydrate	Novartis Europharm Limited	20/06/2022						
Tavneos	AVACOPAN	Vifor Fresenius Medical Care Renal Pharma France	11/01/2022	✓				✓	
Tecovirimat SIGA	Tecovirimat	SIGA Technologies Netherlands B.V.	06/01/2022						
Tecvayli	Teclistamab	Janssen-Cilag International N.V.	23/08/2022		✓	✓		✓	
Tepmetko	tepotinib hydrochloride monohydrate	Merck Europe B.V.	16/02/2022						
Tezspire	TEZEPELUMAB	AstraZeneca AB	19/09/2022						
Uplizna	Inebilizumab	Horizon Therapeutics Ireland DAC	25/04/2022						
Upstaza	Eladocagene exuparvovec	PTC Therapeutics International Limited	18/07/2022	✓			✓		
Vabysmo	faricimab	Roche Registration GmbH	15/09/2022						
Voraxaze	glucarpidase	SERB SAS	11/01/2022	✓			✓		
Vydura	Rimegepant	Pfizer Europe MA EEIG	25/04/2022						
Vyepti	eptinezumab	H. Lundbeck A/S	24/01/2022						
Vyvgart	Efgartigimod alfa	Argenx	10/08/2022	✓					
Xenpozyme	Olipudase alfa	Genzyme Europe BV	24/06/2022	✓	✓			✓	
Yselty	linzagolix choline	ObsEva Ireland Ltd	14/06/2022						
Zokinvy	Lonafarnib	EigerBio Europe Limited	18/07/2022	✓			✓		
Zynlonta	loncastuximab tesirine	ADC Therapeutics (NL) B.V	20/12/2022	✓		✓			

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

NASs approved by FDA in 2022

Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Exp. rev.*	Accel. App.**	Break. desig.†	Fast track	RTOR‡	Project Orbis	Rolling review
Adstiladrin	nadofaragene firadenovec	Ferring Pharmaceuticals A/S	16/12/2022		✓		✓	✓			✓
Amvuttra	vutrisiran	Alnylam Pharmaceuticals, Inc	13/06/2022	✓				✓			
Briumvi	ublituximab-xiiy	TG Therapeutics, Inc.	28/12/2022								
Camzyos	mavacamten	MyoKardia, Inc	28/04/2022	✓			✓				
Carvykti	ciltacabtagene autoleucel	Janssen Biotech, Inc.	28/02/2022	✓	✓		✓				
Cibinqo	ABROCITINIB	Pfizer Inc	14/01/2022		✓		✓				✓
Elahere	mirvetuximab soravtansine-gynx	ImmunoGen, Inc	14/11/2022	✓	✓	✓		✓			
Elucirem	gadopiclenol	Guerbet LLC	21/09/2022		✓						
Enjaymo	sutimlimab-jome	Bioverativ USA Inc.	04/02/2022	✓	✓		✓				✓
Hemgenix	etranacogene dezaparvovec-drlb	CSL Behring LLC	22/11/2022	✓	✓		✓				
Imjudo	tremelimumab-actl	AstraZeneca AB	21/10/2022	✓	✓						
Kimmtrak	tebentafusp-tebn	Immunocore Limited	25/01/2022	✓	✓		✓	✓		✓	✓
Krazati	adagrasib	Mirati Therapeutics, Inc.	12/12/2022	✓		✓	✓	✓	✓		✓
Locametz	gallium Ga-68 gozetotide	Advanced Accelerator Applications USA, Inc	23/03/2022								
Lunsumio	mosunetuzumab-axgb	Genentech, Inc	22/12/2022	✓	✓	✓	✓				✓
Lytgobi	futibatinib	Taiho Oncology, Inc.	30/09/2022	✓	✓	✓	✓	✓		✓	✓
Mounjaro	tirzepatide	Eli Lilly and Company	13/05/2022		✓						
Omlonti	Omidenepag isopropyl	Santen, Inc	22/09/2022								
Opdualag	nivolumab and relatlimab-rmbw	Bristol-Myers Squibb Company	18/03/2022	✓	✓			✓	✓	✓	
Pluvicto	lutetium Lu 177 vipivotide tetraxetan	Advanced Accelerator Applications USA, Inc	23/03/2022		✓		✓			✓	
Pyrukynd	mitapivat	Agios Pharmaceuticals, Inc	17/02/2022	✓	✓			✓			
Quviviq	Daridorexant	Idorsia Pharmaceuticals Ltd.	07/01/2022								
Relyvrio	sodium phenylbutyrate and taurursodiol	Amylyx Pharmaceuticals, Inc.	29/09/2022	✓	✓						

*: *'Expedited review' refers to FDA/PMDA/Health Canada/Swissmedic/TGA 'Priority Review'.*
**: *Accelerated approval.*
†: *Breakthrough designation.*
‡: *Real-time oncology review.*

NASs approved by FDA in 2022

Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Exp. rev.*	Accel. App.**	Break. desig.†	Fast track	RTOR‡	Project Orbis	Rolling review
Rezlidhia	olutasidenib	Forma Therapeutics, Inc.	01/12/2022	✓							
Rolvedon	eflapegrastim-xnst	Spectrum Pharmaceuticals, Inc.	09/09/2022								
Skysona	elivaldogene autotemcel	Bluebird Bio, Inc.	16/09/2022	✓	✓	✓	✓				✓
Sotyktu	deucravacitinib	Bristol-Myers Squibb Company	09/09/2022								
Spevigo	spesolimab-sbzo	Boehringer Ingelheim Pharmaceuticals, Inc	01/09/2022	✓	✓		✓				
Sunlenca	lenacapavir	Gilead Sciences, Inc	22/12/2022		✓		✓	✓			
Tecvayli	teclistamab-cqyv	Janssen Biotech, Inc	25/10/2022	✓	✓	✓	✓			✓	
Terlivaz	Terlipressin	Mallinckrodt Pharmaceuticals Ireland Ltd	14/09/2022	✓	✓			✓			✓
Tzield	teplizumab-mzwv	Provention Bio, Inc	17/11/2022		✓		✓				✓
Vabysmo	faricimab-svoa	Genentech, Inc	28/01/2022		✓						
Vivjoa	oteseconazole	Mycovia Pharmaceuticals, Inc	26/04/2022		✓			✓			
Vonjo	pacritinib	CTI BioPharma Corp	28/02/2022	✓	✓	✓		✓			✓
Voquezna Triple Pak	vonoprazan, amoxicillin, clarithromycin	Phathom Pharmaceuticals, Inc.	03/05/2022		✓			✓			
Vtama	tapinarof	Dermavant Sciences, Inc.	23/05/2022								
Xenoview	hyperpolarized Xe-129	Polarean Inc.	23/12/2022								
Xenpozyme	olipudase alfa-rpcp	Genzyme Corporation	31/08/2022	✓	✓		✓	✓			✓
Ztalmy	ganaxolone	Marinus Pharmaceuticals, Inc	18/03/2022	✓	✓						
Zynteglo	betibeglogene autotemcel	Bluebird Bio, Inc.	17/08/2022	✓	✓		✓	✓			✓

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**: *Accelerated approval.*
†: *Breakthrough designation.*
‡: *Real-time oncology review.*

NASs approved by PMDA in 2022

Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Expedited review*	Sakigake	Conditional early approval
Adtralza	Tralokinumab (genetical recombination)	LEO Pharma KK	23/12/2022				
Amvuttra Subcutaneous Injection 25 mg Syringe (Alnylam Japan, K.K.)	vutrisiran sodium	Alnylam Japan, K.K.	26/09/2022	✓	✓		
Arokaris	Fosnetupitant chloride hydrochloride	Taiho Pharmaceutical Co., Ltd.	28/03/2022				
Bimzelx	Bimekizumab (genetical recombination)	UCB Japan Co., Ltd.	20/01/2022				
Cablivi Injection 10 mg (Sanofi K.K.)	Caplacizumab (genetical recombination)	Sanofi K.K.	26/09/2022	✓	✓		
Carogra	Carotegrast methyl	EA Pharma Co., Ltd.	28/03/2022				
CRESEMBA	ISAVUCONAZONIUM SULFATE	Asahi Kase Pharma KK	23/12/2022				
Darvias	Darinaparsin	Solasia Pharma K.K.	20/06/2022				
Dysval	Valbenazine tosilate	MITSUBISHI TANABE PHARMA CORPORATION	28/03/2022				
Enjaymo	Sutimlimab (genetical recombination)	Sanofi	20/06/2022	✓	✓		
Ezharmia Tablets 50 mg Ezharmia Tablets 100 mg (Daiichi Sankyo Company, Limited)	Valemetostat tosilate	Daiichi Sankyo Company, Limited	26/09/2022	✓	✓		
Imjudo	Tremelimumab (genetical recombination)	AstraZeneca K.K.	23/12/2022				
Jeselhy	Pimitespib	Taiho Pharmaceutical Co., Ltd.	20/06/2022				
Kerendia	finerenone	Bayer Yakuhin, Ltd.	28/03/2022				
Koselugo Capsules 10 mg Koselugo Capsules 25 mg (Alexion Pharma GK)	Selumetinib sulfate	Alexion Pharma GK	26/09/2022	✓	✓		

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NASs approved by PMDA in 2022

Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Expedited review*	Sakigake	Conditional early approval
LIBTAYO	Cemiplimab (genetical recombination)	Sanofi K.K.	23/12/2022				
Lumakras	sotorasib	Amgen K.K.	20/01/2022	✓	✓		
Lyfnua	Gefapixant citrate	MSD K.K.	20/01/2022				
Mepsevii	Vestronidase alfa (genetical recombination)	Amicus Therapeutics, Inc.	20/01/2022	✓	✓		
Mitchga	Nemolizumab (genetical recombination)	Maruho Co., Ltd.	28/03/2022				
Mounjaro	tirzepatide	Eli Lilly Japan K.K.	26/09/2022				
Nanozora 30 mg Syringes for S.C. Injection (Taisho Pharmaceutical Co., Ltd.)	Ozoralizumab (genetical recombination)	Taisho Pharmaceutical Co., Ltd.	26/09/2022				
Ngenla	Somatrogon (genetical recombination)	Pfizer Japan inc	20/01/2022				
Ondexxya	Andexanet alfa (genetical recombination)	Alexion Pharma G.K.	28/03/2022	✓	✓		
Pivlaz	Clazosentan sodium	Idorsia Pharmaceuticals Japan Ltd.	20/01/2022				
Reyvow	lasmiditan succinate	Eli Lilly Japan K.K.	20/01/2022				
Scemblix	asciminib hydrochloride	Novartis Pharma K.K.	28/03/2022	✓	✓		
Sotyktu	deucravacitinib	Bristol-Myers Squibb K.K.	26/09/2022				
Spevigo 450 mg for I.V. Infusion (Nippon Boehringer Ingelheim Co., Ltd.)	Spesolimab (genetical recombination)	Nippon Boehringer Ingelheim Co., Ltd.	26/09/2022				
TAKHZYRO	Lanadelumab (genetical recombination)	Takeda Pharmaceutical Company Limited	28/03/2022	✓	✓		
Tavalisse	Fostamatinib Sodium Hydrate	Kissei Pharma KK	23/12/2022	✓	✓		
Tezspire Subcutaneous Injection 210 mg Syringe (AstraZeneca K.K.)	Tezepelumab (genetical recombination)	AstraZeneca K.K.	26/09/2022				
Vabysmo	Faricimab (genetical recombination)	Chugai Pharmaceutical Co., Ltd.	28/03/2022				

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NASs approved by PMDA in 2022

Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Expedited review*	Sakigake	Conditional early approval
Vocabria	cabotegravir	ViiV Healthcare K.K.	31/05/2022	✓	✓		
Voxzogo	Vosoritide (genetical recombination)	BioMarin Pharmaceutical K.K	20/06/2022	✓	✓		
Vyalev	Foslevodopa/Fos carbidopa Hydrate	Abbie	23/12/2022				
Vyvgart	Efgartigimod alfa (genetical recombination)	Argenx Japan K.K.	20/01/2022	✓	✓		
Xenpozyme	Olipudase alfa (genetical recombination)	Sanofi K.K.	28/03/2022	✓	✓	✓	

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NASs approved by Health Canada in 2022

Brand Name	Generic Name	Sponsor	Approval Date	Expedited review.*	Conditional approval	Access Consortium	Project Orbis	Rolling review
Albrioza	SODIUM PHENYLBUTYRATE, URSODOXICOLTAURINE	AMYLYX PHARMACEUTICALS INC.	10/06/2022		✓			
Bimzelx	bimekizumab	UCB CANADA INC	14/02/2022					
Breyanzi	LISOCABTAGENE MARALEUCEL	CELGENE INC	06/05/2022					
Camzyos	mavacamten	BRISTOL-MYERS SQUIBB CANADA	08/11/2022					
Cibinqo	ABROCITINIB	PFIZER CANADA ULC	29/06/2022					
Empaveli	pegcetacoplan	SWEDISH ORPHAN BIOVITRUM AB (PUBL)	08/12/2022	✓				
Evusheld	TIXAGEVIMAB, CILGAVIMAB	astrazeneca canada inc	14/04/2022		✓			✓
Illuccix	GALLIUM (68GA) GOZETOTIDE	TELIX PHARMACEUTICALS (US) INC	13/10/2022					
Kerendia	finerenone	bayer inc	14/10/2022					
Kimmtrak	tebentafusp	IMMUNOCORE IRELAND LIMITED	07/06/2022	✓			✓	
Korsuva	DIFELIKEFALIN (SUPPLIED AS DIFELIKEFALIN ACETATE)	VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA LTD	16/08/2022			✓		
Koselugo	SELUMETINIB (AS SELUMETINIB SULFATE)	astrazeneca canada inc	31/08/2022				✓	
Livtencity	maribavir	TAKEDA CANADA INC	15/09/2022	✓				
Mounjaro	tirzepatide	Eli Lilly Canada Inc	24/11/2022			✓		
Netvision	GALLIUM 68 GA OXODOTREOTIDE	CANADIAN MOLECULAR IMAGING PROBE CONSORTIUM (CANPROBE)	24/02/2022					
Orladeyo	BEROTRALSTAT (SUPPLIED AS BEROTRALSTAT HYDROCHLORIDE)	BIOCRYST PHARMACEUTICALS INC	02/06/2022					
Oxlumo	LUMASIRAN (SUPPLIED AS LUMASIRAN SODIUM)	Alnylam Netherlands B.V.	07/03/2022	✓				
Palynziq	pegvaliase	BIOMARIN INTERNATIONAL LIMITED	30/03/2022					
Paxlovid	RITONAVIR, NIRMATRELVIR	PFIZER CANADA ULC	17/01/2022					✓

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NASs approved by Health Canada in 2022

Brand Name	Generic Name	Sponsor	Approval Date	Expedited review.*	Conditional approval	Access Consortium	Project Orbis	Rolling review
Pluvicto	LUTETIUM (177LU) VIPIVOTIDE TETRAXETAN	ADVANCED ACCELERATOR APPLICATIONS USA, INC.	25/08/2022	✓			✓	
Poteligeo	mogamulizumab	KYOWA KIRIN, INC.	02/06/2022					
Qulipta	ATOGEPANT	ABBVIE CORPORATION	22/12/2022					
Rholistiq	BELUMOSUDIL (SUPPLIED AS LUMASIRAN MESYLATE)	KADMON PHARMACEUTICALS LLC	23/03/2022	✓			✓	
Rybrevant	amivantamab	JANSSEN INC	30/03/2022		✓		✓	
Scemblix	ASCIMINIB (SUPPLIED AS LUMASIRAN HYDROCHLORIDE)	Novartis Pharmaceuticals Canada Inc	22/06/2022			✓		
Sohonos	PALOVAROTENE	IPSEN BIOPHARMACEUTICALS CANADA INC	21/01/2022	✓				
Sotyktu	deucravacitinib	BRISTOL-MYERS SQUIBB CANADA	24/11/2022					
Sunlenca	LENACAPAVIR (SUPPLIED AS LENACAPAVIR SODIUM)	gilead sciences canada inc	02/11/2022	✓				
Tabrecta	CAPMATINIB (SUPPLIED AS CAPMATINIB HYDROCHLORIDE)	Novartis Pharmaceuticals Canada Inc	26/05/2022		✓		✓	
Tavneos	AVACOPAN	VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA LTD	14/04/2022			✓		
Tezspire	TEZEPELUMAB	astrazeneca canada inc	28/07/2022					
Ubrelvy	UBROGEPANT	ABBVIE CORPORATION	10/11/2022					
Vabysmo	faricimab	Hoffmann-La Roche Limited	27/05/2022			✓		
Vraylar	CARIPRAZINE (SUPPLIED AS CARIPRAZINE HYDROCHLORIDE)	ALLERGAN INC	22/04/2022					
Welireg	belzutifan	MERCK CANADA INC	11/07/2022				✓	
Xpovio	selinexor	FORUS THERAPEUTICS INC	31/05/2022					

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NASs approved by Swissmedic in 2022

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
Adtralza	tralokinumab	Leo Pharmaceutical Products Sarath Ltd.	24/02/2022									
Bimzelx	bimekizumab	UCB-Pharma SA	27/10/2022									
Blenrep	belantamab mafodotin	GlaxoSmithKline AG	20/06/2022	✓			✓					
Breyanzi	LISOCABTAGENE MARALEUCEL	Celgene GmbH	28/03/2022	✓								
Brukinsa	zanubrutinib	Beigene Switzerland Gmbh	08/02/2022	✓				✓				
Carvykti	ciltacabtagene autoleucel	Janssen-Cilag AG	08/08/2022	✓	✓							
Cibinqo	ABROCITINIB	Pfizer AG	05/04/2022							✓		
Drovelis	Drospirenone, estetrol	Gedeon Richter (Schweiz) AG	05/05/2022									
Evusheld	TIXAGEVIMAB, CILGAVIMAB	AstraZeneca AG	09/09/2022				✓					
Exkivity	Mobocertinib	Takeda Pharma AG	01/06/2022	✓			✓				✓	
Idefirix	imlifidase	Voisin Consulting CH Sàrl	06/05/2022	✓			✓	✓				
Jemperli	dostarlimab	GlaxoSmithKline AG	17/02/2022			✓	✓					
Kapruvia	difelikefalin	Vifor Fresenius Medical Care	16/08/2022							✓		
Klisyri	tirbanibulin	Almirall AG	03/02/2022									
Koselugo	selumetinib	AstraZeneca AG	29/07/2022	✓			✓	✓				
Lamzede	velmanase alfa	Chiesi SA	26/08/2022	✓			✓					
Lyfnua	Gefapixant	MSD Merck Sharp & Dohme AG	24/05/2022			✓						
Minjuvi	tafasitamab	Incyte Biosciences International	22/03/2022	✓			✓				✓	
Mounjaro	tirzepatide	Eli Lilly (Suisse) SA	02/11/2022							✓		
Ngenla	somatrogon	Pfizer AG	09/09/2022	✓								
Nityr	Nitisinone	Curatis AG	24/01/2022	✓					✓			
Ontozry	cenobamate	Arvelle Therapeutics International GmbH	19/05/2022			✓						
Opdualag	nivolumab, relatlimab	Bristol-Myers Squibb SA	23/12/2022								✓	✓
Orladeyo	berotralstat	BioCryst Schweiz GmbH	07/06/2022	✓				✓				

*: *'Expedited review' refers to FDA/PMDA/Health Canada/Swissmedic/TGA 'Priority Review'.*
**: *Prior notification.*
†: *Conditional approval.*
‡: *Access Consortium.*

NASs approved by Swissmedic in 2022

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
Paxlovid	PF-07321332, ritonavir	Pfizer AG	15/06/2022				✓					✓
Quviviq	Daridorexant	Idorsia Pharmaceuticals Ltd	01/12/2022									
Rapibloc	Landiolol	OrPha Swiss GmbH	19/10/2022									
Regkirona	regdanvimab	IQONE HEALTHCARE SWITZERLAND	12/01/2022				✓					✓
Rybrevant	amivantamab	Janssen-Cilag AG	20/01/2022		✓		✓					
Saphnelo	anifrolumab	AstraZeneca AG	31/08/2022									
Scemblix	Asciminib	Novartis Pharma Schweiz AG	09/06/2022	✓						✓		
Sunosi	solriamfetol	Clinipace AG	22/03/2022									
Tavneos	AVACOPAN	Vifor Fresenius Medical Care	19/09/2022	✓						✓		
Tecvayli	Teclistamab	Janssen-Cilag AG	22/12/2022	✓			✓				✓	✓
Tenkasi	oritavancin	A. Menarini GmbH	07/04/2022									
Tezspire	TEZEPELUMAB	AstraZeneca AG	13/06/2022		✓							
Vabysmo	faricimab	Roche Pharma (Schweiz) AG	25/05/2022							✓		
Vazkepa	icosapent ethyl	Amarin Switzerland GmbH	22/11/2022									
Xevudy	sotrovimab	GlaxoSmithKline AG	14/01/2022				✓					✓

*: *'Expedited review' refers to FDA/PMDA/Health Canada/Swissmedic/TGA 'Priority Review'.*
**: *Prior notification.*
†: *Conditional approval.*
‡: *Access Consortium.*

NASs approved by TGA in 2022

Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Exp. rev.*	Prov. App.†	COR-A	COR-B	Access Cons.‡	Project Orbis
Bimzelx	bimekizumab	UCB Australia Pty Ltd T/A UCB Pharma Division of UCB Australia	17/03/2022							
Camzyos	mavacamten	BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD	15/09/2022							
Empaveli	pegcetacoplan	Apellis Australia Pty Ltd	28/01/2022	✓						
Evusheld	cilgavimab, tixagevimab	ASTRAZENECA PTY LTD	24/02/2022			✓				
Exkivity	mobocertinib succinate	Takeda Pharmaceuticals Australia Pty Ltd	14/07/2022			✓				✓
Isturisa	osilodrostat phosphate	Recordati Rare Diseases Australia Pty Ltd	06/05/2022	✓				✓		
Jemperli	dostarlimab	GlaxoSmithKline Australia Pty Ltd	15/02/2022			✓				
Kimmtrak	tebentafusp	Adjutor Healthcare Pty Ltd	27/05/2022	✓	✓					✓
Korsuva	difelikefalin acetate	Vifor Pharma Pty Ltd	09/11/2022						✓	
Lagevrio	molnupiravir	MERCK SHARP & DOHME (AUSTRALIA) PTY LTD	18/01/2022			✓				
Livtencity	maribavir	Takeda Pharmaceuticals Australia Pty Ltd	27/09/2022	✓	✓					
Lumakras	sotorasib	Amgen Australia Pty Ltd	28/03/2022	✓		✓				✓
Mounjaro	tirzepatide	Eli Lilly Australia Pty Ltd	22/12/2022						✓	
Onpattro	patisiran	Alnylam Australia Pty Ltd	18/11/2022	✓				✓		
Opdualag	nivolumab, relatlimab	BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD	05/10/2022							✓
Padcev	enfortumab vedotin	Astellas Pharma Australia Pty Ltd	30/06/2022							✓
Paxlovid	nirmatrelvir, ritonavir	Pfizer Australia Pty Ltd	18/01/2022			✓				
Pemazyre	pemigatinib	Specialised Therapeutics Alim Pty Ltd	12/09/2022	✓		✓				
Ponvory	ponesimod	Janssen-Cilag Pty Ltd	07/03/2022				✓			
Rybrevant	amivantamab	Janssen-Cilag Pty Ltd	28/11/2022			✓				✓
Ryeqo	estradiol, norethisterone acetate, relugolix	Gedeon Richter Australia Pty Ltd	31/08/2022							

*: *'Expedited review' refers to FDA/PMDA/Health Canada/Swissmedic/TGA 'Priority Review'.*
†: *Provisional approval.*
‡: *Access Consortium.*

NASs approved by TGA in 2022

Brand Name	Generic Name	Sponsor	Approval Date	Orphan	Exp. rev.*	Prov. App.†	COR-A	COR-B	Access Cons.‡	Project Orbis
Saphnelo	anifrolumab	ASTRAZENECA PTY LTD	24/03/2022							
Scemblix	asciminib hydrochloride	Novartis Pharmaceuticals Australia Pty Ltd	14/07/2022						✓	
Sogroya	somapacitan	Novo Nordisk Pharmaceuticals Pty Ltd	14/02/2022					✓		
Sotyktu	deucravacitinib	BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD	29/11/2022							
Tepmetko	tepotinib hydrochloride monohydrate	Merck Healthcare Pty Ltd	10/01/2022	✓		✓				✓
Trecondi	treosulfan	Link Medical Products Pty Ltd T/A Link Pharmaceuticals	19/09/2022	✓						
Vabysmo	faricimab	ROCHE PRODUCTS PTY LTD	04/08/2022						✓	
Vazkepa	icosapent ethyl	AA-Med Pty Ltd	02/11/2022					✓		
Voxzogo	vosoritide	BioMarin Pharmaceutical Australia Pty Ltd	29/06/2022	✓			✓			
Vumerity	diroximel fumarate	Biogen Australia Pty Ltd	18/03/2022							
Welireg	belzutifan	MERCK SHARP & DOHME (AUSTRALIA) PTY LTD	20/12/2022	✓		✓				✓
Xpovio	selinexor	Antengene (AUS) PTY LTD	03/03/2022							

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†: *Provisional approval.*
‡: *Access Consortium.*

About CIRS

Mission

To maintain a leadership role in identifying and applying scientific principles for the purpose of advancing regulatory and health technology assessment (HTA) policies and processes in developing and facilitating access to pharmaceutical products

How we operate

The Centre for Innovation in Regulatory Science (CIRS) is a neutral, independently managed UK-based subsidiary of Clarivate plc. We operate as a not-for-profit organisation, deriving funding from membership dues, special projects and grants to cover our operating and research costs.

We are governed by our own dedicated advisory boards made up of external international experts from academia, industry, regulatory agencies and HTA bodies. Our Scientific Advisory Council (SAC) and HTA Steering Committee advise on workshop topics and content, as well as our research programme.

What makes us unique

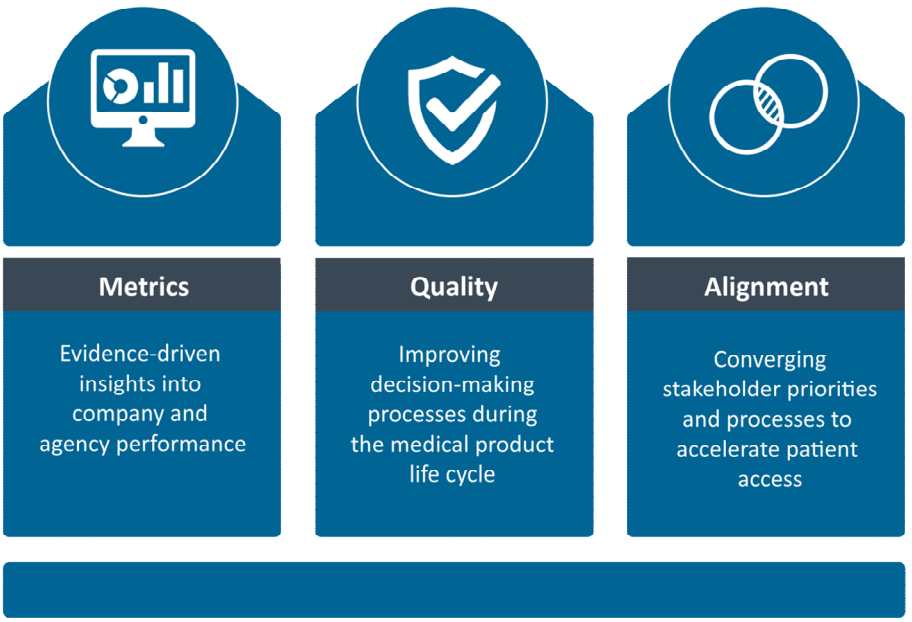
What sets us apart is our ability to bring **global** industry, regulators, HTA bodies, payers and academics together in a **neutral** atmosphere to identify and address key issues in the development, licensing and reimbursement of new medicines. We have been doing this for over 35 years through **focused** meetings and collaborative research.

Our workshops have consistently received positive feedback ratings of over 90% and resulted in recommendations that inform strategic and policy level thinking. The strong support for our research as well as attendance in meetings demonstrates the trust and confidence our stakeholders have in us.

We are also **evidence-driven** and **transparent** in our work. The data we collect are used to support our workshops and we endeavour to make these publicly available through peer-reviewed journals or our R&D Briefings.

Our small but dedicated team of experienced scientists strive to ensure that the needs and priorities of our stakeholders are at the heart of CIRS activities. Our door is always open to new ideas and suggestions that fit with our mission.

Three pillars of CIRS activities



Metrics - evidence-driven insights into company and agency performance

CIRS provides unique insights and an independent viewpoint on the performance of companies, regulatory and HTA agencies through its metrics programmes. Data are collected and analysed to give a better understanding of regulatory and HTA assessment times and evidentiary requirements. This form of benchmarking details regulatory and HTA processes and practices, identifies where improvements can be made and informs company and agency strategies.

Quality– improving decision-making processes during the medical product life cycle

CIRS works with companies and agencies to evaluate the quality of their processes, identify challenges, and implement best practices. Tools developed from these projects support decision-making practices and their documentation in general or are specific to areas such as benefit-risk assessment. The aim is to foster learning and improve transparency, predictability and consistency of critical decisions during development, regulatory review and health technology assessment.

Alignment – converging stakeholder priorities and processes to accelerate patient access

Through collaborative research projects and multi-stakeholder workshops, CIRS promotes harmonisation and alignment across HTA agencies and regulators, as well as between HTA agencies and regulators themselves. Not only does this facilitate capacity building but also helps to enable more efficient and effective development of medicines.

Meet the CIRS team

Anna Somuyiwa

Head

Dr Neil McAuslane

Director

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Senior Manager, Regulatory Programme and Strategic Partnerships

Dr Tina Wang

Senior Manager, HTA Programme and Strategic Partnerships

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Founder and Senior Advisor*

Dr Lawrence Liberti

Senior Advisor*

Dr Mario Alanis

Senior Consultant*

*working on a contractual basis on region-specific CIRS projects

The Centre for Innovation in Regulatory Science (CIRS) is a neutral, independently managed UK-based subsidiary of Clarivate plc. Its mission is to maintain a leadership role in identifying and applying scientific principles for the purpose of advancing regulatory and health technology assessment (HTA) policies and processes. 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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