New Active Substances (NASs) approved by six major authorities in 2020

Prepared by:

Magda Bujar, PhD, Manager, Strategic Development

Neil McAuslane, PhD, Scientific Director

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Centre for Innovation in Regulatory Science (CIRS)
Friars House
160 Blackfriars Road
London
SE1 8EZ
UK
Email: cirs@cirsci.org
Website: www.cirsci.org
Follow us on LinkedIn

CIRS Centre for Innovation in Regulatory Science

EMA NAS approvals in 2020

Brand Name	Generic Name	Sponsor	Approval Date	Expedited Review*	Orphan	Exceptional Circumstances	Conditional Approval	PRIME designation
Adakveo	crizanlizumab	Novartis Europharm Limited	28/10/2020					
Ayvakyt	avapritinib	Blueprint Medicines (Netherlands) B.V.	24/09/2020					
Beovu	brolucizumab	Novartis Europharm Limited	13/02/2020					
Blenrep	belantamab mafodotin	GlaxoSmithKline (Ireland) Limited	25/08/2020					
Calquence	acalabrutinib	AstraZeneca AB	05/11/2020					
Daurismo	glasdegib	Pfizer Europe MA EEIG	26/06/2020					
Fetcroja	cefiderocol	Shionogi B.V.	23/04/2020					
Givlaari	givosiran	Alnylam Netherlands B.V.	02/03/2020					
Hepcludex	bulevirtide	MYR GmbH	31/07/2020					
Idefirix	imlifidase	Hansa Biopharma AB	25/08/2020					
Isturisa	osilodrostat	Recordati Rare Diseases	09/01/2020					
Jyseleca	filgotinib	Gilead Sciences Ireland UC	24/09/2020					
Kaftrio	ivacaftor, tezacaftor, elexacaftor	Vertex Pharmaceuticals (Ireland) Limited	21/08/2020					
Leqvio	Inclisiran	Novartis Europharm Limited	09/12/2020					
Libmeldy	Autologous CD34+ cells encoding ARSA gene	Orchard Therapeutics (Netherlands) BV	17/12/2020					
Mayzent	siponimod	Novartis Europharm Limited	13/01/2020					
Nubeqa	darolutamide	Bayer AG	27/03/2020					
Nustendi	bempedoic acid, ezetimibe	Daiichi Sankyo Europe GmbH	27/03/2020					
Obiltoxaximab SFL	obiltoxaximab	SFL Pharmaceuticals Deutschland GmbH	18/11/2020					
Oxlumo	Lumasiran	Alnylam Netherlands B.V.	19/11/2020					
Piqray	alpelisib	Novartis Europharm Limited	27/07/2020					
Polivy	polatuzumab vedotin	Roche Registration GmbH	16/01/2020					
Pretomanid FGK	pretomanid	FGK Representative Service GmbH	31/07/2020					

**Expedited review refers to EMA Accelerated Assessment*

EMA NAS approvals in 2020

Brand Name	Generic Name	Sponsor	Approval Date	Expedited Review*	Orphan	Exceptional Circumstances	Conditional Approval	PRIME designation
Reblozyl	luspatercept	Celgene Europe B.V.	25/06/2020					
Recarbrio	imipenem, cilastatin, relebactam	Merck Sharp & Dohme B.V.	13/02/2020					
Rozlytrek	entrectinib	Roche Registration GmbH	31/07/2020					
Sarclisa	isatuximab	sanofi-aventis groupe	30/05/2020					
Staquis	crisaborole	Pfizer Europe MA EEIG	27/03/2020					
Sunosi	solriamfetol	Jazz Pharmaceuticals Ireland Limited	16/01/2020					
Tavlesse	fostamatinib	Instituto Grifols S.A.	09/01/2020					
Veklury	remdesivir	Gilead Sciences Ireland UC	03/07/2020					
Vocabria	cabotegravir	ViiV Healthcare B.V.	17/12/2020					
Xenleta	lefamulin	Nabriva Therapeutics Ireland DAC	27/07/2020					
Zeposia	ozanimod	Bristol-Myers Squibb Pharma EEIG	20/05/2020					
Zolgensma	onasemnogene abeparvovec	Novartis Gene Therapies EU Limited	18/05/2020					

**Expedited review refers to EMA Accelerated Assessment*

FDA NAS approvals in 2020

Brand Name	Generic Name	Sponsor	Approval Date	Expedited Review*	Orphan	Fast Track	Break-through	Accelerated Approval	RTOR	Project Orbis
Ayvakit	avapritinib	Blueprint Medicines Corporation	09/01/2020							
Blenrep	belantamab mafodotin-blmf	GlaxoSmitKline Intellectual Property Development Ltd. England	05/08/2020							
Byfavo	remimazolam besylate	Cosmo Technologies, Ltd.	02/07/2020							
Cerianna	fluoroestradiol F18	Zionexa-US Corporation	20/05/2020							
Danyelza	naxitamab-gqgk	Y-mAbs Therapeutics, Incorporated	25/11/2020							
Detectnet	copper Cu 64 dotatate injection	RadioMedix,Inc	03/09/2020							
Dojolvi	triheptanoin	Ultraenyx Pharmaceutical Inc	30/06/2020							
Ebanga	ansuvimab-zykl	Ridgeback Biotherapeutics, LP	21/12/2020							
Enspryng	satralizumab-mwge	Genentech, Inc	14/08/2020							
Evrysdi	risdiplam	Genentech, Inc	07/08/2020							
Gavreto	pralsetinib	Blueprint Medicines Corporation	04/09/2020							
Gemtesa	vibegron	Urovant Sciences GmbH	23/12/2020							
Imcivree	setmelanotide	Rhythm Pharmaceuticals, Inc.	25/11/2020							
Inmazeb	atoltivimab, maftivimab, and odesivimab-ebgn	Regeneron Pharmaceuticals, Inc	14/10/2020							
Inqovi	decitabine and cedazuridine	Astex Pharmaceuticals	07/07/2020							
Isturisa	osilodrostat	Novartis Pharmaceuticals Corporation	06/03/2020							
Klisyri	tirbanibulin	Athenex Inc	14/12/2020							
Koselugo	selumetinib	AstraZeneca Pharmaceuticals LP	10/04/2020							
Lampit	nifurtimox	Bayer HeatlhCare Pharmaceuticals, Inc.	06/08/2020							
Margenza	margetuximab (anti-HER2 mAb	MacroGenics, Inc	16/12/2020							
Monjuvi	tafasitamab-cxix	MorphoSys US Inc.	31/07/2020							
Nexletol	bempedoic acid	Esperion Therapeutics, Inc	21/02/2020							
Nurtec ODT	rimegepant	Biohaven Pharmaceuticals	27/02/2020							
Olinvyk	oliceridine	Trevena, Inc	07/08/2020							
Ongentys	opicapone	Neurocrine Biosciences, Inc	24/04/2020							
Orgovyx	relugolix	Myovant Sciences GmbH	18/12/2020							

** Expedited review refers to FDA Priority Review*

FDA NAS approvals in 2020

Brand Name	Generic Name	Sponsor	Approval Date	Expedited Review*	Orphan	Fast Track	Break-through	Accelerated Approval	RTOR	Project Orbis
Orladeyo	berotralstat	BioCryst Pharmaceuticals, Inc	03/12/2020							
Oxlumo	lumasiran	Alnylam Pharmaceuticals	23/11/2020							
Pemazyre	pemigatinib	Incyte Corporation	17/04/2020							
Qinlock	ripretinib	Deciphera Pharmaceuticals	15/05/2020							
Retevmo	selpercatinib	Loxo Oncology Inc., a wholly owned subsidiary of Eli Lilly and Compan	08/05/2020							
Rukobia	fostemsavir	ViiV Healthcare Company	02/07/2020							
Sarclisa	isatuximab	Sanofi Aventis US LLC	02/03/2020							
Sogroya	somapacitan-beco	Novo Nordisk Inc	28/08/2020							
Tabrecta	capmatinib	Novartis Pharmaceuticals Corporation	06/05/2020							
Tauvid	flortaucipir F18	Avid Radiopharmaceuticals, Inc	28/05/2020							
Tazverik	tazemetostat	Epizyme, Inc.	23/01/2020							
Tecartus	brexucabtagene autoleucel	Kite Pharma, Inc.	24/07/2020							
Tepezza	teprotumumab-trbw	Horizon Therapeutics Ireland DAC	21/01/2020							
Trodelvy	sacituzumab govitecan-hziy	Immunomedics, Inc	22/04/2020							
Tukysa	tucatinib	Seattle Genetics, Inc.	17/04/2020							
Uplizna	inebilizumab-cdon	Viela Bio	11/06/2020							
Veklury	remdesivir	Gilead Sciences, Inc	22/10/2020							
Viltepso	viltolarsen	Nippon Shinyaku Co., Ltd.	12/08/2020							
Vyepti	eptinezumab-jjmr	Lundbeck Seattle BioPharmaceuticals, Inc	21/02/2020							
Winlevi	clascoterone	Cassiopea SpA	26/08/2020							
Xeglyze	abametapir	Dr. Reddy's Laboratories	24/07/2020							
Zeposia	ozanimod	Celgene Corporation	25/03/2020							
Zepzelca	lurbinectedin	Pharma Mar USA, Inc	15/06/2020							
Zokinvy	lonafarnib	Eiger BioPharmaceuticals, Inc.	20/11/2020							

** Expedited review refers to FDA Priority Review*

PMDA NAS approvals in 2020

Brand Name	Generic Name	Sponsor	Approval Date	Expedited Review*	Orphan	Sakigake	Conditional Early Approval
Anerem	Remimazolam besilate	Mundipharma K.K	23/01/2020				
Beovu Kit for Intravitreal Injection 120 mg/mL	Brolucizumab (genetical recombination)	Novartis Pharma K.K	25/03/2020				
Cabometyx	Cabozantinib malate	Takeda Pharmaceutical Company Limited	25/03/2020				
Corectim Ointment 0.5%	Delgocitinib	Japan Tobacco Inc.	23/01/2020				
Dayvigo	Lemborexant	Eisai Co., Ltd.	23/01/2020				
Duvroq	Daprodustat	GlaxoSmithKline K.K.	29/06/2020				
Ecclock	Sofpironium Bromide	Kaken Pharmaceutical Co., Ltd.	25/09/2020				
Enaroy	Enarodustat	Japan Tobacco Inc.	25/09/2020				
Enhertu	Trastuzumab deruxtecan	Daiichi Sankyo Company, Limited	25/03/2020				
Enspryng	Satralizumab (genetical recombination)	Chugai Pharmaceutical Co., Ltd	29/06/2020				
Entresto	Sacubitril valsartan sodium hydrate	Novartis Pharma K.K	29/06/2020				
Ilumya	Tildrakizumab (genetical recombination) A	Sun Pharma Japan Ltd.	29/06/2020				
Jyseleca	Filgotinib Maleate	AbbVie GK	25/09/2020				
Latuda	Lurasidone hydrochloride	Sumitomo Dainippon Pharma Co., Ltd	25/03/2020				
Lokelma	Sodium zirconium cyclosilicate hydrate	AstraZeneca K.K	25/03/2020				
Mayzent	Siponimod fumaric acid	Novartis Pharma K.K	29/06/2020				
Noxafil	Posaconazole	MSD K.K	23/01/2020				
Nubeqa	Darolutamide	Bayer Yakuhin, Ltd	23/01/2020				
Ongentys	Opicapone	Ono Pharmaceutical Co., Ltd.	29/06/2020				
Pifeltro	Doravirine	MSD K.K	14/01/2020				
Rinvoq	Upadacitinib hydrate	AbbVie GK	23/01/2020				
Sarclisa	Isatuximab (genetical recombination)	Sanofi K.K	29/06/2020				
Steboronine	Borofalan	Stella Pharma Corporation	25/03/2020				
Tabrecta	Capmatinib hydrochloride hydrate	Novartis Pharma K.K	29/06/2020				
Tepmetko	Tepotinib hydrochloride hydrate	Merck Biopharma Co., Ltd	25/03/2020				
Urece	Dotinurad	Fuji Yakuhin Co., Ltd.	23/01/2020				
Vafseo	Vadadustat	Mitsubishi Tanabe Pharma Corporation	29/06/2020				
Veklury	Remdesivir	Gilead Sciences K.K.	07/05/2020				
Velexbru	Tirabrutinib hydrochloride	Ono Pharmaceutical Co., Ltd.	25/03/2020				
Viltepso	Viltolarsen	Nippon Shinyaku Co., Ltd	25/03/2020				
Zejula	Niraparib Tosilate Hydrate	Takeda Pharmaceutical Company Limited	25/09/2020				

** Expedited review refers to PMDA Priority Review*

Health Canada NAS approvals in 2020

Brand Name	Generic Name	Sponsor	Approval Date	Expedited Review*	Conditional - Notice of Compliance with conditions	ACSS works-haring	Project Orbis
Ajovy	Fremanezumab	Teva Canada Limited	09/04/2020				
Anthim	Obiltoxaximab	Elusys Therapeutics Inc	30/07/2020				
Beovu	Brolucizumab	Novartis Pharmaceuticals Canada Inc	12/03/2020				
Cablivi	Caplacizumab	Sanofi-Aventis Canada Inc	28/02/2020				
Corzyna	Ranolazine	Kye Pharmaceuticals Inc	31/12/2020				
Daurismo	Glasdegib	Pfizer Canada Ulc	28/04/2020				
Dayvigo	Lemborexant	Eisai Limited	04/11/2020				
Enspryng	Satralizumab	Hoffmann La Roche Limited	01/06/2020				
Firdapse	Amifampridine (Supplied As Amifampridine Phosphate)	Kye Pharmaceuticals Inc	31/07/2020				
Givlaari	Givosiran (Supplied As Givosiran Sodium)	Alnylam Netherlands B.V.	09/10/2020				
Ibsrela	Tenapanor Hydrochloride	Knight Therapeutics Inc.	15/04/2020				
Increlex	Mecasermin	Ipsen Biopharmaceuticals Canada Inc	17/12/2020				
Inqovi	Cedazuridine	Otsuka Pharmaceutical Co Ltd	07/07/2020				Y
Inrebic	Fedratinib (Supplied As Fedratinib Hydrochloride)	Celgene Inc	27/07/2020				
Luxturna	Voretigene Neparvovec	Novartis Pharmaceuticals Canada Inc	13/10/2020				
Mayzent	Siponimod	Novartis Pharmaceuticals Canada Inc	20/02/2020				
Nubeqa	Darolutamide	Bayer Inc.	20/02/2020				
Odomzo	Sonidegib Phosphate	Sun Pharma Global Fze	12/06/2020				
Piqray	Alpelisib	Novartis Pharmaceuticals Canada Inc	11/03/2020				
Polivy	Polatuzumab Vedotin	Hoffmann La Roche Limited	09/07/2020				
Qinlock	Ripretinib	Deciphera Pharmaceuticals. Llc	19/06/2020				Y
Reblozyl	Luspatercept	Celgene Inc	25/07/2020				
Rozlytrek	Entrectinib	Hoffmann La Roche Limited	10/02/2020				
Sarclisa	Isatuximab	Sanofi-Aventis Canada Inc	29/04/2020				
Tavalisse	Fostamatinib (Supplied As Fostamatinib Disodium)	Rigel Pharmaceuticals Inc.	19/11/2020				
Tukysa	Tucatinib	Seattle Genetics Inc	05/06/2020				Y
Veklury	Remdesivir	Gilead Sciences Canada Inc	27/07/2020				
Vocabria, Cabenuva	Cabotegravir Sodium/rilpivine	Viiv Healthcare Ulc	18/03/2020				
Vyndaqel	Tafamidis Meglumine	Pfizer Canada Ulc	20/01/2020				
Xenleta	Lefamulin Acetate	Sunovion Pharmaceuticals Canada Inc	10/07/2020				
Xofluza	Baloxavir Marboxil	Hoffmann La Roche Limited	19/02/2020				
Zeposia	Ozanimod (Supplied As Ozanimod Hydrochloride)	Celgene Inc	02/10/2020				
Zolgensma	Onasemnogene Abeparvovec	Novartis Pharmaceuticals Canada Inc	15/12/2020				

**Expedited review refers to Health Canada Priority Review*

Swissmedic NAS approvals in 2020

Brand Name	Generic Name	Sponsor	Approval Date	Expedited Review*	Orphan	Procedure with prior notification (VmVA)	Condi-tional approval	Art.13 TPA	Art.14 TPA	ACSS work-sharing	Project Orbis
Aklief, Crème	trifarotenum	Galderma SA	16/12/2020								
Beovu, Injektionslösung in Fertigspritze	brolucizumabum	Novartis Pharma Schweiz AG	16/01/2020								
Besremi, Injektionslösung im Fertigpen	ropeginterferonum alfa-2b	OrPha Swiss GmbH	01/07/2020								
Carbaglu, Tabletten zur Herstellung einer Suspension zum Einnehmen	acidum carglumicum	RECORDATI AG	28/07/2020								
Cerdelga, gélules	eliglustati tartras	Sanofi-Aventis (Suisse) SA	19/02/2020								
Crysvita, Injektionslösung	burosumabum	Kyowa Kirin Sàrl	20/01/2020								
Defitelio, Konzentrat zur Herstellung einer Infusionslösung	defibrotidum	Clinipace AG	21/09/2020								
Enspryng, Injektionslösung zur subkutanen Anwendung	satralizumabum	Roche Pharma (Schweiz) AG	13/07/2020								
Evenity, solution injectable en stylo prérempli	romosozumabum	UCB-Pharma SA	01/07/2020								
Isturisa, Filmtabletten	osilodrostati phosphas	RECORDATI AG	12/10/2020								
Libtayo, solution à diluer pour perfusion	cemiplimabum	Sanofi-Aventis (Suisse) SA	27/05/2020								
Lorviqua, Filmtabletten	lorlatinibum	Pfizer AG	19/02/2020								
Luxturna, Konzentrat und Lösungsmittel zur Herstellung einer Injektionslösung	voretigen neparvovec	Novartis Pharma Schweiz AG	14/02/2020								
Mayzent, Filmtabletten	siponimodi fumaras	Novartis Pharma Schweiz AG	22/10/2020								
Nerlynx, Filmtabletten	neratinibum	Voisin Consulting CH Sàrl	20/03/2020								
Nilemdo, Filmtabletten	acidum bempedoicum	PharmaContext GmbH	14/12/2020								
NUBEQA, Filmtabletten	darolutamidum	Bayer (Schweiz) AG	19/06/2020								
Ondexxya, Pulver zur Herstellung einer Infusionslösung	andexanet alfa	Alexion Pharma GmbH	02/12/2020								
Pheburane, Granulat	natrii phenylbutyras	NordMedica SA	29/07/2020								
Piqray, Filmtabletten	alpelisib	Novartis Pharma Schweiz AG	24/03/2020								
Quofenix, Tabletten	delafloxacinum megluminum	A. Menarini AG	28/05/2020								

Expedited review refers to Swissmedic Fast-Track

Swissmedic NAS approvals in 2020

Brand Name	Generic Name	Sponsor	Approval Date	Expedited Review*	Orphan	Procedure with prior notification (VmVA)	Condi-tional approval	Art.13 TPA	Art.14 TPA	ACSS work-sharing	Project Orbis
Rinvoq, Retardtablette	upadacitinibum	AbbVie AG	20/01/2020								
Rozlytrek, Hartkapseln	entrectinibum	Roche Pharma (Schweiz) AG	05/11/2020								
Rubraca, Filmtabletten	rucaparibum	Clovis Oncology Switzerland GmbH	26/11/2020								
Sarclisa, solution à diluer pour perfusion	isatuximabum	Sanofi-Aventis (Suisse) SA	18/03/2020								
Spravato, Nasenspray, Lösung	esketamini hydrochloridum	Janssen-Cilag AG	25/02/2020								
Trikafta, Filmtabletten	elexacaftorum, ivacaftorum, tezacaftorum	Vertex Pharmaceuticals (CH) GmbH	10/12/2020								
Tukysa, Filmtabletten	tucatinibum	Seagen International GmbH	07/05/2020								
Ultomiris, Konzentrat zur Herstellung einer Infusionslösung	ravulizumabum	Alexion Pharma GmbH	20/01/2020								
Veklury, Pulver für ein Konzentrat zur Herstellung einer Infusionslösung	remdesivirum	Gilead Sciences Switzerland Sàrl	25/11/2020								
Vitrakvi, Kapseln	larotrectinibi sulfas	Bayer (Schweiz) AG	28/05/2020								
Vyndaqel 20 mg, Weichkapseln	tafamidisum megluminum	Pfizer AG	05/03/2020								
Xofluza, Filmtabletten	baloxavirum marboxilum	Roche Pharma (Schweiz) AG	19/02/2020								
Xospata, Filmtabletten	gilteritinib	Astellas Pharma AG	24/09/2020								
Zebinix, comprimés	eslicarbazepini acetas	Bial SA	02/04/2020								
Zeposia, Hartkapseln	ozanimodum	Celgene GmbH	11/08/2020								

**Expedited review refers to Swissmedic Fast-Track*

TGA NAS approvals in 2020

Brand Name	Generic Name	Sponsor	Approval Date	Expedited Review*	Orphan	Conditional - Provisional Approval	ACSS worksharing	Project Orbis
BEOVU	brolucizumab	Novartis Pharmaceuticals Australia Pty Ltd	15/01/2020					
CABLIVI	caplacizumab	Sanofi-Aventis Australia Pty Ltd	31/01/2020					
DEFITELIO	defibrotide	Link Medical Products Pty Ltd T/A Link Pharmaceuticals	15/07/2020					
ENSPRYNG	satralizumab	Roche Products Pty Ltd	13/11/2020					
EPIDYOLEX	cannabidiol	Emerge Health Pty Ltd	18/09/2020					
IDHIFA	enasidenib	Celgene Pty Ltd	16/01/2020					
INQOVI 35/100	cedazuridine; decitabine	Otsuka Australia Pharmaceutical Pty Ltd	29/10/2020					
LIBTAYO	cemiplimab	Sanofi-Aventis Australia Pty Ltd	16/07/2020					
LUXTURNA	voretigene neparvovec	Novartis Pharmaceuticals Australia Pty Ltd	04/08/2020					
MYLOTARG	gemtuzumab ozogamicin	Pfizer Australia Pty Ltd	08/04/2020					
NUBEQA	darolutamide	Bayer Australia Ltd	20/02/2020					
ONGENTYS	opicapone	Maxx Pharma Pty Ltd	18/09/2020					
PIQRAY	alpelisib	Novartis Pharmaceuticals Australia Pty Ltd	19/03/2020					
QARZIBA	dinutuximab beta	Emerge Health Pty Ltd	18/03/2020					
QINLOCK	ripretinib	Tudorrose Consulting Pty Ltd	10/07/2020					
REAGILA	cariprazine hydrochloride	Gedeon Richter Australia Pty Ltd	13/11/2020					
RINVOQ	upadacitinib hemihydrate	Abbvie Pty Ltd	17/01/2020					
ROZLYTREK	entrectinib	Roche Products Pty Ltd	18/05/2020					
SARCLISA	isatuximab	Sanofi-Aventis Australia Pty Ltd	05/05/2020					
SCENESSE	afamelanotide acetate	Clinuvel Pharmaceuticals Ltd	26/10/2020					
TUKYSA	tucatinib	AA-Med Pty Ltd	13/08/2020					
VEKLURY	remdesivir	Gilead Sciences Pty Ltd	10/07/2020					
VITRAKVI	larotrectinib sulfate	Bayer Australia Ltd	10/11/2020					
VYNDAQEL	tafamidis meglumine	Pfizer Australia Pty Ltd	13/03/2020					
XOFLUZA	baloxavir marboxil	Roche Products Pty Ltd	21/02/2020					
XOSPATA	gilteritinib fumarate	Astellas Pharma Australia Pty Ltd	02/04/2020					
ZEPOSIA	ozanimod hydrochloride	Celgene Pty Ltd	16/07/2020					

** Expedited review refers to TGA priority review*

Definitions

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 (NAS)

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)

Report prepared by

Magda Bujar, PhD, Manager, Strategic Development

Neil McAuslane, PhD, Scientific Director

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Email: cirs@cirsci.org
Website: www.cirsci.org
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