



# MEDS ENTRY WATCH

## NEW MEDICINES APPROVED IN 2021

The following table provides supplementary information on the manufacturer and approved indication(s) for each medicine that received first-time market authorization by the US Food and Drug Administration (FDA), the European Medicines Agency (EMA), and/or Health Canada in 2021.

### Indications for new medicines approved by the FDA, the EMA, and/or Health Canada in 2021

Medicine (trade name)*	Approved indications	Manufacturer
Abrocitinib (Cibinqo)	Dermatitis	Pfizer Canada ULC
Aducanumab (Aduhelm) <sup>B</sup>	Alzheimer's disease	Biogen Inc.
Allogeneic processed thymus tissue (Rethymic) <sup>B</sup>	Pediatric congenital athymia	Enzyvant Therapeutics GmbH
Amivantamab (Rybrevant) <sup>B</sup>	Non-small cell lung cancer	Janssen Inc.
Anifrolumab (Saphnelo) <sup>B</sup>	Systemic lupus erythematosus	AstraZeneca Canada Inc.
Asciminib (Scemblix) <sup>C</sup>	Philadelphia chromosome-positive chronic myeloid leukemia	Novartis Pharmaceuticals
Atogepant (Qulipta)	Migraines	AbbVie Corporation Vifor Fresenius Medical Care Renal Pharma Ltd
Avacopan (Tavneos) <sup>O</sup>	Severe active anti-neutrophil cytoplasmic autoantibody-associated vasculitis	Sanofi-Aventis Canada Inc.
Avalglucosidase alfa (Nexviazyme) <sup>B</sup>	Late-onset Pompe disease	Sanofi-Aventis Canada Inc.
Belumosudil (Rezurock) <sup>O</sup>	Chronic graft-versus-host disease	Merck Canada Inc.
Belzutifan (Welireg) <sup>O</sup>	Von Hippel-Lindau disease	UCB Canada Inc.
Bimekizumab (Bimzelx) <sup>B</sup>	Psoriasis	Sarepta Therapeutics inc.
Casimersen (Amondys-45) <sup>O</sup>	Duchenne muscular dystrophy	Roche Registration GmbH
Casirivimab (Ronapreve) <sup>B</sup>	COVID-19 treatment	Zealand Pharma
Dasiglucagon (Zegalogue)	Severe hypoglycemia	Vifor Fresenius Medical Care Renal Pharma Ltd
Difelikefalin (Korsuva)	Pruritus	

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Indications for new medicines approved by the FDA, the EMA, and/or Health Canada in 2019 (continued)

Medicine (trade name)*	Approved indications	Manufacturer
Dostarlimab (Jemperli) <sup>B</sup>	Endometrial cancer	GlaxoSmithKline Inc.
Efgartigimod (Vyvgart) <sup>B</sup>	Generalized myasthenia gravis	Argenx B.V.
Estetrol (Nextstellis)	Pregnancy prevention	Gedeon Richter Plc.
Evinacumab (Evkeeza) <sup>B</sup>	Homozygous familial hypercholesterolemia	Regeneron Pharmaceuticals
Fexinidazole (Fexinidazole) <sup>O</sup>	Human African trypanosomiasis caused by the parasite <i>Trypanosoma brucei gambiense</i>	Sanofi
Finerenone (Kerendia)	To reduce the risk of kidney and heart complications in chronic kidney disease associated with type 2 diabetes	Bayer Healthcare
Fosdenopterin (Nulibry)	To reduce the risk of mortality in molybdenum cofactor deficiency Type A	Sentynl Therapeutics, Inc.
Ibrexafungerp (Brexafemme)	Vulvovaginal candidiasis	Scynexis
Idecabtagene vicleucel (Abecma) <sup>B</sup>	Relapsed or refractory multiple myeloma	Celgene Inc.
Infigratinib (Truseltiq) <sup>C</sup>	Cholangiocarcinoma	QED Therapeutics, Inc.
Lisocabtagene maraleucel (Breyanzi) <sup>B</sup>	Relapsed or refractory large B-cell lymphoma	Celgene Inc.
Lonapegsomatropin (Skytrofa) <sup>B</sup>	To treat short stature due to inadequate secretion of endogenous growth hormone	Ascendis Pharma, Encocrinology Div A/S
Loncastuximab tesirine (Zynlonta) <sup>B</sup>	Relapsed or refractory large B-cell lymphoma	ADC Therapeutics SA
Maralixibat (Livmarli) <sup>O</sup>	To treat cholestatic pruritus associated with Alagille syndrome	Mirum Pharmaceuticals
Maribavir (Livtencity)	To treat post-transplant cytomegalovirus (CMV) infection/disease	Takeda Pharmaceuticals USA, Inc.
Melphalan flufenamide (Pepaxto) <sup>C</sup>	To treat relapsed or refractory multiple myeloma	Oncopeptides AB
Mobocertinib (Exkivity) <sup>C</sup>	To treat locally advanced or metastatic non-small cell lung cancer with epidermal growth factor receptor exon 20 insertion mutations	Takeda Pharmaceuticals USA, Inc.
Odevixibat (Bylvay) <sup>O</sup>	To treat pruritus	Albireo
Pafolacianine (Cytalux) <sup>C</sup>	To help identify ovarian cancer lesions	On Target Laboratories
Pegcetacoplan (Empaveli) <sup>O</sup>	To treat paroxysmal nocturnal hemoglobinuria	Apellis Pharmaceuticals
Ponesimod (Ponvory)	To treat relapsing forms of multiple sclerosis	Janssen Pharmaceuticals
Regdanvimab (Regkirona) <sup>B</sup>	COVID-19 treatment	Celltrion Healthcare Hungary Kft.

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Indications for new medicines approved by the FDA, the EMA, and/or Health Canada in 2019 (continued)

Medicine (trade name)*	Approved indications	Manufacturer
Roxadustat (Evrenzo)	Anaemia	Astellas Pharma Europe B.V.
Samidorphan (Lybalvi)	Schizophrenia and certain aspects of bipolar I disorder	Alkermes Inc.
Serdexmethylphenidate (Azstarys)	Attention deficit hyperactivity disorder	Commvave Therapeutics SA
Somatrogon (Ngenla) <sup>B</sup>	Growth hormone deficiency	Pfizer Canada ULC
Sotorasib (Lumakras) <sup>C</sup>	Types of non-small cell lung cancer	Amgen Canada Inc.
Sotrovimab (Xevudy) <sup>B</sup>	COVID-19 treatment	GlaxoSmithKline Trading Services Limited
Tepotinib (Tepmetko) <sup>C</sup>	Non-small cell lung cancer	EMD Serono, A Division of EMD Inc. CANADA
Tezepelumab (Tezspire) <sup>B</sup>	Severe asthma as an add-on maintenance therapy	AstraZeneca AB
Tisotumab vedotin (Tivdak) <sup>B</sup>	Recurrent or metastatic cervical cancer with disease progression on or after chemotherapy	Seagen
Tralokinumab (Adtralza) <sup>B</sup>	Moderate-to-severe atopic dermatitis	LEO Pharma A/S
Trilaciclib (Cosela) <sup>C</sup>	To mitigate chemotherapy-induced myelosuppression in small cell lung cancer	G1 Therapeutics, Inc.
Umbralisib (Ukoniq) <sup>C</sup>	Marginal zone lymphoma and follicular lymphoma	TG Therapeutics
Vaccine, SARS-CoV-2 non-replicating vector (VAC COV2 NRV J.J.) <sup>B</sup>	COVID-19 prevention	Janssen Pharmaceuticals
Vericiguat (Verquvo)	To mitigate the risk of cardiovascular death and hospitalization for chronic heart failure	Merck Sharp & Dohme
Viloxazine (Qelbree)	Attention deficit hyperactivity disorder	Supernus Pharmaceuticals
Voclosporin (Lupkynis)	Lupus nephritis	Aurinia Pharmaceuticals
Vosoritide (Voxzogo) <sup>O</sup>	To improve growth in children five years of age and older with achondroplasia and open epiphyses	BioMarin Pharmaceutical Inc.

Indications from ■ Health Canada; ■ US Food and Drug Administration (FDA); ■ European Medicines Agency (EMA).

\* B: biologic; C: cancer; O: orphan medicine.

Data source: US Food and Drug Administration Novel Drugs 2019; European Medicines Agency Human Medicines Highlights 2019; Health Canada databases.