



# MEDS ENTRY WATCH

## NEW MEDICINES APPROVED IN 2020

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 2020.

### Indications for new medicines approved by the FDA, the EMA, and/or Health Canada in 2020

Medicine (trade name)*	Approved indications	Manufacturer
Ansuvimab-zykl (Ebanga) <sup>B,O</sup>	Indicated to treat Ebola	Ridgeback Biotherapeutics
Atoltivimab, maftivimab, and odesivimab-ebgn (Inmazeb) <sup>B,O</sup>	Indicated to treat Ebola	Jazz Pharmaceuticals
Avapritinib (Ayvakyt) <sup>C,O</sup>	Indicated to treat adults with unresectable or metastatic gastrointestinal stromal tumor (GIST)	Blueprint Medicines Corporation
Belantamab mafodotin (Blenrep) <sup>B,C,O</sup>	Indicated to treat multiple myeloma	GlaxoSmithKline
Bempedoic acid (Nexletol)	Indicated to treat adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C	Esperion Therapeutics, Inc.
Bertralstat (Orladeyo) <sup>B</sup>	Indicated to treat patients with hereditary angioedema	BioCryst Pharmaceuticals, Inc.
Brexucabtagene autoleucel (Tecartus) <sup>B,C,G,O</sup>	Indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL)	Kite Pharma, Inc.
Bulevirtide (Hepcludex) <sup>B,O</sup>	Indicated to treat chronic (long-term) hepatitis delta virus (HDV) infection in adults with compensated liver disease (when the liver is damaged but is still able to work), when the presence of viral RNA (genetic material) has been confirmed by blood tests.	Gilead Sciences Ireland UC
Cabotegravir (Vocabria)	Indicated for short-term treatment of human immunodeficiency virus type 1 (HIV-1) infection	ViiV Healthcare ULC
Capmatinib (Tabrecta) <sup>C,O</sup>	Indicated to treat patients with non-small-cell lung cancer	Novartis Pharmaceuticals Corp.
Cedazuridine (Inqovi) <sup>C,O</sup>	Indicated to treat adult patients with myelodysplastic syndromes	Otsuka Pharmaceutical Co., Ltd
Clascoterone (Winlevi)	Indicated to treat acne	Sun Pharmaceutical Industries Ltd
Coagulation factor VIIa (Recombinant) (Sevenfact) <sup>B</sup>	Indicated for treatment and control of bleeding episodes occurring in adults and adolescents (12 years of age and older) with hemophilia A or B with inhibitors	Laboratoire français du fractionnement et des biotechnologies S.A.
COVID-19 mRNA vaccine (Comirnaty) <sup>B</sup>	Indicated for preventing coronavirus disease 2019 (COVID-19) in people aged 5 years and older	BioNTech Manufacturing GmbH
Eptinezumab (Vyepti) <sup>B</sup>	Indicated for the preventive treatment of migraine in adults	Lundbeck Seattle BioPharmaceuticals, Inc.
Filgotinib (Jyseleca) <sup>B</sup>	Indicated for treating adults with moderate to severe rheumatoid arthritis	Gilead Sciences Ireland UC
Fostemsavir trometamol (Rukobia)	Indicated to treat HIV	ViiV Healthcare ULC
Imlifidase (Idefix) <sup>B</sup>	Indicated to prevent the body from rejecting a newly transplanted kidney	Hansa Biopharma AB
Inebilizumab (Uplizna) <sup>B,O</sup>	Indicated to treat neuromyelitis optica spectrum disorder	Vielia Bio, Inc.
Isatuximab (Sarclisa) <sup>B,C,O</sup>	Indicated to treat multiple myeloma	Sanofi-Aventis Canada Inc.
Lonafarnib (Zokinvy) <sup>O</sup>	Indicated to treat rare conditions related to premature aging	Eiger BioPharmaceuticals

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Medicine (trade name)*	Approved indications	Manufacturer
Lumasiran (Oxlumo) <sup>O</sup>	Indicated to treat hyperoxaluria type 1	Alynham Pharmaceuticals Inc.
Lurbinectedin (Zepzelca) <sup>C,O</sup>	Indicated to treat metastatic small cell lung cancer	Jazz Pharmaceuticals
Naxitamab (Danyelza) <sup>B,C,O</sup>	Indicated to treat high-risk refractory or relapsed neuroblastoma	Y-mAbs Therapeutics, Inc.
Oliceridine (Olinvyk)	Indicated to manage acute pain in certain adults	Trevena Inc.
Osilodrostat (Isturisa) <sup>O</sup>	Indicated to treat adults with Cushing's disease who either cannot undergo pituitary gland surgery or have undergone the surgery but still have the disease	Recordati Rare Diseases Inc.
Ozanimod (Zeposia)	Indicated to treat relapsing forms of multiple sclerosis	Celgene Inc.
Pemigatinib (Pemazyre) <sup>C,O</sup>	Indicated to treat certain patients with cholangiocarcinoma, a rare form of cancer that forms in bile ducts	Incyte Corp.
Pralsetinib (Gavreto) <sup>C,O</sup>	Indicated to treat non-small-cell lung cancer	Genentech USA, Inc.
Relugloix (Orgovyx) <sup>C</sup>	Indicated to treat advanced prostate cancer	Myovant Sciences Ltd
Remdesivir (Veklury)	Indicated to treat COVID-19	Gilead Sciences Canada Inc.
Remimazolam (Anerem)	Indicated for sedation	Acacia Pharma Ltd
Rimegepant (Nurtec)	Indicated to treat migraine	Biohaven Pharmaceuticals
Ripretinib (Qinlock) <sup>C,O</sup>	Indicated to treat advanced gastrointestinal-stromal tumors	Deciphera Pharmaceuticals, LLC
Risdiplam (Evrysdi) <sup>O</sup>	Indicated to treat spinal muscular atrophy	Genentech USA, Inc.
Sacituzumab govitecan (Trodelvy) <sup>B,C</sup>	Indicated to treat adult patients with metastatic triple-negative breast cancer who received at least two prior therapies for metastatic disease	Immunomedics Inc.
Satralizumab (Enspryng) <sup>B,O</sup>	Indicated to treat neuromyelitis optica spectrum disorder	Hoffmann-La Roche Ltd
Selpercatinib (Retevmo) <sup>C,O</sup>	Indicated to treat lung and thyroid cancers	Eli Lilly and Co.
Selumetinib (Koselugo) <sup>O</sup>	Indicated to treat neurofibromatosis type 1, a genetic disorder of the nervous system causing tumors to grow on nerves	AstraZeneca
Setmelanotide (Imcivree) <sup>O</sup>	Indicated to treat obesity and the control of hunger associated with pro-opiomelanocortin deficiency, a rare disorder that causes severe obesity that begins at an early age	Rhythm Pharmaceuticals, Inc.
Somapacitan (Sogroya) <sup>B</sup>	Indicated as a growth hormone	Novo Nordisk, Inc.
Tafasitamab (Monjuvi) <sup>B,C,O</sup>	Indicated to treat relapsed or refractory diffuse large B-cell lymphoma	MorphoSys US, Inc.
Tazemetostat (Tazverik) <sup>C,O</sup>	Indicated to treat epithelioid sarcoma	Epizyme, Inc.
Teprotumumab (Teprezza) <sup>B,O</sup>	Indicated to treat thyroid eye disease	Horizon Therapeutics
Tirbanibulin (Klisyri)	Indicated to treat actinic Keratosis of the face or scalp	Almirall
Triheptanoin (Dojolvi) <sup>O</sup>	Indicated to treat molecularly long-chain fatty acid oxidation disorders	Ultragenyx Pharmaceutical Inc.
Tucatinib (Tukysa) <sup>C,O</sup>	Indicated to treat advanced unresectable or metastatic HER2-positive breast cancer	Seagen Inc.
Vibegron (Gemtesa, Beova)	Indicated to treat overactive bladder	Urovant Sciences
Viltolarsen (Viltepso) <sup>O</sup>	Indicated to treat Duchenne muscular dystrophy	NS Pharma, Inc.

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

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

Data source: US Food and Drug Administration Novel Drugs 2020; European Medicines Agency Human Medicines Highlights 2020; Health Canada databases.