

22 March 2022
EMA/144373/2022 - Corr
Human Medicines Division

Applications for new human medicines under evaluation by the CHMP

Data extracted 03 March 2022

This list with initial marketing authorisation applications for human medicines currently under evaluation by the Committee for Medicinal Products for Human Use (CHMP), includes the international non-proprietary names (INN) (salt, ester, derivative, etc.) or common name. For generic medicines, it includes active moiety only, with no information on salt, ester or derivative.

This list only includes information for medicines whose applications have been validated and evaluation started at the time the data was extracted. For generics, biosimilar and duplicates where there are several applications with the same substance there is a row per application.

Where the timetable changes from accelerated to standard timetable, the month and year of the switch to standard Time Table is included.

Entries are removed from this list once the medicine has received a positive or negative opinion from the CHMP or when the applicant has withdrawn the application. The Agency publishes information on these opinions and withdrawn applications on its website. Information on designated orphan medicines that are being assessed for marketing authorisation is also available in the monthly reports of the Committee for Orphan Medicinal Products (COMP).

International non-proprietary name (INN) (salt, ester, derivative, etc.) / Common Name	Substance type (classification)	Therapeutic area (ATC level 2)	Accelerated Assessment (Art. 14(9) Reg 726/2004)	Revert to standard Time Table (MM/YY)	Orphan Product	Generic, hybrid or Biosimilar	Start of evaluation
Abaloparatide	Chemicals	Calcium homeostasis	N		N	N	25-11-21
Adrenalin	Chemicals	Cardiac therapy	N		N	N	26-11-20
Amifampridine	Chemicals	Other nervous system medicines	N		N	Y	20-05-21
Arimoclomol (citrate)	Chemicals	Other nervous system medicines	N		Y	N	26-11-20
Artesunate	Chemicals	Antiprotozoals	N		Y	N	24-12-20
Asciminib (hydrochloride)	Chemicals	Antineoplastic medicines	N		Y	N	15-07-21

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Autologous glioma tumor cells, inactivated / autologous glioma tumor cell lysates, inactivated / allogeneic glioma tumor cells, inactivated / allogenei	ATMP	Antineoplastic medicines	N		Y	N	01-10-20
Bardoxolone (methyl)	Chemicals	Immunosuppressants	N		Y	N	28-10-21
Bevacizumab	Biologicals	Antineoplastic medicines	N		N	Y	24-12-20
Bevacizumab	Biologicals	Antineoplastic medicines	N		N	Y	28-10-21
Birch bark extract	Biologicals	Medicines for wounds and ulcers	N		Y	N	25-03-21
Budesonide	Chemicals	Antidiarrheals, intestinal antiinflammatory/antiinfective medicines	N	9/21	Y	Y	17-06-21
Capmatinib (dihydrochloride monohydrate)	Chemicals	Antineoplastic medicines	N		N	N	20-05-21
Ciltacabtagene autoleucel	ATMP	Antineoplastic medicines	N	9/21	Y	N	20-05-21
Cipaglucosidase alfa	Biologicals	Other alimentary tract and metabolism products	N		Y	N	25-11-21
Dabigatran etexilate	Chemicals	Antithrombotic medicines	N		N	Y	16-07-20
Dabigatran etexilate	Chemicals	Antithrombotic medicines	N		N	Y	24-02-22
Dapagliflozin	Chemicals	Medicines used in diabetes	N		N	Y	24-02-22
Dengue tetravalent vaccine (live, attenuated)	Biologicals	Vaccines	N	6/21	N	N	25-03-21
Deucravacitinib	Chemicals	Immunosuppressants	N		N	N	28-10-21
Difelikefalin (acetate)	Chemicals	Other therapeutic medicines	N		N	N	25-03-21
Dimethyl fumarate	Chemicals	Immunosuppressants	N		N	Y	30-09-21
Dimethyl fumarate	Chemicals	Immunosuppressants	N		N	Y	01-12-21
Dimethyl fumarate	Chemicals	Immunosuppressants	N		N	Y	24-12-21
Doxorubicin	Chemicals	Antineoplastic medicines	N		N	Y	20-06-19
Doxorubicin	Chemicals	Antineoplastic medicines	N		N	Y	30-01-20
Efbemalenograstim alfa	Biologicals	Immunostimulants	N		N	N	30-09-21
Efgartigimod alfa	Biologicals	Immunosuppressants	N		Y	N	19-08-21
Eladocagene exuparvovec	ATMP	Other nervous system medicines	N		Y	N	28-01-20
Eptacog alfa (activated)	Biologicals	Antihemorrhagics	N		N	Y	15-07-21
Eptacog beta (activated)	Biologicals	Antihemorrhagics	N		N	N	25-02-21

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Ertapenem	Chemicals	Antibacterials for systemic use	N		N	Y	25-02-21
Faricimab	Biologicals	Ophthalmologicals	N		N	N	17-06-21
Filgrastim	Biologicals	Immunostimulants	N		N	Y	24-02-22
Fosdenopterin	Chemicals	Other alimentary tract and metabolism products	Y		Y	N	25-11-21
Gadopiclesol	Chemicals	Contrast media	N		N	N	24-02-22
Ganaxolone	Chemicals	Antiepileptics	N	1-22	Y	N	28-10-21
Ganirelix	Chemicals	Pituitary and hypothalamic hormones and analogues	N		N	Y	25-03-21
Gefapixant	Chemicals	Other nervous system medicines	N		N	N	25-02-21
Gefapixant	Chemicals	Other nervous system medicines	N		N	N	26-02-21
Germanium (68Ge) chloride / gallium (68Ga) chloride	Radiopharmaceuticals	Diagnostic radiopharmaceuticals	N		N	N	19-08-21
Gozetotide	Chemicals	Diagnostic radiopharmaceuticals	N		N	N	28-10-21
Infigratinib (monophosphate)	Chemicals	Antineoplastic medicines	N		Y	N	25-11-21
Lasmiditan (succinate)	Chemicals	Analgesics	N		N	N	26-11-20
Lenacapavir (sodium)	Chemicals	Antivirals for systemic use	N		N	N	19-08-21
Lenadogene nolpharvec	ATMP	Ophthalmologicals	N		Y	N	29-10-20
Leuprorelin	Chemicals	Endocrine therapy	N		N	Y	26-03-20
Lonafarnib	Chemicals	Other alimentary tract and metabolism products	N	7/20	Y	N	23-04-20
Loncastuximab tesirine	Biologicals	Antineoplastic medicines	N		Y	N	28-10-21
Lutetium (177Lu) chloride	Radiopharmaceuticals	Therapeutic radiopharmaceuticals	N		N	N	19-08-21
Lutetium (177Lu) vipivotide tetraxetan	Chemicals	Therapeutic radiopharmaceuticals	N		N	N	28-10-21
Maralixibat (choride)	Chemicals	Bile and liver therapy	N		Y	N	30-09-21
Maribavir	Chemicals	Antivirals for systemic use	N		Y	N	17-06-21
Mavacamten	Chemicals	Cardiac therapy	N		N	N	30-09-21
Melphalan (flufenamide hydrochloride)	Chemicals	Antineoplastic medicines	N		Y	N	20-05-21
Miglustat	Chemicals	Other alimentary tract and metabolism products	N		Y	Y	25-11-21

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Mitapivat (sulfate)	Chemicals	Other hematological medicines	N		Y	N	15-07-21
Mobocertinib	Chemicals	Antineoplastic medicines	N		N	N	15-07-21
Molnupiravir	Chemicals	Antivirals for systemic use	N		N	N	23-11-21
Mosunetuzumab	Biologicals	Antineoplastic medicines	Y		Y	N	28-10-21
Nirsevimab	Biologicals	Vaccines	Y		N	N	17-02-22
Octreotide (acetate)	Chemicals	Pituitary and hypothalamic hormones and analogues	N		Y	Y	19-08-21
Olipudase alfa	Biologicals	Other alimentary tract and metabolism products	Y		Y	N	25-11-21
Omburtamab I-131	Biologicals	Therapeutic radiopharmaceuticals	N		Y	N	20-05-21
Paclitaxel	Chemicals	Antineoplastic medicines	N		N	Y	20-01-22
Palovarotene	Chemicals	Other medicines for disorders of the musculo-skeletal system	N		Y	N	20-05-21
Parsaclisib (hydrochloride)	Chemicals	Antineoplastic medicines	N		Y	N	24-12-21
Pegfilgrastim	Biologicals	Immunostimulants	N		N	Y	30-09-21
Pegfilgrastim	Biologicals	Immunostimulants	N		N	Y	28-10-21
Pegunigalsidase alfa	Biologicals	Other alimentary tract and metabolism products	N		Y	N	24-02-22
Pemetrexed	Chemicals	Antineoplastic medicines	N		N	Y	19-08-21
Pirfenidone	Chemicals	Immunosuppressants	N		N	Y	20-05-21
Pirfenidone	Chemicals	Immunosuppressants	N		N	Y	25-11-21
Plerixafor	Chemicals	Immunostimulants	N		N	Y	28-10-21
Ranibizumab	Biologicals	Ophthalmologicals	N		N	N	20-05-21
Ranibizumab	Biologicals	Ophthalmologicals	N		N	Y	15-07-21
Ranibizumab	Biologicals	Ophthalmologicals	N		N	Y	30-09-21
Relatlimab / nivolumab	Biologicals	Antineoplastic medicines	N		N	N	30-09-21
Ruxolitinib (phosphate)	Chemicals	Other dermatological medicines	N		N	N	28-10-21
Sirolimus	Chemicals	Immunosuppressants	N		Y	Y	24-12-21
Sitagliptin / metformin	Chemicals	Medicines used in diabetes	N		N	Y	20-05-21
Sitagliptin/metformin	Chemicals	Medicines used in diabetes	N		N	Y	24-02-22
Sodium phenylbutyrate / ursodoxicoltaurine	Chemicals	Other nervous system medicines	N		Y	N	24-02-22

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Sodium thiosulfate	Chemicals	Other therapeutic medicines	N		N	N	27-02-20
Sorafenib	Chemicals	Antineoplastic medicines	N		N	Y	15-07-21
Spesolimab	Biologicals	Immunosuppressants	N		N	N	28-10-21
Spironolactone	Chemicals	Diuretics	N		N	Y	25-11-21
Sugammadex	Chemicals	Other therapeutic medicines	N		N	Y	25-03-21
Sugammadex	Chemicals	Other therapeutic medicines	N		N	Y	25-11-21
Surufatinib	Chemicals	Antineoplastic medicines	N		N	N	15-07-21
Sutimlimab	Biologicals	Immunosuppressants	N		Y	N	28-10-21
Tabelecleucel	ATMP	Other therapeutic medicines	Y		Y	N	25-11-21
Teclistamab	Biologicals	Antineoplastic medicines	Y		Y	N	17-02-22
Teriflunomide	Chemicals	Immunosuppressants	N		N	Y	30-09-21
Teriflunomide	Chemicals	Immunosuppressants	N		N	Y	28-10-21
Teriparatide	Biologicals	Calcium homeostasis	N		N	Y	01-10-20
Teriparatide	Chemicals	Calcium homeostasis	N		N	Y	21-01-21
Tezepelumab	Biologicals	Medicines for obstructive airway diseases	N		N	N	17-06-21
Thalidomide	Chemicals	Immunosuppressants	N		N	Y	20-05-21
Tirzepatide	Chemicals	Medicines used in diabetes	N		N	N	28-10-21
Tolvaptan	Chemicals	Diuretics	N		N	Y	24-12-21
Trastuzumab	Biologicals	Antineoplastic medicines	N		N	Y	23-05-19
Trastuzumab	Biologicals	Antineoplastic medicines	N		N	Y	25-02-21
Trastuzumab	Biologicals	Antineoplastic medicines	N		N	Y	20-01-22
Tremelimumab	Biologicals	Antineoplastic medicines	N		N	N	24-12-21
Ublituximab	Biologicals	Immunosuppressants	N		N	N	24-12-21
Vadadustat	Chemicals	Antianemic medicines	N		N	N	25-11-21
Valoctocogene roxaparvovec	ATMP	Antihemorrhagics	Y		Y	N	15-07-21
Voclosporin	Chemicals	Immunosuppressants	N		N	N	15-07-21
Vutrisiran (sodium)	Chemicals	Other nervous system medicines	N		Y	N	30-09-21