

8 March 2022
EMA/144373/2022
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from this list once the medicine has received a positive or negative opinion from the CHMP or when the applicant has withdrawn the application. The Agency publishes information on these opinions and withdrawn applications on its website.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
Dabigatran etexilate	Chemicals	Antithrombotic medicines	N		N	Y	24-02-22
Dapagliflozin	Chemicals	Medicines used in diabetes	N		N	Y	24-02-22
Filgrastim	Biologicals	Immunostimulants	N		N	Y	24-02-22
Gadopiclenol	Chemicals	Contrast media	N		N	N	24-02-22
Pegunigalsidase alfa	Biologicals	Other alimentary tract and metabolism products	N		Y	N	24-02-22
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
Nirsevimab	Biologicals	Vaccines	Y		N	N	17-02-22

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Teclistamab	Biologicals	Antineoplastic medicines	Y		Y	N	17-02-22
Paclitaxel	Chemicals	Antineoplastic medicines	N		N	Y	20-01-22
Trastuzumab	Biologicals	Antineoplastic medicines	N		N	Y	20-01-22
Dimethyl fumarate	Chemicals	Immunosuppressants	N		N	Y	24-12-21
Parsaclisib (hydrochloride)	Chemicals	Antineoplastic medicines	N		Y	N	24-12-21
Sirolimus	Chemicals	Immunosuppressants	N		Y	Y	24-12-21
Tolvaptan	Chemicals	Diuretics	N		N	Y	24-12-21
Tremelimumab	Biologicals	Antineoplastic medicines	N		N	N	24-12-21
Ublituximab	Biologicals	Immunosuppressants	N		N	N	24-12-21
Dimethyl fumarate	Chemicals	Immunosuppressants	N		N	Y	01-12-21
Abaloparatide	Chemicals	Calcium homeostasis	N		N	N	25-11-21
Cipagliflozin alfa	Biologicals	Other alimentary tract and	N		Y	N	25-11-21
Fosdenopterin	Chemicals	Other alimentary tract and metabolism products	Y		Y	N	25-11-21
Infigratinib (monophosphate)	Chemicals	Antineoplastic medicines	N		Y	N	25-11-21
Miglustat	Chemicals	Other alimentary tract and	N		Y	Y	25-11-21
Olipudase alfa	Biologicals	Other alimentary tract and	Y		Y	N	25-11-21
Pirfenidone	Chemicals	Immunosuppressants	N		N	Y	25-11-21
Spirolactone	Chemicals	Diuretics	N		N	Y	25-11-21
Sugammadex	Chemicals	Other therapeutic medicines	N		N	Y	25-11-21
Tabelecleucel	ATMP	Other therapeutic medicines	Y		Y	N	25-11-21
Vadadustat	Chemicals	Antianemic medicines	N		N	N	25-11-21
Molnupiravir	Chemicals	Antivirals for systemic use	N		N	N	23-11-21
Bardoxolone (methyl)	Chemicals	Immunosuppressants	N		Y	N	28-10-21
Bevacizumab	Biologicals	Antineoplastic medicines	N		N	Y	28-10-21
Deucravacitinib	Chemicals	Immunosuppressants	N		N	N	28-10-21
Ganaxolone	Chemicals	Antiepileptics	Y		Y	N	28-10-21
Gozetotide	Chemicals	Diagnostic radiopharmaceuticals	N		N	N	28-10-21

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Loncastuximab tesirine	Biologicals	Antineoplastic medicines	N		Y	N	28-10-21
Lutetium (177Lu) vipivotide	Chemicals	Therapeutic	N		N	N	28-10-21
Mosunetuzumab	Biologicals	Antineoplastic medicines	Y		Y	N	28-10-21
Pegfilgrastim	Biologicals	Immunostimulants	N		N	Y	28-10-21
Plerixafor	Chemicals	Immunostimulants	N		N	Y	28-10-21
Ruxolitinib (phosphate)	Chemicals	Other dermatological medicines	N		N	N	28-10-21
Spesolimab	Biologicals	Immunosuppressants	N		N	N	28-10-21
Sutimlimab	Biologicals	Immunosuppressants	N		Y	N	28-10-21
Teriflunomide	Chemicals	Immunosuppressants	N		N	Y	28-10-21
Tirzepatide	Chemicals	Medicines used in diabetes	N		N	N	28-10-21
Dimethyl fumarate	Chemicals	Immunosuppressants	N		N	Y	30-09-21
Efbemalenograstim alfa	Biologicals	Immunostimulants	N		N	N	30-09-21
Maralixibat (choride)	Chemicals	Bile and liver therapy	N		Y	N	30-09-21
Mavacamten	Chemicals	Cardiac therapy	N		N	N	30-09-21
Pegfilgrastim	Biologicals	Immunostimulants	N		N	Y	30-09-21
Ranibizumab	Biologicals	Ophthalmologicals	N		N	Y	30-09-21
Relatlimab / nivolumab	Biologicals	Antineoplastic medicines	N		N	N	30-09-21
Teriflunomide	Chemicals	Immunosuppressants	N		N	Y	30-09-21
Vutrisiran (sodium)	Chemicals	Other nervous system	N		Y	N	30-09-21
Efgartigimod alfa	Biologicals	Immunosuppressants	N		Y	N	19-08-21
Germanium (68Ge) chloride / gallium (68Ga) chloride	Radiopharmaceuticals	Diagnostic radiopharmaceuticals	N		N	N	19-08-21
Lenacapavir (sodium)	Chemicals	Antivirals for systemic use	N		N	N	19-08-21
Lutetium (177Lu) chloride	Radiopharmaceuticals	Therapeutic	N		N	N	19-08-21
Octreotide (acetate)	Chemicals	Pituitary and hypothalamic	N		Y	Y	19-08-21
Pemetrexed	Chemicals	Antineoplastic medicines	N		N	Y	19-08-21
Asciminib (hydrochloride)	Chemicals	Antineoplastic medicines	N		Y	N	15-07-21

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Eptacog alfa (activated)	Biologicals	Antihemorrhagics	N		N	Y	15-07-21
Mitapivat (sulfate)	Chemicals	Other hematological medicines	N		Y	N	15-07-21
Mobocertinib	Chemicals	Antineoplastic medicines	N		N	N	15-07-21
Ranibizumab	Biologicals	Ophthalmologicals	N		N	Y	15-07-21
Sorafenib	Chemicals	Antineoplastic medicines	N		N	Y	15-07-21
Surufatinib	Chemicals	Antineoplastic medicines	N		N	N	15-07-21
Valoctocogene roxaparvovec	ATMP	Antihemorrhagics	Y		Y	N	15-07-21
Voclosporin	Chemicals	Immunosuppressants	N		N	N	15-07-21
Budesonide	Chemicals	Antidiarrheals, intestinal antiinflammatory/antiinfectiv	N	9/21	Y	Y	17-06-21
Faricimab	Biologicals	Ophthalmologicals	N		N	N	17-06-21
Maribavir	Chemicals	Antivirals for systemic use	N		Y	N	17-06-21
Tezepelumab	Biologicals	Medicines for obstructive	N		N	N	17-06-21
Amifampridine	Chemicals	Other nervous system	N		N	Y	20-05-21
Capmatinib (dihydrochloride)	Chemicals	Antineoplastic medicines	N		N	N	20-05-21
Ciltacabtagene autoleucl	ATMP	Antineoplastic medicines	N	9/21	Y	N	20-05-21
Melphalan (flufenamide)	Chemicals	Antineoplastic medicines	N		Y	N	20-05-21
Omburtamab I-131	Biologicals	Therapeutic	N		Y	N	20-05-21
Palovarotene	Chemicals	Other medicines for disorders of the musculo-	N		Y	N	20-05-21
Pirfenidone	Chemicals	Immunosuppressants	N		N	Y	20-05-21
Ranibizumab	Biologicals	Ophthalmologicals	N		N	N	20-05-21
Sitagliptin / metformin	Chemicals	Medicines used in diabetes	N		N	Y	20-05-21
Thalidomide	Chemicals	Immunosuppressants	N		N	Y	20-05-21
Birch bark extract	Biologicals	Medicines for wounds and ulcers	N		Y	N	25-03-21
Dengue tetravalent vaccine (live,	Biologicals	Vaccines	N	6/21	N	N	25-03-21
Difelikefalin (acetate)	Chemicals	Other therapeutic medicines	N		N	N	25-03-21
Ganirelix	Chemicals	Pituitary and hypothalamic	N		N	Y	25-03-21

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Sugammadex	Chemicals	Other therapeutic medicines	N		N	Y	25-03-21
Gefapixant	Chemicals	Other nervous system medicines	N		N	N	26-02-21
Eptacog beta (activated)	Biologicals	Antihemorrhagics	N		N	N	25-02-21
Ertapenem	Chemicals	Antibacterials for systemic	N		N	Y	25-02-21
Gefapixant	Chemicals	Other nervous system medicines	N		N	N	25-02-21
Trastuzumab	Biologicals	Antineoplastic medicines	N		N	Y	25-02-21
Teriparatide	Chemicals	Calcium homeostasis	N		N	Y	21-01-21
Artesunate	Chemicals	Antiprotozoals	N		Y	N	24-12-20
Bevacizumab	Biologicals	Antineoplastic medicines	N		N	Y	24-12-20
Adrenalin	Chemicals	Cardiac therapy	N		N	N	26-11-20
Arimoclomol (citrate)	Chemicals	Other nervous system medicines	N		Y	N	26-11-20
Lasmiditan (succinate)	Chemicals	Analgesics	N		N	N	26-11-20
Lenadogene nolparvovec	ATMP	Ophthalmologicals	N		Y	N	29-10-20
Autologous glioma tumor cells,	ATMP	Antineoplastic medicines	N		Y	N	01-10-20
Teriparatide	Biologicals	Calcium homeostasis	N		N	Y	01-10-20
Dabigatran etexilate	Chemicals	Antithrombotic medicines	N		N	Y	16-07-20
Lonafarnib	Chemicals	Other alimentary tract and	N	7/20	Y	N	23-04-20
Leuprorelin	Chemicals	Endocrine therapy	N		N	Y	26-03-20
Sodium thiosulfate	Chemicals	Other therapeutic medicines	N		N	N	27-02-20
Doxorubicin	Chemicals	Antineoplastic medicines	N		N	Y	30-01-20
Eladocagene exuparvovec	ATMP	Other nervous system	N		Y	N	28-01-20
Doxorubicin	Chemicals	Antineoplastic medicines	N		N	Y	20-06-19
Trastuzumab	Biologicals	Antineoplastic medicines	N		N	Y	23-05-19