5 December 2014
EMA/759365/2014
Procedure Management and Business Support Division

Applications for new human medicines under evaluation by the Committee for Medicinal Products for Human Use

December 2014

This document lists information on applications for centralised marketing authorisation for human medicines that the European Medicines Agency has received for evaluation. It includes the international non-proprietary names (INN) and therapeutic areas for all new innovative medicines under evaluation by the Committee for Medicinal Products for Human Use (CHMP). For generic and biosimilar medicines, it includes the INN (active moiety only, with no information on salt, ester or derivative) and therapeutic area.

This list only includes information for medicines whose applications have been validated at the time the report was compiled. The information in this report was compiled on **4 December 2014**.

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).

Information in **bold** corresponds to new entries in the monthly list.

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from this list once the medicine has received a positive or negative opinion from the CHMP or when the applicant has withdrawn the application. The Agency publishes information on these opinions and withdrawn applications on its website.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 CHMP opinions is also published in the monthly CHMP highlights.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Non-orphan medicinal products

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area[1]
Atazanavir (sulfate) / cobicistat	Antivirals for systemic use
Betulae cortex dry extract (5-10 : 1); extraction solvent: n-heptane 95% (w/w)	Medicines for wounds and ulcers
Cangrelor	Antithrombotic medicines
Ceftolozane (sulfate) / tazobactam (sodium)	Antibacterials for systemic use
Ceritinib	Antineoplastic medicines
Ciclosporin	Ophthalmologicals
Cobimetinib (hemifumarate)	Antineoplastic medicines
Dalbavancin (hydrochloride)	Antibacterials for systemic use
Edoxaban (tosylate)	Antithrombotic medicines
Empagliflozin / metformin (hydrochloride)	Medicines used in diabetes
Evolocumab	Lipid modifying medicines
Fentanyl (hydrochloride)	Analgesics
Ferric citrate coordination complex	Other therapeutic medicines
Guanfacine (hydrochloride)	Antihypertensives
Human alpha1-proteinase inhibitor	Antihemorrhagics
Human fibrinogen / human thrombin	Antihemorrhagics
Human papillomavirus vaccine [types 6, 11, 16, 18, 31, 33, 45, 52, 58] (recombinant, adsorbed)	Vaccines
Lamivudine (hydrate) / raltegravir (potassium)	Antivirals for systemic use
Levodopa /carbidopa (monohydrate)	**Anti-parkinson medicines**
Liraglutide	Medicines used in diabetes
Lutetium (177 Lu) (chloride)	Diagnostic radiopharmaceuticals
Mepolizumab	**Immunosuppressants**
Naltrexone (hydrochloride) / bupropion (hydrochloride)	Antiobesity medicines
Netupitant / palonosetron (hydrochloride)	Antiemetics and antinauseants
Nivolumab	Antineoplastic medicines

[1] Based on the ATC therapeutic sub-group.

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area[1]
Oritavancin (diphosphate)	Antibacterials for systemic use
Pegaspargase	Antineoplastic medicines
Pegfilgrastim	Immunostimulants
Pembrolizumab	Antineoplastic medicines
Phenylephrine (hydrochloride) / ketorolac (trometamol)	Ophthalmologicals
Safinamide (methanesulfonate)	Anti-parkinson medicines
Sevelamer (hydrochloride)	Other therapeutic medicines
Sonidegib (phosphate)	Antineoplastic medicines
Spheroids of human autologous matrix-associated chondrocytes	Other medicines for disorders of the musculo-skeletal system
Talimogene laherparepvec	Antineoplastic medicines
Tedizolid (phosphate)	Antibacterials for systemic use

Non-orphan generic and biosimilar medicinal products

International non-proprietary name / Common Name	Therapeutic area[2]	Total number of applications
Aripiprazole	Psycholeptics	5
Bortezomib	Antineoplastic medicines	1
Clopidogrel	Antithrombotic medicines	1
Docetaxel	Antineoplastic medicines	1
Duloxetine	Psychoanaleptics	3
Insulin human	Medicines used in diabetes	1
Pemetrexed	Antineoplastic medicines	5
Pregabalin	Antiepileptics	6
Sufentanil	Anesthetics	1
Voriconazole	Antimycotics for systemic use	1

[2] Based on the ATC therapeutic sub-group.

Orphan medicinal products[3]

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area[4]
Allogeneic human heterologous liver cells	Other alimentary tract and metabolism products
Allogeneic T cells genetically modified to express suicide gene	Antineoplastic medicines
Asfotase alfa	Other alimentary tract and metabolism products
Blinatumomab	Antineoplastic medicines
Dasiprotimut-T	Immunostimulants
Dexamethasone (acetate)	**Corticosteroids for systemic use**
Dinutuximab	Antineoplastic medicines
Efmoroctocog alfa	Antihemorrhagics
Ex vivo autologous corneal epithelial cells including stem cells	Ophthalmologicals
Glycerol phenylbutyrate	Other alimentary tract and metabolism products
Idebenone	Other nervous system medicines
Isavuconazole (isavuconazonium sulfate)	Antimycotics for systemic use
Ketoconazole	Other therapeutic medicines
Lenvatinib (mesylate)	Antineoplastic medicines
Levofloxacin	Antibacterials for systemic use
Lumacaftor / ivacaftor	**Other respiratory system medicines**
Mercaptamine (hydrochloride)	Ophthalmologicals
Mifepristone	Systemic hormonal preparations, excl. sex hormones and insulins
Panobinostat (lactate anhydrous)	Antineoplastic medicines
Parathyroid hormone	**Calcium homeostasis**
Pitolisant (hydrochloride)	Psychoanaleptics
Recombinant L-asparaginase	Antineoplastic medicines
Susoctocog alfa	Antihemorrhagics
Tasimelteon	Psycholeptics
Tolvaptan	Urologicals

[3] In line with the Principles for publication of agendas and minutes of EMA scientific committees (EMA/555647/2013), and further to the information in the CHMP Minutes of March 2014 that the invented names of orphan products would no longer be disclosed in the Agendas and Minutes of the CHMP, this document includes (from September 2014 onwards) only the international non-proprietary names (INN) and therapeutic areas for designated orphan medicines under evaluation.

[4] Based on the ATC therapeutic sub-group.