

1 June 2012  
EMA/362726/2012  
Product Data Management

## Applications for new human medicines under evaluation by the Committee for Medicinal Products for Human Use June 2012

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 **31<sup>st</sup> May 2012**.

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from this list once the medicine has received a positive or negative opinion from the CHMP or when the applicant has withdrawn the application. The Agency publishes information on these opinions and withdrawn applications on its website.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



## Non-orphan medicinal products

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area <sup>1</sup>
Aflibercept	Antineoplastic medicines Ophthalmologicals
<b>Alogliptin</b>	<b>Medicines used in diabetes</b>
Autologous cultured chondrocytes	Other medicines for disorders of the musculo-skeletal system
Autologous oral mucosal epithelial cells	Ophthalmologicals
Autologous peripheral blood mononuclear cells activated with PAP-GM-CSF	Immunostimulants
Avanafil	Urologicals
Budesonide/salmeterol	Medicines for obstructive airway diseases
Ceftaroline fosamil	Antibacterials for systemic use
<b>Cobicistat</b>	<b>Antivirals for systemic use</b>
Colestilan	Other therapeutic medicines
Copper (64 CU) (chloride)	Various (radiolabelling)
Crizotinib	Antineoplastic medicines
Cultured autologous chondrocytes on hyaluronan based scaffold	Other medicines for disorders of the musculo-skeletal system
Dextromethorphan (hydrobromide)/quinidine (sulfate)	Other nervous system medicines
Dimethyl fumarate	Other nervous system medicines
Elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil	Antivirals for systemic use
Fenofibrate/simvastatin	Lipid modifying medicines
Fibrinogen human/thrombin human	Antihemorrhagics
Florbetapir (18F)	Diagnostic radiopharmaceuticals
Glycopyrronium (bromide)	Medicines for obstructive airway diseases
Human coagulation factor VIII / von Willebrand factor	Antihemorrhagics
Human normal immunoglobulin/recombinant	Immune sera and immunoglobulins

<sup>1</sup> Based on the ATC therapeutic sub-group.

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area <sup>1</sup>
human hyaluronidase	
Iloperidone	Psycholeptics
Imatinib (mesilate)	Antineoplastic medicines
Ingenol (mebutate)	Immunostimulants
Insulin degludec	Medicines used in diabetes
Insulin degludec/insulin aspart	Medicines used in diabetes
Linaclotide	Medicines for functional gastrointestinal disorders
Li pegfilgrastim	Immunostimulants
Lixisenatide	Medicines used in diabetes
Lomitapide	Lipid modifying medicines
Lorcaserin (hydrochloride)	Antiobesity medicines
Loxapine	Psycholeptics
Memantine (hydrochloride)/donepezil (hydrochloride)	Psychoanaleptics
Meningococcal group B vaccine (rDNA, adsorbed)	Vaccines
Mipomersen	Lipid modifying medicines
Mirabegron	Urologicals
Modified vaccinia Ankara virus	Vaccines
Nalmefene	Other nervous system medicines
Nonacog gamma	Antihemorrhagics
Ocriplasmin	Ophthalmologicals
Peginesatide	Antianemic medicines
Pegloticase	Antigout medicines
Pertuzumab	Antineoplastic medicines
Phentermine/topiramate	Antiobesity medicines
<b>Regorafenib</b>	<b>Antineoplastic medicines</b>
Secretin human	Diagnostic medicines
Semuloparin (sodium)	Antithrombotic medicines

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area <sup>1</sup>
Somatropin	Pituitary and hypothalamic hormones and analogues
Strontium ranelate/cholecalciferol	
Teriflunomide	Immunosuppressants
Tesamorelin	Pituitary and hypothalamic hormones and analogues
Tofacitinib (citrate)	Immunosuppressants
Vismodegib	Antineoplastic medicines

## Non-orphan generic and biosimilar medicinal products

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area <sup>2</sup>	Total number of applications
Capecitabine	Antineoplastic medicines	1
<b>Filgrastim</b>	<b>Immunostimulants</b>	<b>1</b>
Follitropin alfa	Sex hormones and modulators of the genital system	1
Ibandronic acid	Medicines for bone diseases	1
Imatinib	Antineoplastic medicines	2
Imiquimod	Antibiotics and chemotherapeutics for dermatological use	1
Infliximab	Immunosuppressants	1
Insulin human	Medicines used in diabetes	3
Megestrol	Endocrine therapy	1
<b>Telmisartan</b>	<b>Medicines acting on the renin-angiotensin system</b>	<b>1</b>
<b>Telmisartan/hidrochlorothiazide</b>	<b>Medicines acting on the renin-angiotensin system</b>	<b>1</b>
Zoledronic acid	Medicines for bone diseases	3

<sup>2</sup> Based on the ATC therapeutic sub-group.

## Orphan medicinal products

International non-proprietary name / Common Name	Product name	Marketing authorisation applicant	Therapeutic area <sup>3</sup>
Afamelanotide	Scenesse	Clinuvel (UK) Limited	Emollients and protectives
Bosutinib	Bosulif	Pfizer Ltd.	Antineoplastic medicines
Brentuximab vedotin	Adcetris	Takeda Global Research and Development Centre (Europe) Ltd.	Antineoplastic medicines
Bromelain enriched proteolytic enzyme preparation from <i>Ananas comosus</i>	NexoBrid	Teva Pharma GmbH	Medicines for wounds and ulcers
Cholic Acid	Cholic Acid FGK	FGK Representative Service GmbH	Bile and liver therapy
Cysteamine	Cysteamine bitartrate	Raptor Pharmaceuticals Europe B.V.	Other alimentary tract and metabolism products
Decitabine	Dacogen	Janssen-Cilag International N.V.	Antineoplastic medicines
Defibrotide	Defitelio	Gentium SpA	Antithrombotic medicines
Delamanid	Delamanid	Otsuka Novel Medicines GmbH	Antimycobacterials
Idebenone	SAN idebenone	Santhera Pharmaceuticals (Deutschland) GmbH	Psychoanaleptics
Mercaptopurine	Loulla	Only For Children Pharmaceuticals	Antineoplastic medicines
Para-aminosalicylic acid	PAS-GR	Lucane Pharma SA	Antimycobacterials
Ridaforolimus	Jenzyly	Merck Sharp & Dohme Ltd.	Antineoplastic medicines
Romidepsin	Istodax	Celgene Europe Ltd.	Antineoplastic medicines
Sodium 4-phenylbutyrate	Pheburane	Lucane Pharma	Other alimentary tract and metabolism products
Taliglucerase alfa	Elelyso	Pfizer Ltd.	Other alimentary tract and metabolism medicines
Teduglutide	Revestive	Nycomed Danmark APS.	Other alimentary tract and metabolism medicines

<sup>3</sup> Based on the ATC therapeutic sub-group.