



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 September 2020
EMA/PDCO/439902/2020
Human Medicines Division

Paediatric Committee (PDCO)

Agenda for the meeting on 1-4 September 2020

Chair: Koenraad Norga – Vice-Chair: Sabine Scherer

1 September 2020, 14:00- 19:00, Virtual meeting

2 September 2020, 08:30- 19:00, Virtual meeting

3 September 2020, 08:30- 19:00, Virtual meeting

4 September 2020, 08:30- 13:00, Virtual meeting

Health and safety information

In accordance with the Agency's health and safety policy, delegates are to be briefed on health, safety and emergency information and procedures prior to the start of the meeting.

Disclaimers

Some of the information contained in this agenda is considered commercially confidential or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. Additional details on some of these procedures will be published in the PDCO Committee meeting reports (after the PDCO Opinion is adopted), and on the Opinions and decisions on paediatric investigation plans webpage (after the EMA Decision is issued).

Note on access to documents

Some documents mentioned in the agenda cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).



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1. Introductions

1.1. Welcome and declarations of interest of members, alternates and experts

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the PDCO plenary session to be held 1-4 September 2020. See September 2020 PDCO minutes (to be published post September 2020 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 1-4 September 2020

1.3. Adoption of the minutes

PDCO minutes for 21-24 July 2020

2. Opinions

Disclosure of some information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

2.1. Opinions on Products

2.1.1. Glycopyrronium bromide - EMEA-002383-PIP01-18

Hyperhidrosis / Treatment of primary axillary hyperhidrosis

Day 120 opinion

Action: For adoption

Dermatology

2.1.2. Ruxolitinib - EMEA-002618-PIP01-19

Vitiligo

Day 120 opinion

Action: For adoption

Dermatology

2.1.3. Danicopan - Orphan - EMEA-002310-PIP01-17

Alexion Europe SAS; Treatment of paroxysmal nocturnal haemoglobinuria

Day 120 opinion

Action: For adoption

Haematology-Hemostaseology

2.1.4. Plasma kallikrein inhibitor - EMEA-002723-PIP01-19

Treatment of hereditary angioedema

Day 120 opinion

Action: For adoption

Haematology-Hemostaseology

2.1.5. Doravirine / islatravir - EMEA-002707-PIP01-19

Treatment of human immunodeficiency virus-1 (HIV-1) infection / Doravirine/islatravir is indicated alone or in combination with other antiretroviral medicinal products for the treatment of HIV-1 infection in paediatric patients from 28 days to less than 18 years of age

Day 120 opinion

Action: For adoption

Infectious Diseases

2.1.6. Mixture of 2 synthetic double-stranded N-acetyl-galactosamine conjugated siRNA oligonucleotides that are directed against the hepatitis B virus - EMEA-002694-PIP01-19

Treatment of chronic viral hepatitis B / Treatment of chronic hepatitis B infection

Day 120 opinion

Action: For adoption

Infectious Diseases

2.1.7. EMEA-002693-PIP01-19

Treatment of chronic viral hepatitis B / Treatment of chronic hepatitis B infection

Day 120 opinion

Action: For adoption

Infectious Diseases

2.1.8. The whole range of unmanipulated autologous mononuclear cells derived from human umbilical cord blood (Hau-UCB-mnc) - Orphan - EMEA-001799-PIP03-19

BrainRepair UG (haftungsbeschränkt); Periventricular leukomalacia (PVL)

Day 120 opinion

Action: For adoption

Neonatology - Paediatric Intensive Care

2.1.9. RAAVrh74.MHCK7.microdystrophin - Orphan - EMEA-002677-PIP01-19

Sarepta Therapeutics Ireland; Duchenne muscular dystrophy

Day 120 opinion

Action: For adoption

Neurology

2.1.10. Recombinant human granulocyte colony-stimulating factor – human immunoglobulin Fc fusion protein - EMEA-002507-PIP02-19

Treatment of chemotherapy-induced neutropenia, prevention of chemotherapy-induced febrile neutropenia/ Reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes)

Day 120 opinion

Action: For adoption

Oncology

2.1.11. 17-mer, 2'-O-methyl modified phosphorothioate RNA oligonucleotide - Orphan - EMEA-002717-PIP01-19

ProQR Therapeutics; Treatment of inherited retinal disorders / Treatment of Leber's congenital amaurosis due to the p.Cys998X mutation (C2991 +1655A>G) in the CEP290 gene

Day 120 opinion

Action: For adoption

Ophthalmology

2.1.12. 4-{(2S,4S)-4-Ethoxy-1-[(5-methoxy-7-methyl-1H-indol-4-yl)methyl]piperidin-2-yl}benzoic acid hydrochloride(1/1) - Orphan - EMEA-002705-PIP01-19

Novartis Europharm Limited; C3 glomerulopathy

Day 120 opinion

Action: For adoption

Other

2.1.13. EMEA-002705-PIP02-19

IgA Nephropathy

Day 120 opinion

Action: For adoption

Other

2.1.14. Colchicine - EMEA-002837-PIP01-20

Secondary prevention of atherothrombotic events in patients with coronary artery disease by reducing local plaque inflammation and subsequent plaque erosion and/or rupture

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.15. Fenofibrate / ezetimibe / eravastatin - EMEA-002835-PIP01-20

Treatment of mixed hyperlipidaemia

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.16. Dupilumab - EMEA-001501-PIP06-20

Prurigo nodularis

Day 60 opinion

Action: For adoption

Dermatology

2.1.17. Autologous T lymphocyte-enriched population of cells transduced with a lentiviral vector encoding a chimeric antigen receptor targeting human B cell maturation antigen with 4-1BB and CD3-zeta intracellular signalling domains - EMEA-002823-PIP01-20

Treatment of multiple myeloma / Treatment of patients with relapsed and/or refractory multiple myeloma (RRMM) who have received at least one proteasome inhibitor (PI), one immunomodulatory agent (IMiD), and one anti-CD38 monoclonal antibody (mAb). The patients shall have received at least 3 prior lines of therapy for MM

Day 60 opinion

Action: For adoption

Oncology

2.1.18. Sacituzumab govitecan - EMEA-002645-PIP02-20

Treatment of urothelial carcinoma

Day 60 opinion

Action: For adoption

Oncology

2.1.19. Tiragolumab - EMEA-002721-PIP02-20

Treatment of cervical cancer

Day 60 opinion

Action: For adoption

Oncology

2.1.20. Tiragolumab - EMEA-002721-PIP03-20

Treatment of oesophageal carcinoma

Day 60 opinion

Action: For adoption

Oncology

2.1.21. Alpha-R-lipoic acid choline ester tosilate - EMEA-002811-PIP01-20

Treatment of presbyopia

Day 60 opinion

Action: For adoption

Ophthalmology

2.1.22. Brolucizumab - EMEA-002691-PIP02-20

Diabetic retinopathy

Day 60 opinion

Action: For adoption

Ophthalmology

2.2. Opinions on Compliance Check

The following compliance checks have been put up for discussion and the members of the PDCO have been invited to comment on issues of possible non-compliance

2.2.1. Evinacumab - EMEA-C1-002298-PIP01-17-M01

Regeneron Ireland DAC; Treatment of elevated cholesterol

Day 60 letter

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism / Cardiovascular Diseases

2.2.2. Elivaldogene autotemcel - EMEA-C-001244-PIP01-11-M02

bluebird bio (Netherlands) B.V.; Treatment of adrenoleukodystrophy

Day 60 opinion

Action: For adoption

Neurology

2.2.3. Ad26.ZEBOV (recombinant, replication-incompetent) - EMEA-C2-002307-PIP01-17-M01

Janssen-Cilag International NV; Prevention of Ebola virus disease

Day 60 letter

Action: For adoption

Vaccines

2.2.4. MVA-BN-Filo (recombinant, non-replicating) - EMEA-C2-002308-PIP01-17-M01

Janssen-Cilag International NV; Prevention of Ebola virus disease

Day 60 letter

Action: For adoption

Vaccines

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Etripamil - EMEA-002303-PIP01-17-M02

Milestone Pharmaceuticals, Inc.; Treatment of supraventricular tachycardia / Treatment of acute paroxysmal supraventricular tachycardia (PSVT)

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.2. Edoxaban tosylate - EMEA-000788-PIP02-11-M10

Daiichi Sankyo Europe GmbH; Prevention of arterial thromboembolism / Prevention of venous thromboembolism / Treatment of venous thromboembolism / Prevention of arterial thromboembolism in paediatric cardiac patients at risk of thrombotic events / Acute treatment & secondary prevention of symptomatic recurrent venous thrombotic events (VTE) in paediatric patients at risk

Day 60 opinion

Action: For adoption

Cardiovascular Diseases / Haematology-Hemostaseology

2.3.3. Birch bark extract - Orphan - EMEA-001299-PIP03-17-M01

Amryt Research Limited; Treatment of epidermolysis bullosa

Day 60 opinion

Action: For adoption

Dermatology

2.3.4. Velmanase alfa - Orphan - EMEA-001056-PIP02-12-M01

Chiesi Farmaceutici S.p.A.; Treatment of alpha-mannosidosis

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.5. Ozanimod hydrochloride - EMEA-001710-PIP03-17-M02

Celgene Europe B.V.; Treatment of ulcerative colitis / Treatment of moderate to severely active ulcerative colitis

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.6. Pegylated-fibroblast growth factor 21 - EMEA-002448-PIP01-18-M01

Bristol-Myers Squibb International Corporation; Treatment of non-alcoholic steatohepatitis (NASH) / Treatment of NASH with moderate to severe liver fibrosis

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.7. Mepolizumab - Orphan - EMEA-000069-PIP01-07-M07

GSK Trading Services Limited; Treatment of hypereosinophilic syndrome (HES)

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.8. Vadadustat - EMEA-001944-PIP01-16-M02

Akebia Therapeutics, Inc.; Treatment of anaemia due to chronic disorders / Treatment of anaemia secondary to chronic kidney disease

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.9. Zanamivir - EMEA-001318-PIP01-12-M04

GlaxoSmithKline Trading Services Limited; Treatment of influenza / Prevention of influenza / Treatment of influenza A and B virus infection / Prevention of influenza A and B virus infection

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.10. Eculizumab - Orphan - EMEA-000876-PIP05-15-M04

Alexion Europe SAS; Treatment of myasthenia gravis / Treatment of refractory acetylcholine receptor antibody (AChR-Ab) - positive generalised myasthenia gravis

Day 60 opinion

Action: For adoption

Neurology

2.3.11. Copanlisib - Orphan - EMEA-001757-PIP02-15-M02

Bayer AG; Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid tissue) / Treatment of mature B-cell neoplasms / Treatment of children with a relapsed or refractory neuroblastoma, Ewing sarcoma,

osteosarcoma or rhabdomyosarcoma including at first relapse, in combination with chemotherapy

Day 60 opinion

Action: For adoption

Oncology

2.3.12. Dabrafenib - EMEA-001147-PIP01-11-M07

Novartis Europharm Limited; Treatment of solid malignant tumours (excluding melanoma and glioma) / Treatment of melanoma / Treatment of paediatric patients with solid malignant tumours containing BRAF V600 mutations / Treatment of adolescent patients with melanoma with a BRAF V600 mutation

Day 60 opinion

Action: For adoption

Oncology

2.3.13. Daratumumab - Orphan - EMEA-002152-PIP01-17-M02

Janssen-Cilag International NV; Treatment of lymphoid malignancies (except mature B-cell neoplasms) / Treatment of paediatric patients from birth to less than 18 years of age with a lymphoid malignancy (except mature B-cell neoplasms)

Day 60 opinion

Action: For adoption

Oncology

2.3.14. Lenvatinib - EMEA-001119-PIP02-12-M07

Eisai GmbH; Treatment of osteosarcoma / Treatment of papillary thyroid carcinoma / Treatment of follicular carcinoma / Treatment of refractory or relapsed osteosarcoma in children and adolescents / Treatment of progressive, radioiodine-refractory differentiated thyroid cancer in children and adolescents

Day 60 opinion

Action: For adoption

Oncology

2.3.15. Trametinib - EMEA-001177-PIP01-11-M06

Novartis Europharm Limited; Treatment of all conditions included in the category of malignant neoplasms (except melanoma, glioma, haematopoietic and lymphoid tissue) / Treatment of melanoma / Treatment of paediatric patients with a solid malignant tumour with known or expected RAS, RAF or MEK pathway activation / Treatment of adolescent patients with melanoma containing BRAF V600 activating mutations

Day 60 opinion

Action: For adoption

Oncology

2.3.16. Ivacaftor / tezacaftor / elexacaftor - Orphan - EMEA-002324-PIP01-17-M01

Vertex Pharmaceuticals (Ireland) Limited; Treatment of cystic fibrosis

Day 60 opinion

Action: For adoption

Other / Pneumology - Allergology

2.3.17. Dupilumab - EMEA-001501-PIP02-13-M06

sanofi-aventis recherche & développement; Treatment of asthma

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.3.18. Peanut allergen extract - EMEA-001481-PIP01-13-M04

DBV Technologies S.A.; Peanut allergy

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.3.19. Ravulizumab - Orphan - EMEA-001943-PIP01-16-M05

Alexion Europe SAS; Treatment of atypical haemolytic uremic syndrome

Day 60 opinion

Action: For adoption

Uro-nephrology / Haematology-Hemostaseology

2.3.20. Ravulizumab - Orphan - EMEA-002077-PIP01-16-M03

Alexion Europe SAS; Treatment of paroxysmal nocturnal haemoglobinuria

Day 60 opinion

Action: For adoption

Uro-nephrology / Haematology-Hemostaseology

2.4. Opinions on Re-examinations

No items.

2.5. Opinions on Review of Granted Waivers

No item

2.6. Finalisation and adoption of opinions

2.7. Partial Compliance Checks completed by EMA

For the following partial compliance checks, no need to refer them to PDCO Committee for discussion, were identified by the PME coordinator and PDCO Rapporteur. The PDCO has been informed in writing.

2.7.1. Palonosetron / fosnetupitant - EMEA-C2-001198-PIP03-17-M04

Helsinn Birex Pharmaceuticals Limited; Prevention of chemotherapy-induced nausea and vomiting

Day 30 letter

Action: For information

Gastroenterology-Hepatology

2.7.2. Lasmiditan - EMEA-C2-002166-PIP01-17-M04

Eli Lilly Nederland B.V.; Migraine with and without aura

Day 30 letter

Action: For information

Neurology

2.7.3. Pneumococcal polysaccharide serotype 5, conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 19A, conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 33F, conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 9V, conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 8, conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 19F, conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 23F, conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 10A, conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 7F, conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 15B, conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate /

Pneumococcal polysaccharide serotype 18C, conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 6B, conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 6A, conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 3, conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 4, conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 11A, conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 1, conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 12F, conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 22F, conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 14, conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate -
EMA-C1-002330-PIP01-18

Pfizer Europe MA EEIG; Disease caused by Streptococcus pneumoniae

Day 30 letter

Action: For information

Vaccines

2.7.4. Ivacaftor / tezacaftor / elexacaftor - EMA-C2-002324-PIP01-17

Vertex Pharmaceuticals (Europe) Limited; Treatment of cystic fibrosis

Day 30 letter

Action: For information

Other

2.7.5. Dermatophagoides pteronyssinus / Dermatophagoides farinae - EMA-C2-001258-PIP01-11-M06

ALK-Abelló A/S; Treatment of asthma

Day 30 letter

Action: For discussion

Pneumology - Allergology

3. Discussion of applications

Disclosure of some information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

3.1. Discussions on Products D90-D60-D30

3.1.1. Recombinant human acid alpha-glucosidase - Orphan - EMEA-002447-PIP01-18

Amicus Therapeutics Europe Limited; Treatment of glycogen storage disease type II (Pompe's disease)

Day 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.2. Venglustat - Orphan - EMEA-001716-PIP04-19

Genzyme Europe B.V.; GM2 gangliosidosis, Other gangliosidosis, GM1, GM3, Defects in glycoprotein degradation, sialidosis / Long term treatment of patients with a confirmed diagnosis of late onset GM2 gangliosidosis / Long term treatment in patients within the same biochemical pathway as GM2 gangliosidosis / Long term treatment in patients with juvenile (subacute) and adolescent (late-onset) GM2 gangliosidosis ages 2 years old and older, males/females

Day 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism / Neurology

3.1.3. Guselkumab - EMEA-001523-PIP04-19

Treatment of ulcerative colitis

Day 90 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.4. Bispecific antibody binding to clotting factor IX and X - EMEA-002762-PIP02-20

Treatment of haemophilia A / Routine prophylaxis to prevent or reduce frequency of bleeding episodes in patients with haemophilia A (congenital factor VIII deficiency) with or without factor VIII inhibitors

Day 90 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.5. Garadacimab - EMEA-002726-PIP01-19

Hereditary angioedema attacks (HAE)

Day 90 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.6. [Allogeneic bone marrow derived mesenchymal stromal cells, ex-vivo expanded - Orphan - EMEA-002706-PIP01-19](#)

medac Gesellschaft für klinische Spezialpräparate mbH; Treatment of acute graft-versus-host disease

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.7. [Alpha1-proteinase inhibitor \(human\) - EMEA-001312-PIP03-19](#)

Treatment of acute graft-versus-host disease (GVHD)

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.8. [Bimekizumab - EMEA-002189-PIP03-19](#)

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, spondyloarthritis, psoriatic arthritis and juvenile idiopathic arthritis (JIA)) / Treatment of JIA (enthesitis-related arthritis (ERA) and juvenile psoriatic arthritis (JPsA)) in patients from ≥ 2 years to < 18 years of age

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.9. [Cotadutide - EMEA-002712-PIP01-19](#)

Treatment of non-cirrhotic non-alcoholic steatohepatitis (NASH) or non-alcoholic fatty liver disease (NAFLD) / For the resolution of steatohepatitis with no worsening of fibrosis in obese children and adolescents with non-cirrhotic non-alcoholic steatohepatitis (NASH) and non-alcoholic fatty liver disease (NAFLD)

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.10. Dapirolizumab pegol - EMEA-002702-PIP01-19

Treatment of systemic lupus erythematosus (SLE) / Treatment of children and adolescents ≥ 7 years to < 18 years of age with active SLE despite standard therapy

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.11. Taniborbactam / cefepime - EMEA-002576-PIP01-19

Treatment of bacterial infections / Treatment of complicated urinary tract infections (cUTI) / Treatment of hospital acquired and ventilator acquired pneumonia (HAP/VAP) / Treatment of complicated intra-abdominal infections (CIAI)

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.12. Vonoprazan EMEA-002703-PIP01-19

Helicobacter Pylori / Reflux oesophagitis / Treatment of erosive reflux oesophagitis and relief of heartburn / Eradication of helicobacter pylori (H. pylori) concurrently given with appropriate antibiotic therapy

Day 90 discussion

Action: For discussion

Infectious Diseases / Gastroenterology-Hepatology

3.1.13. Adeno-associated viral vector serotype 9 containing the human mini-dystrophin gene - Orphan - EMEA-002741-PIP01-20

Pfizer Europe MA EEIG; Treatment of Duchenne muscular dystrophy

Day 90 discussion

Action: For discussion

Neurology

3.1.14. Lanadelumab - Orphan - EMEA-001864-PIP03-19

Shire Pharmaceuticals Ireland Limited (a Takeda company); Prevention of attacks of idiopathic non-histaminergic angioedema (INHA)

Day 90 discussion

Action: For discussion

Other

3.1.15. Adrenaline (epinephrine) - EMEA-002749-PIP01-19

Treatment of allergic reactions / The emergency treatment of allergic reactions, including anaphylaxis

Day 90 discussion

Action: For discussion

Pneumology - Allergology

3.1.16. EMEA-002653-PIP01-19

Treatment of Schizophrenia / Treatment of cognitive impairment associated with schizophrenia in patients 13 to <18 years of age

Day 90 discussion

Action: For discussion

Psychiatry

3.1.17. Dupilumab - EMEA-001501-PIP07-20

Treatment of chronic spontaneous urticaria

Day 60 discussion

Action: For discussion

Dermatology

3.1.18. LM-030 - Orphan - EMEA-002770-PIP02-20

LifeMax Laboratories, Inc.; Netherton syndrome

Day 60 discussion

Action: For discussion

Dermatology

3.1.19. Adeno-associated virus serotype 5- (AAV5-) based vector that contains the human phenylalanine hydroxylase (hPAH) gene - Orphan - EMEA-002833-PIP01-20

BioMarin International Limited; Treatment of phenylalanine hydroxylase deficiency / Treatment of patients with phenylketonuria

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.20. Dasiglucagon - Orphan - EMEA-002233-PIP02-20

Zealand Pharma; Congenital Hyperinsulinism

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.21. Hydroxypropyl- β -cyclodextrin (HP β CD) - Orphan - EMEA-002839-PIP01-20

Cyclo Therapeutics Inc; Niemann Pick disease type C / Treatment of Niemann Pick type C1 disease in children, adolescents and adults

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.22. Liposomal annexin - EMEA-002810-PIP01-20

Treatment of acute myeloid leukaemia / Treatment of relapsed acute myeloid leukaemia

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.23. EMEA-002350-PIP02-20

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and juvenile idiopathic arthritis) / Treatment of juvenile psoriatic arthritis (JPsA) in paediatric patients 6 years of age and older

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.24. Human plasma derived c1-inhibitor - EMEA-002818-PIP01-20

Pre-procedure prevention of acute hereditary angioedema (HAE) / Treatment of hereditary angioedema (HAE)

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.25. Bimekizumab - EMEA-002189-PIP04-20

Treatment of hidradenitis suppurativa / Treatment of moderate to severe hidradenitis suppurativa in adolescents from 12 years of age

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Dermatology

3.1.26. Risankizumab - EMEA-001776-PIP05-20

Hidradenitis suppurativa

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Dermatology

3.1.27. 2'-O-(2-methoxyethyl) modified antisense oligonucleotide targeting glial fibrillary acidic protein pre-mRNA - Orphan - EMEA-002822-PIP01-20

Ionis Pharmaceuticals; Alexander disease

Day 60 discussion

Action: For discussion

Neurology

3.1.28. Dabrafenib - EMEA-001147-PIP02-20

Treatment of glioma / Treatment of paediatric patients with glioma with a BRAF V600 mutation in combination with trametinib

Day 60 discussion

Action: For discussion

Oncology

3.1.29. Erdafitinib - EMEA-002042-PIP02-20

Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid tissue neoplasms) / Treatment of locally advanced or metastatic solid tumors, including primary CNS tumors, harboring susceptible FGFR alterations in patients who have progressed following prior therapies and those who have no acceptable standard therapies

Day 60 discussion

Action: For discussion

Oncology

3.1.30. Imetelstat - Orphan - EMEA-001910-PIP03-20

Geron Corporation; Treatment of acute myeloid leukaemia (AML) / Treatment of myelodysplastic syndromes (MDS), including juvenile myelomonocytic leukaemia (JMML) / Treatment of paediatric patients with relapsed or refractory AML or MDS, including JMML, from 1 year to less than 18 years of age

Day 60 discussion

Action: For discussion

Oncology

3.1.31. Trametinib - EMEA-001177-PIP02-20

Treatment of glioma / Treatment of paediatric patients with glioma with a BRAF V600 mutation in combination with dabrafenib

Day 60 discussion

Action: For discussion

Oncology

3.1.32. Recombinant humanised monoclonal antibody (IgG1, Kappa) to IL-5 - EMEA-002836-PIP01-20

Treatment of asthma / Add-on treatment for patients adolescents aged 12 years and older) with severe asthma and an eosinophilic phenotype

Day 60 discussion

Action: For discussion

Pneumology - Allergology

3.1.33. Conditionally replication-defective human cytomegalovirus (CMV) - EMEA-002838-PIP01-20

Congenital CMV infection and disease / Prevention of congenital CMV infection and disease

Day 60 discussion

Action: For discussion

Vaccines

3.1.34. Respiratory Syncytial Virus (RSV) PreF3 recombinant Fusion protein - EMEA-002821-PIP01-20

Prevention of RSV- associated lower respiratory tract illness through maternal immunization / Active immunization of pregnant women during the second and third trimester of pregnancy to prevent respiratory syncytial virus (RSV) -associated lower respiratory tract illness (LRTI) in infants by transfer of maternal antibodies

Day 60 discussion

Action: For discussion

Vaccines

3.1.35. Ezetimibe / atorvastatin - EMEA-002852-PIP01-20

Prevention of cardiovascular events / Treatment of hypercholesterolemia / The combination of atorvastatin and ezetimibe is indicated for the treatment of hypercholesterolemia as substitution therapy in adult patients adequately controlled with the individual substances given concurrently at the same dose level as in the fixed dose combination, but as separate products / Atorvastatin/ezetimibe is indicated as substitution therapy to reduce the risk of cardiovascular events in patients with coronary heart disease (CHD) and a history of acute coronary syndrome (ACS), for adults receiving atorvastatin and ezetimibe concurrently at the same dose level

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.36. Perindopril arginine / indapamide / amlodipine besilate - EMEA-002849-PIP01-20

Hypertension

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.37. Ralinepag - Orphan - EMEA-002432-PIP02-20

United Therapeutics Corporation; Treatment of pulmonary arterial hypertension / Treatment of pulmonary arterial hypertension WHO Group I to improve exercise capacity and to delay clinical worsening

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.38. Sotatercept - EMEA-002756-PIP01-19

Pulmonary arterial hypertension

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.39. [Chimeric fibrin-reactive IgG1k monoclonal antibody 11-1F4 - Orphan - EMEA-002791-PIP01-20](#)

Real Regulatory Limited; Treatment of AL amyloidosis

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.40. [Indometacin / levonorgestrel - EMEA-002820-PIP01-20](#)

Contraceptive management

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.41. [Pioglitazone / spironolactone / metformin - EMEA-002187-PIP01-17](#)

Treatment of polycystic ovary syndrome (PCOS) / Treatment of adolescent polycystic ovary syndrome (PCOS) in post-menarche adolescents <18 yrs and young adult women ≥18 yrs and <24.0 yrs

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.42. [Recombinant fusion protein linking iduronate 2-sulfatase to Fc with binding site for transferrin receptor - EMEA-002845-PIP01-20](#)

Treatment of mucopolysaccharidosis II (Hunter syndrome)

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.43. [EMEA-001475-PIP04-20](#)

Treatment of biliary atresia

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.44. Recombinant monoclonal antibody to sialic acid-binding Ig-like lectin 8 - Orphan - EMEA-002856-PIP01-20

Allakos Inc; Treatment of eosinophilic gastrointestinal inflammatory disorders / Treatment of eosinophilic esophagitis / Treatment of eosinophilic gastritis and/or eosinophilic gastroenteritis

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.45. Pegfilgrastim - EMEA-002671-PIP02-20

Treatment of chemotherapy-induced neutropenia and prevention of chemotherapy-induced febrile neutropenia / Reduction in the duration of neutropenia and the incidence of febrile neutropenia in paediatric patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes)

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.46. EMEA-002350-PIP03-20

Treatment of systemic lupus erythematosus (SLE) / Treatment of lupus nephritis (LN) despite receiving standard of care SoC / Treatment of systemic lupus erythematosus (SLE) despite receiving standard of care (SoC)

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.47. Iscalimab - EMEA-002842-PIP01-20

Prophylaxis against transplant rejection / Prophylaxis of graft rejection in paediatric renal transplant patients 2 years of age and older

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.48. Fasudil - EMEA-002841-PIP01-20

Non-traumatic subarachnoid haemorrhage

Day 30 discussion

Action: For discussion

Neurology

3.1.49. Rimegepant - EMEA-002812-PIP02-20

Acute treatment of migraine

Day 30 discussion

Action: For discussion

Neurology

3.1.50. Viltolarsen - Orphan - EMEA-002853-PIP01-20

NS Pharma, Inc.; Treatment of Duchenne muscular dystrophy / Treatment of Duchenne muscular dystrophy in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping

Day 30 discussion

Action: For discussion

Neurology

3.1.51. Allogeneic BCMA-directed chimeric antigen receptor T Cell - EMEA-002834-PIP01-20

Multiple myeloma

Day 30 discussion

Action: For discussion

Oncology

3.1.52. Lurbinectedin - Orphan - EMEA-002846-PIP01-20

Pharma Mar, S.A.; Treatment of small cell lung cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.53. Serplulimab - EMEA-002859-PIP01-20

Lung cancer/ Extensive stage small cell lung cancer (SCLC)/ Locally advanced or metastatic squamous non-small cell lung cancer (NSCLC)

Day 30 discussion

Action: For discussion

Oncology

3.1.54. Talazoparib - EMEA-002066-PIP01-20

Treatment of Ewing sarcoma / Treatment of refractory or recurrent Ewing sarcoma

Day 30 discussion

Action: For discussion

Oncology

3.1.55. EMEA-002843-PIP01-20

Treatment of ovarian cancer

Day 30 discussion

Action: For discussion

Oncology / Haematology-Hemostaseology

3.1.56. EMEA-002843-PIP02-20

Treatment of breast cancer

Day 30 discussion

Action: For discussion

Oncology / Haematology-Hemostaseology

3.1.57. Flotetuzumab - EMEA-002855-PIP01-20

Acute myeloid leukemia (AML)

Day 30 discussion

Action: For discussion

Oncology / Haematology-Hemostaseology

3.1.58. Atropine - EMEA-002858-PIP01-20

Prevention of myopic progression

Day 30 discussion

Action: For discussion

Ophthalmology

3.1.59. Udonitrectag lysine - Orphan - EMEA-002848-PIP01-20

Recordati Rare Diseases; Neurotrophic keratitis

Day 30 discussion

Action: For discussion

Ophthalmology

3.1.60. (1R,2R,3S,4S,5R,6S)-cyclohexane-1,2,3,4,5,6-hexayl-hexakis (dihydrogen phosphate) - Orphan - EMEA-002854-PIP01-20

Sanifit Therapeutics S.A.; Treatment of calciphylaxis

Day 30 discussion

Action: For discussion

Other

3.1.61. Dapagliflozin - EMEA-000694-PIP05-20

COVID-19, virus identified / COVID-19, virus not identified for the prevention of disease complications and mortality in adults with corona virus disease 2019 (COVID-19) requiring oxygen treatment and at risk of developing serious complications

Day 30 discussion

Action: For discussion

Other

3.1.62. Garetosmab - Orphan - EMEA-002736-PIP01-19

Regeneron Ireland DAC; Treatment of fibrodysplasia ossificans progressiva

Day 30 discussion

Action: For discussion

Other

3.1.63. Ravulizumab - EMEA-001943-PIP02-20

Hematopoietic stem cell transplantation associated / Thrombotic microangiopathy (HSCT-TMA) / Treatment of thrombotic microangiopathy after haematopoietic stem cell transplantation (HSCT-TMA)

Day 30 discussion

Action: For discussion

Uro-nephrology / Haematology-Hemostaseology

3.1.64. Multivalent pneumococcal polysaccharide conjugate to carrier protein - EMEA-002780-PIP02-20

Prevention of disease caused by streptococcus pneumoniae

Day 30 discussion

Action: For discussion

Vaccines

3.2. Discussions on Compliance Check

The following compliance checks have been put up for discussion and the members of the PDCO have been invited to comment on issues of possible non-compliance

3.2.1. Lonapegsomatropin - EMEA-C-002692-PIP01-19

Ascendis Pharma Endocrinology Division A/S; Treatment of growth hormone deficiency

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.2.2. Eptacog beta (activated) - EMEA-C-001203-PIP02-14-M02

LFB SA; Treatment of congenital coagulation disorders

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.2.3. Posaconazole - EMEA-C2-000468-PIP02-12-M06

Merck Sharp & Dohme (Europe), Inc.; Prevention of invasive fungal infections

Day 30 discussion

Action: For discussion

Infectious Diseases

3.2.4. Sofosbuvir / voxilaprevir / velpatasvir - EMEA-C-001822-PIP01-15-M01

Gilead Sciences Ireland UC; Treatment of chronic hepatitis C

Day 30 discussion

Action: For discussion

Infectious Diseases

3.2.5. Arimoclomol citrate - EMEA-C1-001748-PIP01-15

Orphazyme A/S; Treatment of Niemann-Pick disease, type C

Day 30 discussion

Action: For discussion

Neurology

3.2.6. Cobimetinib - EMEA-C3-001425-PIP01-13-M04

Roche Registration GmbH; Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid tissue) with Ras, Raf or MEK pathway activation

Day 30 discussion

Action: For discussion

Oncology

3.2.7. Regorafenib - EMEA-C2-001178-PIP01-11-M05

Bayer AG; Treatment of all conditions contained in the category of malignant neoplasms (except haematopoietic and lymphoid tissue)

Day 30 discussion

Action: For discussion

Oncology

3.2.8. Influenza virus surface antigens (haemagglutinin and neuraminidase) of the following strains: A/(H1N1), A/(H3N2), B/Yamagata lineage, B/Victoria lineage - EMEA-C-001782-PIP01-15-M03

Abbott Biologicals B.V.; Prevention of influenza infection

Day 30 discussion

Action: For discussion

Vaccines

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Bilastine - EMEA-000347-PIP02-16-M02

Faes Farma S.A.; Treatment of allergic conjunctivitis

Day 30 discussion

Action: For discussion

3.3.2. Tralokinumab - EMEA-001900-PIP02-17-M04

LEO Pharma A/S; Treatment of atopic dermatitis

Day 30 discussion

Action: For discussion

Dermatology

3.3.3. [Canagliflozin \(1s\)-1,5-anhydro-1-\[3-\[\[5-\(4-fluorophenyl\)-2-thienyl\]methyl\]-4-methylphenyl\]-D-glucitol hemihydrate - EMEA-001030-PIP01-10-M08](#)

Janssen-Cilag International NV; Type 2 diabetes mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.4. [Drospirenone / estetrol monohydrate - EMEA-001332-PIP01-12-M04](#)

Estetra SPRL; Prevention of pregnancy

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.5. [Lixisenatide - EMEA-000916-PIP01-10-M07](#)

sanofi-aventis R&D; Type 2 diabetes mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.6. [Olipudase alfa - Orphan - EMEA-001600-PIP01-13-M02](#)

Genzyme Europe B.V.; Treatment of Niemann-Pick disease

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.7. [Recombinant parathyroid hormone: rhPTH \(1-84\) - Orphan - EMEA-001526-PIP01-13-M04](#)

Shire Pharmaceuticals Ireland Limited; Treatment of hypoparathyroidism

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.8. Filgotinib - EMEA-001619-PIP03-16-M01

Gilead Sciences International Ltd.; Treatment of paediatric patients 2 years of age and older with moderately-to-severely active ulcerative colitis / Treatment of paediatric patients 2 years of age and older with moderately-to-severely active Crohn's disease

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.9. Potassium chloride / sodium chloride / ascorbic acid / sodium sulfate / sodium ascorbate / polyethylene glycol 3350 - EMEA-001705-PIP02-15-M03

Norgine Limited; Bowel cleansing prior to clinical procedures

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.10. Teduglutide ([gly2] recombinant human glucagon-like peptide) - Orphan - EMEA-000482-PIP01-08-M06

Shire Pharmaceuticals Ireland Limited; Treatment of short bowel syndrome

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.11. Vonicoq alfa - EMEA-001164-PIP01-11-M04

Baxalta Innovations GmbH; Prevention and treatment of bleeding episodes and for surgical and invasive procedures in paediatric patients (less than 18 years of age) with von Willebrand disease

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.12. Apremilast - EMEA-000715-PIP03-11-M06

Amgen Europe B.V.; Treatment of moderate to severe psoriasis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.13. Ustekinumab - EMEA-000311-PIP03-11-M06

Janssen-Cilag International NV; Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, spondyloarthritis, PsA and juvenile idiopathic arthritis (JIA) / Treatment of juvenile idiopathic arthritis (juvenile psoriatic arthritis (jPsA)

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.14. Tazobactam / ceftolozane - EMEA-001142-PIP01-11-M04

Merck Sharp & Dohme (Europe), Inc.; Treatment of complicated urinary tract infections (cUTI) / Treatment of complicated intra-abdominal infections (cIAI)

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.15. Tedizolid - EMEA-001379-PIP01-12-M05

Merck Sharp & Dohme (Europe), Inc.; Treatment of acute bacterial skin and skin structure infections

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.16. Tenofovir alafenamide / emtricitabine / elvitegravir / cobicistat - EMEA-001460-PIP01-13-M05

Gilead Sciences International Ltd.; Treatment of human immunodeficiency virus (HIV-1) infection / treatment of HIV-1 infection in paediatric patients from 6 years to less than 18 years

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.17. Tenofovir disoproxil (as fumarate) - EMEA-000533-PIP01-08-M09

Gilead Sciences International Limited; Treatment of chronic viral hepatitis B / Treatment of chronic hepatitis B in paediatric patients from 2 years of age with compensated liver disease

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.18. Fenfluramine hydrochloride - Orphan - EMEA-001990-PIP01-16-M03

Zogenix International Ltd; The adjunctive treatment of seizures in paediatric patients at least 1 year of age with Dravet syndrome

Day 30 discussion

Action: For discussion

Neurology

3.3.19. Humanised anti-IL-6 receptor (IL-6R) monoclonal antibody - Orphan - EMEA-001625-PIP01-14-M06

Roche Registration GmbH; Treatment of neuromyelitis optica

Day 30 discussion

Action: For discussion

Neurology

3.3.20. Nivolumab - EMEA-001407-PIP01-12-M03

Bristol-Myers Squibb Pharma EEIG; Treatment of all conditions included in the category of malignant neoplasms (except nervous system, haematopoietic and lymphoid tissue) / Treatment of patients with unresectable or metastatic melanoma in the age group from 12 to less than 18 years old / Treatment of a paediatric malignant solid tumour in paediatric patients from 6 months to less than 18 years old

Day 30 discussion

Action: For discussion

Oncology

3.3.21. Nivolumab - EMEA-001407-PIP02-15-M04

Bristol-Myers Squibb Pharma EEIG; Treatment of malignant neoplasms of lymphoid tissue / Treatment of malignant neoplasms of the central nervous system / Treatment of paediatric patients with a relapsed or refractory non-Hodgkin lymphoma in the age group from 6 months to less than 18 years old / Treatment of paediatric patients from 6 months to less than 18 years of age with a recurrent or progressive high-grade glioma / Treatment of paediatric patients with a relapsed or refractory Hodgkin lymphoma in the age group from 5 years to less than 18 years

Day 30 discussion

Action: For discussion

Oncology

3.3.22. Veliparib - EMEA-000499-PIP02-10-M01

AbbVie Ltd; Treatment of high-grade glioma

Day 30 discussion

Action: For discussion

Oncology

3.3.23. Concentrate of proteolytic enzyme enriched in bromelain - Orphan - EMEA-000142-PIP02-09-M10

MediWound Germany GmbH; Treatment of burns of external body surfaces / Removal of eschar in deep partial and/or full thickness burns

Day 30 discussion

Action: For discussion

Other

3.3.24. Palovarotene - Orphan - EMEA-001662-PIP01-14-M04

Ipsen Pharma; Treatment of fibrodysplasia ossificans progressiva

Day 30 discussion

Action: For discussion

Other

3.3.25. Benralizumab - EMEA-001214-PIP01-11-M10

AstraZeneca AB; Treatment of asthma

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.26. Birch pollen extract (*Betula verrucosa*) - EMEA-001879-PIP01-15-M02

ALK-Abelló A/S; Treatment of allergic rhinitis / rhino-conjunctivitis / Treatment of tree pollen allergic rhinitis / rhino-conjunctivitis

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.27. Brexpiprazole - EMEA-001185-PIP01-11-M06

Otsuka Pharmaceutical Development & Commercialisation Europe GmbH; Treatment of schizophrenia from 13 to less than 18 years of age

Day 30 discussion

Action: For discussion

Psychiatry

- 3.3.28. Dengue virus serotype 4* (live, attenuated); *Genes of serotype-specific surface proteins engineered into dengue type 2 backbone / Dengue virus serotype 3* (live, attenuated); *Genes of serotype-specific surface proteins engineered into dengue type 2 backbone / Dengue virus serotype 2 (live, attenuated) / Dengue virus serotype 1* (live, attenuated); *Genes of serotype-specific surface proteins engineered into dengue type 2 backbone - EMEA-001888-PIP01-15-M01
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Takeda Vaccines, Inc.; Prevention of dengue fever

Day 30 discussion

Action: For discussion

Vaccines

4. Nominations

Disclosure of information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

- 4.1. List of letters of intent received for submission of applications with start of procedure 15 September 2020 for Nomination of Rapporteur and Peer reviewer**

Action: For adoption

- 4.2. Nomination of Rapporteur for requests of confirmation on the applicability of the EMA decision on class waiver.**

Action: For adoption

- 4.3. Nominations for other activities**

Action: For adoption

5. Scientific Advice Working Party (SAWP) and Paediatric Committee (PDCO) Interaction

Disclosure of information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

6. Discussion on the applicability of class waivers

Disclosure of some information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

6.1. Discussions on the applicability of class waiver for products

6.1.1. Bevacizumab (ophthalmic formulation) - EMEA-07-2020

Le4d Global Regulatory Science Limited; All classes of medicinal products for treatment of age-related macular degeneration and diabetic macular oedema/ Treatment of neovascular (wet) age-related macular degeneration

Action: For adoption

7. Discussion on the inclusion of an indication within a condition in an agreed PIP/waiver

7.1. Discussion on the possibility to include an indication within a condition in an agreed PIP/waiver

No item

8. Annual reports on deferrals

Note: The annual reports on deferrals to be noted by the members of the PDCO are flagged in the Annex B.

9. Organisational, regulatory and methodological matters

9.1. Mandate and organisation of the PDCO

No item

9.2. Coordination with EMA Scientific Committees or CMDh-v

9.2.1. Committee for Medicinal Products for Human Use (CHMP)

Action: For information

9.3. Coordination with EMA Working Parties/Working Groups/Drafting Groups

9.3.1. Non-clinical Working Group: D30 Products identified

PDCO member: Karen van Malderen

Action: For information

9.3.2. Formulation Working Group

PDCO member: Brian Aylward

Action: For information

9.4. Cooperation within the EU regulatory network

9.4.1. European Network of Paediatric Research (Enpr) - European Medicines Agency (EMA)

Mandate of the Coordinating Group of Enpr-EMA

Action: For information

9.5. Cooperation with International Regulators

None

9.6. Contacts of the PDCO with external parties and interaction with the Interested Parties to the Committee

None

9.7. PDCO work plan

None

9.8. Planning and reporting

9.8.1. Strategic Review and Learning Meeting (SRLM) under the German Presidency to be held virtually on 22nd October 2020

Action: For information

10. Any other business

10.1.1. Covid-19 update

Action: For information

10.1.2. Implementation of the extrapolation guidance - update

Action: For information

10.1.3. Guidance supporting the discussions on grounds for a waiver

Action: For information

10.1.4. Publication on the evaluation of the orphan and paediatric regulation - next steps

Action: For information

10.1.5. EMA Working Parties review

Action: For information

11. Breakout sessions

11.1.1. Paediatric oncology

Action: For discussion on

11.1.2. Neonatology

Action: For discussion on

12. Explanatory notes

The Notes give a brief explanation of relevant agenda items and should be read in conjunction with the agenda.

Paediatric investigation plan (PIP) (section 2.1 Opinion on PIPs and section 3.1 Discussions on PIPs)

A paediatric investigation plan (PIP) is a development plan aimed at ensuring that the necessary data are obtained through studies in children, when it is safe to do so, to support the authorisation of a medicine for children. Pharmaceutical companies submit proposals for PIPs to the European Medicines Agency's Paediatric Committee (PDCO). This Committee is responsible for agreeing or refusing the plan.

Compliance checks (section 2.2 Opinions on Compliance check, section 3.2 Discussions on Compliance check)

A compliance check may be necessary before any application for marketing authorisation (even for an adult indication) can be considered valid, if there was no deferral for at least one of the studies agreed in the PIP, or after the due date of initiation or completion of a study/measure. The same applies to some regulatory applications for authorised products, as described above.

Modification of an Agreed Paediatric Investigation Plan (section 2.3 Opinions on Modification of an agreed PIP, section 3.3 Discussions on Modification of an agreed PIP)

The development plan for a medicine can be modified at a later stage as knowledge increases. Modifications can also be made if the applicant encounters such difficulties with the implementation of a PIP, which render it unworkable or no longer appropriate.

In some cases, studies can be deferred until after the studies in adults have been conducted. This ensures that research in children is done only when it is safe and ethical to do so. Even when studies are deferred, the PIP will include details of the paediatric studies and their timelines.

Class waiver (section 6 Discussion on the applicability of class waiver)

As some diseases do not affect children (for example Parkinson's disease), the development of medicines for these diseases should not be performed in children. In these cases, a PIP is not required and it will be waived. For more information on the classes of diseases subject to waivers, see [class waivers](#).

Annual reports on deferrals (section 8)

If the medicinal product is approved in the EU, annual reports on the deferred measures in the PIP must be submitted to the Agency.

More detailed information on the above terms can be found on the EMA website: www.ema.europa.eu/