

ANNEX - List of the paediatric MAs/variations in 2014ⁱ

Tradename/ Active Substance	MA Date	ATC code	Paediatric indication	Paediatric Age	Orphan designation	MA Variations	Studies including paediatric population in support of MA
PREZISTA/darunavir	12/02/2007	J	treatment of HIV 1 infection in paediatric patients in combination treatment of HIV 1 infection in adult and paediatric patients antiretroviral therapy (ART) naïve treatment of HIV 1 infection in ART experienced paediatric patients with no darunavir resistance-associated mutations (DRV RAMs)	> 3 years >12 years 3-12 years	-	24/10/2012 30/10/2014	3 PK/safety trials 1 compassionate use programme
TIVICAY/dolutegravir	16/01/2014	J	treatment of Human Immunodeficiency Virus (HIV) in combination with other anti-retroviral medicinal products	> 12 years	-		1 PK/safety trial
GRANUPAS (PARA-AMINOSALICYLIC ACID LUCANE)/para-aminosalicylic acid	07/04/2014	J	combination regimen for multi-drug resistant tuberculosis (second line)	>28 days	Treatment of tuberculosis		Bibliographic data
HEMANGIOL/ propranolol hydrochloride	23/04/2014	C	treatment of proliferating infantile haemangioma requiring systemic therapy	>5 weeks	-		2 PK trials 1 efficacy/safety trial
REVINTY ELLIPTA/ ^x fluticasone furoate /vilanterol	02/05/2014	R	regular treatment of asthma, where use of a combination product is appropriate	>12 years	-		-
VIMIZIM/elosulfase alfa	28/04/2014	A	treatment of mucopolysaccharidosis, type IVA (Morquio A Syndrome, MPS IVA)	all ages	Treatment of mucopolysaccharidosis, type IVA (Morquio A syndrome)		1 dose-escalation trial 1 efficacy/safety trial

TEDDY Network is coordinated by:

Consorzio per Valutazioni Biologiche e Farmacologiche
I-27100 PAVIA Via Luigi Porta 14 – Tel. +39 0382 25075
I-70125 BARI Corso Alcide De Gasperi 435 – Tel. +39 080 8641260
www.teddyyoung.net • teddynetwork@cvbf.net

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TRANSALRNA/ataluren	31/07/2014	not yet assigned	treatment of Duchenne muscular dystrophy resulting from a nonsense mutation in the dystrophin gene.	>5 years	Treatment of Duchenne muscular dystrophy		1 dose-ranging 2 dose- ranging/efficacy/safety trials 2 PD trials
TRIUMEQ/abacavir sulfate/dolutegravir sodium/lamivudine	01/09/2014	J	treatment of Human Immunodeficiency Virus (HIV) infected adults and adolescents	>12 years	-		-
NUWIQ/simocetocog alfa (rFVIII)	24/07/2014	B	treatment and prophylaxis of bleeding in patients with haemophilia A	all ages	-		2 PK/efficacy/safety 1 efficacy/safety
KETOKONAZOLE HRA/ ketoconazole	19/11/2014	J	treatment of endogenous Cushing's syndrome	> 12 years	Treatment of Cushing's syndrome		bibliographic
XOLAIR/omalizumab	25/10/2005	R	add-on therapy to improve asthma control in patients with severe persistent allergic asthma. with convincing IgE (immunoglobulin E) mediated asthma. add-on therapy for the treatment of chronic spontaneous urticaria with inadequate response to H1 antihistamine	>6 years >12 years	-	28/02/2014	7 PK/PD/efficacy/safety trials 3 dose- ranging/efficacy/safety trials 3 efficacy/safety trials 1 efficacy trial 1 safety trial
NOVO THIRTEEN/ catidecacog	03/09/2012	B	Long-term prophylactic treatment of bleeding in patients with congenital factor-XIII-A- subunit deficiency.	All ages	-	21/02/2014	1 efficacy/safety trial 2 long-term safety trials 1 PK/safety trial
ISENTRESS/ raltegravir	20/12/2007	J	treatment of human immunodeficiency virus (HIV 1) infection in combination with other anti-retroviral medicinal products for the	>4 weeks	-	28/08/2014	1 PK, efficacy, safety trial
HUMIRA/ adalimumab	08/09/2003	L	treatment of active polyarticular juvenile idiopathic in combination with methotrexate treatment of severe active Crohn's disease treatment of active enthesitis-related arthritis	> 2 years >6 years >6 years	-	01/09/2014	3 PK, efficacy, safety trials 1 efficacy, long-term safety 1 compassionate use programme

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			treatment of severe chronic plaque psoriasis	>4 years			
ABASAGLAR (previously ABASRIA)/ insulin glargine**	09/09/2014	A	treatment of diabetes mellitus	>2 years	-	-	-
ACCOFIL/ filgrastim**	18/09/2014	L	reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy for malignancy or undergoing myeloablative therapy mobilisation of peripheral blood progenitor cells (PBPCs). severe congenital, cyclic, or idiopathic neutropenia with an absolute neutrophil count (ANC) of $\leq 0.5 \times 10^9/L$ treatment of persistent neutropenia in patients with advanced HIV infection	children	-	-	-
BUSULFAN FRESENIUS KABI/ busulfan*	22/09/2014	L	conditioning treatment prior to conventional haematopoietic progenitor cell transplantation followed by cyclophosphamide (BuCy4) or melphalan (BuMel)	All ages	-		-
EBILFUMIN/ oseltamivir*	22/05/2014	J	treatment of influenza - when influenza virus is circulating in the community during a pandemic influenza outbreak prevention of influenza - Post-exposure prevention and seasonal prevention post-exposure prevention of influenza during a pandemic influenza outbreak.	>1 year <1 year > 1 years <1 years	-	-	-

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KOLBAM (previously Cholic Acid FGK)/ cholic acid	04/04/2014	A	treatment of inborn errors in primary bile acid synthesis	>1 month	Treatment of inborn errors in primary bile acid synthesis	-	3 efficacy/safety trials
LEVETIRACETAM HOSPIRA/ Levetiracetam*	08/01/2014	N	monotherapy in the treatment for partial onset seizures with or without secondary generalisation in newly diagnosed epilepsy adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation treatment of myoclonic seizures primary generalised tonic-clonic seizures	>16 years >4 years >12 years >12 years	-	-	-
BARACLUDE/ entecavir	26/06/2006	J	Treatment of chronic HBV infection in nucleoside naive paediatric patients who have evidence of active viral replication	>2 years	-		1 PK/efficacy/safety trial 1 efficacy/safety trial
INVEGA/ paliperidone	25/06/2007	N	treatment of schizophrenia in adults and in adolescents	>15 years	-	23/05/2014	1 PK/safety 2 efficacy/safety trial 1 long-term safety trial
XGEVA/ denosumab	13/07/2011	M	treatment of adults and skeletally mature adolescents with giant cell tumour of bone	Adolescent with skeletal maturation	-	01/09/2014	-
GRASTOFIL/ filgrastim**	18/10/2013	L	reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy for malignancy or undergoing myeloablative therapy mobilisation of peripheral blood progenitor cells (PBPCs). severe congenital, cyclic, or idiopathic neutropenia with an absolute neutrophil count (ANC) of $\leq 0.5 \times 10^9/L$ treatment of persistent neutropenia in patients with advanced HIV infection	Children	-	22/05/2014	-

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<i>*generic</i> <i>** biosimilar</i> <i>×The legal basis for this application refers to article 10(c) of Directive 2001/83/EC – relating to informed consent from a marketing authorisation holder for an authorised medicinal product. The application submitted is composed of administrative information, quality, non-clinical and clinical data with a letter from a MAH allowing the cross reference to relevant quality, non-clinical and/or clinical data.</i>							

ⁱ This document has been prepared by TEDDY Network as part of its research activity. It does not replace the official data that can be accessed directly from the EMA website. The material cannot be distributed nor re-utilised without acquiring a specific preliminary consent from TEDDY Network. Reference to this document and to TEDDY Network should be included when citing data deriving from it.

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