Annex 2 – detailed information on unsuccessful CMAs

Annex to the EMA report on 10 years of experience with conditional marketing authorisations

Description of data in tables and table columns:

Product name	Invented name of the product
Active substance	Active substance(s) of the product
Orphan	Indication whether the product had (Y) or did not have (N) orphan medicinal product designation
Proc. start date	Date of start of the MAA procedure
Procedure outcome	Description of the procedure outcome
CHMP outcome date	Date of the (final) CHMP opinion or, if not available, date of withdrawal of the application
SA/PA	Indication whether the product had previously received CHMP scientific advice or protocol assistance
CMA first raised	Step of the procedure, when CMA was first requested or proposed
1 (a-f), 2-5	CMA criteria considered by the CHMP not to be met in the latest assessment report (for negative B/R balance also categories or arguments for such conclusion) – “x” indicated that the criterion applies
Therapeutic area	Therapeutic area of the product

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Product Name	Active substance	Orphan	Proc. Start date	Procedure outcome	CHMP Outcome date	SA / PA	CMA first raised	1. Negative B/R	a) failed efficacy study	b) inconclusive results / uncertainties about efficacy / clinical relevance	c) overall insufficiency of data	d) particular safety risk identified requiring more data	e) methodological, GCP and/or statitical issues make data unreliable	f) quality and/or manufacturing aspects	2. Benefits or early access do not outweight the risks	3. no fulfilment of unmet medical need	4. Withdrawn by applicant after positive opinion	5. Unlikely that compr. data can be provided	Therapeutic area
Cerepro (WD)	ADENOVIRUS-MEDIATED HERPES SIMPLEX VIRUS-THYMIDINE KINASE GENE	Y	26/10/2005	Negative by consensus	26/04/2007	Y	During the assessment	X		X	X									Oncology
Rhucin (RJD)	CONESTAT ALFA	Y	16/08/2006	Negative by majority	19/03/2008	Y	During re-examination	X			X	X								Immunology
Kiacta	EPRODISATE DISODIUM	Y	27/09/2006	Negative by consensus	13/12/2007	Y	During the assessment	X	X			X	X							Rheumatology
Spanidin	gusperimus hydrochloride	Y	27/12/2006	Withdrawn before opinion	18/06/2008	Y	Initial MAA	X			X		X							Rheumatology

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Sovrima	GOLIMUMAB	Y	15/08/2007	Negative by consensus	20/11/2008	Y	During the assessment	X	X	X	X				X				Neurology
Oncophage	VITESPEN	Y	22/10/2008	Negative by consensus	19/11/2009	Y	Initial MAA	X	X		X			X					Oncology
Movectro	CLADRIBINE	N	22/07/2009	Negative by majority	20/01/2011	N	During the assessment	X		X		X			X	X			Neurology
Folotyn	PRALATREXATE	Y	15/12/2010	Negative by majority	19/04/2012	Y	Initial MAA	X		X	X		X		X				Oncology

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Istodax	ROMIDEPSIN	Y	23/03/2011	Negative by majority	15/11/2012	Y	During the assessment	X			X		X	X					Oncology
Oranera	autologous oral mucosal epithelial cells	N	22/06/2011	Withdrawn before opinion	14/03/2013	Y	Initial MAA	X		X			X	X					Ophthal-mology[1]
Kynamro	MIPOMERSEN	N	17/08/2011	Negative by majority	21/03/2013	Y	During re-examination	X		X		X						X	Metabolism

[1] Correction: typographical error corrected in word “Ophthalmology”

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Hyalograft C autograft	cultured autologous chondrocytes on hyaluronan based scaffold	N	21/03/2012	Withdrawn before opinion	14/01/2013	Y	Initial MAA	X		X		X	X	X					Musculo-sceletal
Masican	MASITINIB	Y	18/07/2012	Negative by consensus	08/05/2014	Y	Initial MAA	X	X				X	X					Oncology
Winfuran	NALFURAFINE	Y	18/07/2012	Withdrawn before opinion	17/01/2014	Y	Initial MAA	X	X	X			X						Nephrology
Masiviera	MASITINIB	Y	19/09/2012	Negative by consensus	22/04/2014	N	Initial MAA	X	X				X	X					Oncology

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Folcepri	etarfolatide	Y	21/11/2012	Withdrawn after positive op.	16/05/2014	Y	Initial MAA										X		In vivo diagnostic
Neocepri	folic acid	Y	21/11/2012	Withdrawn after positive op.	16/05/2014	Y	Initial MAA										X		In vivo diagnostic
Vynfinit	vintafolide	Y	21/11/2012	Withdrawn after positive op.	16/05/2014	Y	Initial MAA										X		Oncology

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Reasanz	SERELAXIN	N	30/01/2013	Negative by majority	22/05/2014	Y	During re-examination	X		X			X		X				Cardiovascular
Heparesc	HUMAN HETEROLOGOUS LIVER CELLS	Y	26/12/2013	Negative by majority	22/10/2015	Y	Initial MAA	x		x	x		x						Metabolism
Begedina	begelomab	Y	29/10/2015	Withdrawn before opinion	04/07/2016	Y	Initial MAA	x			x					x			Transplant
Xegafri	rociletinib	N	20/08/2015	Withdrawn before opinion	20/06/2016	Y	Initial MAA	x			x	x							Oncology