

Biopharmaceuticals approved in the US and EU

Product	Protein	Protein class	Therapeutic area	Company USA	Approval date	Cell line 1st indication
Orthoclone OKTR3 (Muromonab)	CD3	Murine Mab	Transplant rejection	Ortho Biotech/J&J	1986	Hybridoma
ActivaseR (alteplase)	human tPA	Enzyme	Thrombolysis	Genentech	1987	CHO
EpogenR (epoetin-alfa)	EPO	Cytokine/receptor antagonist/growth factor	Anaemia	Amgen	1989	CHO
ProcritR (epoetin-alfa)	EPO	Cytokine/receptor antagonist/growth factor	Anaemia	Ortho Biotech/J&J	1990	CHO
RcombinateR	Factor VIII	Blood factor	Hemophilia	Baxter Healthcare	1992	CHO
KogenateR	Factor VIII	Blood factor	Hemophilia	Bayer	1993	BHK
PulmozymeR (dornase alfa)	Deoxyribonuclease	Enzyme	Cystic fibrosis	Genentech	1993	CHO
ReoProR (rituximab)	Platelet GPIIb/IIIa receptor	Chimeric Mab	Cardiovascular disease	Eli Lilly/Centocor/J&J	1994	Sp2/0
CerezymeR (imiglucerase)	Beta-glucocerebrosidase	Enzyme	Gauchers disease	Genzyme	1994	CHO
SerostimR (somatotropin)	hGH	Hormone	AIDS-associated wasting	Serono	1996	Mouse C127
AvonesR	Interferon beta-1a	Cytokine/receptor antagonist/growth factor	Multiple Sclerosis	Biogen Idec	1996	CHO
RituxanR (rituximab)	CD20	Chimeric Mab	Non-Hodgkin's lymphoma	Genentech/Biogen Idec	1997	CHO
ZenapaxR (daclizumab)	IL-2 receptor	Humanized Mab	Transplant rejection	Hoffmann La Roche	1997	NS0
FollistimR (follitropin-beta)	FSH	Hormone	Infertility	Organon	1997	CHO
BeneFIXR	Factor IX	Blood factor	Hemophilia	Genetics Institute/Wyeth	1997	CHO
Gonal-FR (follitropin-alfa)	FSH	Hormone	Infertility	Serono	1997	CHO
SimulectR (basiliximab)	IL-2 receptor	Chimeric Mab	Transplant rejection	Novartis	1998	NS0
SynagisR (palivizumab)	Respiratory syncytial virus	Humanize Mab	Respiratory syncytial virus infection	Medimmune	1998	NS0
RemicadeR (infliximab)	Tumor necrosis factor	Chimeric Mab	Crohn's disease/rheumatoid arthritis	Centocor/J&J	1998	Sp2/0
HerceptinR (trastuzumab)	HER2 receptor	Humanized Mab	Breast cancer	Genentech	1998	CHO
EnbrelR (etanercept)	Tumor necrosis factor	Fusion protein	Rheumatoid arthritis	Amgen/Wyeth	1998	CHO
NovoSevenR	Factor VIIa	Blood factor	Hemophilia	Novo Nordisk	1999	BHK
MylotargR (gemtuzumab/ozogamicin)	CD33 with cytotoxin	Humanized Mab	Acute myeloid leukemia	Wyeth Pharmaceuticals	2000	NS0
ReFactorR (moroctocog-alfa)	Factor VIII	Blood factor	Hemophilia	Genetics Institute/Wyeth	2000	CHO
TNKaseR (tenecteplase)	Modified human TPA	Enzyme	Thrombolysis	Genentech	2000	CHO
OvidrelR (choriogonadotropin alfa)	HCG	Hormone	Infertility	Serono	2000	CHO
CampathR (alemtuzumab)	CD52	Humanized Mab	Chronic lymphocytic leukemia	Berlex/Ilex Oncology	2001	CHO
XigrisR (drotrecogin alfa)	Human activated Protein C	Blood factor	Sepsis	Eli Lilly	2001	CHO
AranespR (darbepoietin alfa)	EPO analogue	Cytokine/receptor antagonist/growth factor	Anaemia	Amgen	2001	CHO
Osteogenic protein 1	Bone morphogenic protein-7	Cytokine/receptor antagonist/growth factor	Bone repair	Stryker Biotech	2001	CHO
ZevalinR (ibritumomab tiuxetan)	CD20 with Yttrium 90	Murine Mab	Non-Hodgkin's lymphoma	Biogen Idec	2002	CHO
HumiraR (adalimumab)	Tumor necrosis factor alfa	Human Mab	Rheumatoid arthritis	Abbot Laboratories	2002	CHO
RebifR	Interferon beta 1a	Cytokine/receptor antagonist/growth factor	Multiple sclerosis	Serono	2002	CHO
InFuseR (dibotermis alfa)	Bone morphogenic protein-2	Cytokine/receptor antagonist/growth factor	Bone repair	Medtronic Sofamor	2002	CHO
Amevive (alefacept)	Leukocyte antigen-3/IgG	Fusion protein	Psoriasis	Biogen Idec	2003	CHO
XolairR (omalizumab)	IgE	Humanized Mab	Asthma	Genentech/Novartis/Tanox	2003	CHO
AldurazymeR (laronidase)	Alfa-L-Iduronidase	Enzyme	Mucopolysaccharidosis I	Genzyme/BioMarin	2003	CHO
FabrazymeR (agalsidase beta)	Human alfa-galactosidase	Enzyme	Fabry disease	Genzyme	2003	CHO
Advate	Factor VIII	Blood factor	Hemophilia	Baxter Healthcare	2003	CHO
BexxarR (tositumomab) + I-131	CD20 with iodine I-131	Murine Mab	Non-Hodgkin lymphoma	GSK/Corixa	2003	
RaptivaR (efalizumab)	CD11a	Humanized Mab	Psoriasis	Genentech/Xoma	2003	CHO
ErbixR (cetuximab)	Epiderm. growth fac. receptor	Chimeric Mab	Colorectal cancer	Imclone/Bristol-Myers Squibb	2004	Mouse myeloma
AvastinR (bevacizumab)	Vascular endoth.growth fac.	Humanized Mab	Colorectal cancer	Genentech	2004	CHO
TysabriR (natalizumab)	alfa4beta1 integrin	Humanized Mab	Multiple sclerosis	Biogen Idec	2004	CHO?
SolirisR (eculizumab)	C5	Humanized Mab	Hemolytic anaemia	Alexion	2007	
LucentisR (ranibizumab)	Vascular endoth. Growth fac.	Humanized Mab/Fab	Age-related macular degeneration (AMD)	Genentech	2006	CHO ???
HumiraR (adalimumab)	TNFalfa	Humanized Mab	RA, Crohn's, PsA, AS, JIA, PP	CAT Abbott	2008	
VectibixR	Epiderm. Growth fac. Receptor	Humanized Mab	Colorectal cancer	Amgen	2007	CHO????
Actemra	IL-6 receptor	Humanized Mab	Rheumatoid arthritis	Chugai/Roche	2008	CHO????

Sources:
UCB presentation Cambridge 2008

Biopharmaceutical Proteins: opportunities and challenges. JR Birch and Y. Onakunle
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