

### **Monoclonal antibodies approved for therapeutic use**

In total, 22 mAbs are approved by the United States and Drug Administration (FDA) for therapeutic use. The table below gives a listing.

#### **FDA approved monoclonal antibodies for therapeutic use:**

<b>Trade name</b>	<b>Company</b>	<b>Target</b>	<b>Source</b>	<b>Year</b>	<b>Indication</b>
Orthoclone <sup>®</sup>	Ortho Biotech, Inc. (subsidiary of J&J)	CD3	all rodent	1986	Transplantation rejection
ReoPro <sup>™</sup>	Centocor, Inc. (subsidiary of Johnson & Johnson) and Eli Lilly	GP1Ib, IIIa	chimeric	1994	High risk angioplasty
Rituxan <sup>™</sup>	Biogen Idec and Genentech, Inc.	CD20	chimeric	1994	Non-Hodgkin's lymphoma, rheumatoid arthritis
REMICADE <sup>®</sup>	Centocor, Inc. (subsidiary of Johnson & Johnson)	TNF- $\alpha$	chimeric	1998	Crohn's disease
Simulect <sup>®</sup>	Novartis	CD25	chimeric	1998	Transplantation rejection
Synagis <sup>™</sup>	Medimmune	RSV F protein	humanized	1998	RSV infection
Zenapax <sup>®</sup>	Hoffmann-La Roche Inc., Protein Design Labs	CD25	humanized	1997	Transplantation rejection
Herceptin <sup>®</sup>	Genentech	HER-2	humanized	1998	Breast cancer
Mylotarg <sup>™</sup>	UCB and Wyeth	CD33	humanized	2000	Acute Myeloid Leukemia
Campath <sup>®</sup>	Millenium Pharmaceuticals, Inc. and Berlex Laboratories, Inc.	CD52	humanized	2001	Chronic lymphocytic leucemia, T-cell lymphoma
Zevalin <sup>®</sup>	Idec Pharmaceuticals Corporation	CD20	murine – with yttrium-90 or indium-111	2002	Non-Hodgkin's lymphoma
HUMIRA <sup>™</sup>	Abbott Laboratories/Cambridge Antibody Technology	TNF- $\alpha$	human	2002	Inflammatory diseases – mostly autoimmune disorders like rheumatoid arthritis, psoriadic arthritis, Morbus Chron
Bexxar <sup>®</sup>	Corixa Corp. and GlaxoSmithKline	CD20	murine – covalently bound to Iodine 131	2003	Non-Hodgkin's lymphoma

Xolair <sup>®</sup>	Genentech, Tanox, Inc., Novartis Pharmaceuticals	IgE	humanized	2003	Severe (allergic) asthma
Avastin <sup>™</sup>	Genentech	VEGF	humanized	2004	Metastatic colorectal cancer, non- small cell lung cancer, metastatic breast cancer
TYSABRI <sup>®</sup>	Biogen Idec and Elan Corp.	$\alpha$ 4 subunit of $\alpha$ 4 $\beta$ 1	humanized	2004	Multiple Sclerosis, Chron's disease
Erbix <sup>™</sup>	Merck KG aA / Bristol- Myers Squibb / ImClone Systems	EGFR	chimeric	2004	Colorectal cancer, head and neck cancer
Vectibix <sup>™</sup>	Amgen	EGFR	human	2006	Metastatic colorectal carcinoma
LUCENTIS <sup>™</sup>	Genentech	VEGF- A	humanized Fab	2006	Wet Macular Degeneration
Soliris <sup>®</sup>	Alexion Pharmaceuticals, Inc.	CD59	humanized	2007	Paroxysmal nocturnal hemoglobinuria
CIMZIA <sup>®</sup>	UCB	TNF- $\alpha$	Humanized (Fab)	2008	Morbus Chron, rheumatoid arthritis
Simponi <sup>™</sup>	Centocor (subsidiary of Johnson & Johnson)	TNF $\alpha$	human	2009	Rheumatoid & psoriatic arthritis, active ankylosing spondylitis

- TheraCIM, a therapeutic humanized mAb, developed by CIM/CIMAB/YM Biosciences, targeting EGFR has been approved in China and Cuba for nasopharyngeal carcinomas and in Argentina, Colombia and Cuba for head and neck tumors in 2005. Clinical trials for approval by the FDA and the EMEA are ongoing.
- Cotara, an Iodine-131 radiolabeled TNT monoclonal antibody developed by Peregrine Pharmaceuticals, has been launched in China in 2003 to treat lung cancer. EMEA and FDA granted Orphan Drug status, a phase III clinical trial is currently ongoing.
- Actemra, a humanized anti-interleukin-6 receptor monoclonal antibody developed by In 2005, Chugai Pharmaceuticals, the Japanese subsidiary of Roche, has been launched in Japan. The FDA approval is expected for later in 2009.
- Removab<sup>®</sup>, a trifunctional antibody developed by TRION Pharma for the intraperitoneal treatment of malignant ascites in patients with EpCAM-positive carcinomas, has been approved by EMEA in 2009.