

Therapeutic monoclonal antibodies. Information extracted from Thomson CenterWatch for FDA approvals (M.-P. Lefranc, December 27, 2005)

<http://www.centerwatch.com/patient/drugs/druglsal.html>

2005

None

2004

Gastroenterology

Avastin (bevacizumab); For the treatment of metastatic carcinoma of the colon or rectum; Genentech; Approved February 2004

Erbix (cetuximab); For the treatment of EGFR-expressing, metastatic colorectal cancer; Imclone, Bristol-Myers Squibb; Approved February 2004

Neurology

TYSABRI (natalizumab); For the treatment of relapsing forms of multiple sclerosis; Elan Pharmaceuticals / Biogen Idec; Approved November 2004 -- UPDATED: SUSPENDED FEBRUARY 2005

Oncology

Avastin (bevacizumab); For the treatment of metastatic carcinoma of the colon or rectum; Genentech; Approved February 2004

Erbix (cetuximab); For the treatment of EGFR-expressing, metastatic colorectal cancer; Imclone, Bristol-Myers Squibb; Approved February 2004

2003

Immunology/Infectious Diseases

Amevive (alefacept); For moderate to severe chronic plaque psoriasis.; Biogen; Approved January 2003

Amevive (alefacept) is a LFA3-IgG1Fc fusion protein obtained by recombinant technology (note added by M.-P. Lefranc)

Oncology

Bexxar; For the treatment of patients with CD20 positive, follicular, non-Hodgkin's lymphoma following chemotherapy relapse; Corixa; Approved June 2003

Not retrieved in the list but information found on the Genetech site (note added by M.-P. Lefranc, 29 December 2005):

Immunology

Raptiva (efalizumab)

RAPTIVA is approved for the treatment of chronic moderate-to-severe plaque psoriasis. The U.S. Food and Drug Administration (FDA) approved RAPTIVA in October 2003.

Xolair (omalizumab)

Xolair is indicated for adults and adolescents (12 years of age and above) with moderate-to-severe persistent asthma. The U.S. Food and Drug Administration (FDA) approved Xolair in June 2003.

2002

Musculoskeletal

Remicade; Intravenous infusion for the treatment of rheumatoid arthritis;
Centocor; Approved February 2002

Oncology

Zevalin (ibritumomab tiuxetan); For the treatment of non-Hodgkin's lymphoma; IDEC Pharmaceuticals; Approved February 2002

Rheumatology

Enbrel (etanercept); For the treatment of psoriatic arthritis; Immunex;
Approved January 2002.

Enbrel (etanercept) is a TNFReceptor2-IgG1Fc fusion protein obtained by recombinant technology (note added by M.-P. Lefranc)

Humira (adalimumab); For the treatment of moderately to severely active rheumatoid arthritis; Abbott Laboratories; Approved December 2002

Remicade; Intravenous infusion for the treatment of rheumatoid arthritis;
Centocor; Approved February 2002

2001

Oncology

Campath; Injectable treatment of B-cell chronic lymphocytic leukemia; Berlex Laboratories; Approved May 2001

Rheumatology

Remicade (infliximab); For inhibiting the progression of structural damage in patients with rheumatoid arthritis; Centocor; Approved January 2001

2000

Oncology

Mylotarg (gemtuzumab ozogamicin); For the treatment of CD33 positive acute myeloid leukemia (AML); Wyeth Pharmaceuticals; Approved May 2000

1998

Immunology/Infectious Diseases

Simulect; Treatment for acute organ transplant rejection; Novartis; Approved May 1998

Nephrology/Urology

Simulect; Treatment for acute organ transplant rejection; Novartis; Approved May 1998

Obstetrics/Gynecology

Herceptin; Treatment for metastatic breast cancer; Genentech; Approved October 1998

Inform HER-2/neu breast cancer test; Treatment for breast cancer prediction; Oncor; Approved January 1998

Oncology

Herceptin; Treatment for metastatic breast cancer; Genentech; Approved October 1998

Inform HER-2/neu breast cancer test; Treatment for breast cancer prediction; Oncor; Approved January 1998

Pulmonary/Respiratory Diseases

Synagis; Treatment for the prevention of serious lower respiratory tract disease in infants; MedImmune; Approved June 1998

1997

Nephrology/Urology

Zenapax; Treatment to prevent rejection of kidney transplants; Roche; Approved December 1997

Oncology

Rituxan; Treatment for non-hodgkin's lymphoma; Idec Pharmaceuticals, Genentech; Approved November 1997

1996

Oncology

CEA-Scan; **Diagnostic** imaging product for colorectal cancer; Immunomedics; Approved April 1996

Other Diagnostic antibodies were not retrieved see “About the FDA Approved Listings” below.

1995

None

Prior to 1995

FDA Approvals prior to 1995 could not be retrieved. They concern:

Hematology

ReoPro (abciximab), Centocor; Approved December 2004

Immunology

Orthoclone OKT3 (muromonab), Ortho Biotech Products; Approved June 1986
(note added by M.-P. Lefranc, 29 December 2005).

About the FDA Approved Listings

The criteria for CenterWatch's FDA Approval Listings follow the definitions set forth by the Tufts Center for the Study of Drug Development and the FDA definitions of a new drug approval or a new molecular entity.

Our "Drugs Approved by the FDA" listings include:

New Molecular Entities (NME), defined by the FDA as a medication containing an active substance that has **never before** been approved for marketing in any form in the United States. The listing also includes some recombinant proteins and biologics that were approved by the FDA's Center for Drug Evaluation and Research (CDER).

The listings do NOT include:

Diagnostic agents, generics, over-the-counter products, medical devices, biologic compounds not approved by CDER and most vaccines. We also exclude new dosages, new indications and new administrations of previously-approved compounds.