



Voice of Innovation

Hindsight is 20/20. Foresight is 1/10,000.

Only one out of 10,000 potential medicines investigated by America's research-based biopharmaceutical companies makes it through the exacting quest of research and development to be approved for patient use by the Food and Drug Administration. Very long odds. But the biopharmaceutical companies of the New York Health Products Council see it through, and make the billions in investments, to save lives and improve the very quality of life for millions.

Below are thirteen new medicines that have received FDA approval to be marketed. These drugs have been proven effective through the most stringent process of development. After FDA applications, the compounds were subjected to years of exacting testing and screening in three uncompromising phases of clinical trials in humans. And the manufacturers will continue to monitor long term effects and results.

With hindsight, making a medicine may appear rather easy to some. But nothing could blur the truth more. Successful FDA approval demands the focused, consummate expertise of tens of thousands of skilled scientists, support staff and state-of-the-art labs. The approved drugs described below were the exceptional foresights of yesterday, and now show the potential to join many of our other products as the commonly seen miracles of tomorrow.

Autistic Disorder The U.S. Food and Drug Administration has approved **RISPERDAL®** (risperidone), for the treatment of irritability associated with autistic disorder, including symptoms of aggression, deliberate self-injury, temper tantrums and quickly changing moods, in children and adolescents aged five to 16 years.

Autism is usually diagnosed by age three and may affect one in 250 children. The core symptoms of autism include communication deficits, impaired social interactions and stereotypic behaviors or interests. *October*

2006; Johnson & Johnson

Cholesterol Management The U.S Food and Drug Administration has approved **SIMCOR®** the first fixed-dose combination of two widely prescribed cholesterol therapies, Niaspan® (Abbott's proprietary niacin extended-release) and simvastatin. SIMCOR® is approved for use along with diet to lower levels of elevated total cholesterol, LDL "bad" cholesterol and triglycerides, and to raise HDL "good" cholesterol in patients with complex lipid disease when treatment with simvastatin or Niaspan monotherapies are not considered adequate.

An estimated 80 Million American have high levels of the bad LDL cholesterol, and more than 44 million have low levels of the good HDL cholesterol, which the body uses to remove bad cholesterol from the blood stream. *February 2008; Abbott*

Colorectal Cancer The U.S. Food and Drug Administration has approved **VECTIBIX™** (panitumumab) following priority review. VECTIBIX™ is the first entirely human monoclonal antibody for the treatment of patients with epidermal growth factor receptor- (EGFr) expressing metastatic colorectal cancer after disease progression on, or following fluoropyrimidine-, oxaliplatin-, and irinotecan- containing chemotherapy regimens. VECTIBIX™ is the first anti-EGFr antibody shown to significantly improve progression-free survival in patients with metastatic colorectal cancer. It provides another option for patients with metastatic colorectal cancer that have progressed on all available chemotherapy regimens.

One out of 18 people in this country will develop colorectal cancer in their lifetime and 20 percent of colorectal cancers are found after the disease has spread to distant organs. According to the American Cancer Society colorectal cancer is the second leading cause of cancer death among men and women in the United States and Canada (after lung cancer). *September 2006; Amgen*

Hemophilia A The U.S. Food and Drug Administration has approved **XYNTHA™**(Antihemophilic Factor [Recombinant], Plasma/Albumin-Free), a recombinant factor VIII product, for patients with hemophilia A for both the control and prevention of bleeding episodes and surgical prophylaxis.

Hemophilia A is a rare, inherited blood-clotting disorder. People with hemophilia A deficient a key protein – factor VIII – which is vital in the clotting mechanism to prevent bleeding. Hemophilia A can be characterized

by spontaneous hemorrhages or prolonged bleeding, typically into joints and soft tissue. Most patients with hemophilia A are dependant on factor VIII replacement therapy. *February 2008; Wyeth*

HIV The U.S. Food and Drug Administration has approved **SELZENTRY™** (maraviroc) tablets, the first in a new class of oral HIV medicines known as CCR5 antagonists. SELZENTRY™ blocks viral entry into white blood cells, significantly reducing viral load and increasing T-cell counts in treatment-experienced patients infected with a specific type of HIV. SELZENTRY™ has been approved for combination antiretroviral treatment of adults infected with only CCR5-tropic HIV-1 detectable, who have evidence of viral replication and have HIV-1 strains resistant to multiple antiretroviral agents.

SELZENTRY™ is not a cure for HIV infection or AIDS nor does it prevent the transmission of HIV. *August 2007; Pfizer Inc.*

The U.S. Food and Drug Administration has granted accelerated approval to the anti-HIV medication **PREZISTA™** (darunavir) tablets. PREZISTA™, is a protease inhibitor previously known as TMC114. PREZISTA™, co-administered with 100 mg ritonavir (PREZISTA™/rtv) and with other antiretroviral agents, is indicated for the treatment of human immunodeficiency virus infection in eh antiretroviral treatment-experienced adult patients, such as those with HIV-1 strains resistant to more than one protease inhibitor.

PREZISTA™ does not cure HIV infection or AIDS nor does it prevent passing HIV to others. *June 2006; Johnson & Johnson*

The U.S. Food and Drug Administration has granted accelerated approval to the anti-HIV medication **INTELENCE™** (etravirine) tablets. INTELENCE™ is the first non-nucleoside reverse transcriptase inhibitor (NNRTI) to show antiviral activity in treatment-experienced adult patients with HIV resistant to a NNRTI and other antiretroviral (ARV) agents.

INTELENCE™ does not cure HIV infection or AIDS, and does not prevent passing HIV to others. *January 2008; Johnson & Johnson*

Infectious Disease The U.S. Food and Drug Administration has approved **ERAXIS™** (anidulafungin) to treat candidemia, a potentially life-threatening bloodstream infection. Candidemia is the most deadly of the common hospital acquired bloodstream infections, with a mortality rate of

approximately 40 percent. ERAXIS™, an antifungal medicine of the echinocandin class, also was approved by the FDA to treat two additional infections caused by the Candida fungus – peritonitis and intra-abdominal abscesses – as well as esophageal candidiasis, a fungal infection of the esophagus.

In the United States, candidemia affects approximately one in 5,000 people, resulting in an estimated 60,000 cases each year. Patients with candidemia on average spend an additional 10 days in the hospital at an average increase in hospital charges of about \$39,000 per patient. *February 2006; Pfizer Inc.*

The U.S. Food and Drug Administration has approved **ALTABAX™** (retapamulin ointment) for the topical treatment of impetigo due to susceptible strains of Staphylococcus aureus or Streptococcus pyogenes, the two most common types of bacteria in this kind of infection. By binding to a site on the 50S sub-unit of the bacterial ribosome, ALTABAX™ inhibits protein synthesis through interaction with the ribosome that is unique to the pleuromutilin class.

Impetigo is a highly contagious infection of the top layer of the skin and is most common among infants and children ages 2 to 6 years. *April 2007; GlaxoSmithKline*

Oral Contraceptive The U.S. Food and Drug Administration has approved **LYBREL™** (90 mcg levonorgestrel/20 mcg ethinyl estradiol) tablets for the prevention of pregnancy in women who elect to use oral contraceptives and who have no known contraindications for this method of contraception. LYBREL™ is intended for women who are seeking contraception and who are interested in putting their menstrual cycle on hold. LYBREL™ provides a steady low dose of hormones so that over time women may become cycle-free.

Oral contraceptives do not protect against HIV infection (AIDS) or sexually transmitted diseases. *May 2007; Wyeth*

Plaque Psoriasis The U.S. Food and Drug Administration has approved **REMICADE®** (infliximab) for the treatment of adult patients with chronic severe (i.e., extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate.

Psoriasis is an inflammatory disorder characterized by raised, inflamed, red lesions or plaques, which can cause physical pain and emotional distress. Commonly diagnosed between the ages of 20 and 30, it is estimated that as many as 7.5 million people in the U.S. have psoriasis, which can present in various forms and can range from mild to severe and disabling. September 2006; Johnson & Johnson

The U.S. Food and Drug Administration has approved HUMIRA® (adalimumab) as a treatment for adult patients with moderate to severe chronic plaque psoriasis, an autoimmune disease characterized by skin lesions that are sometimes painful and itchy. HUMIRA® has been approved for the treatment of adults with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate. January 2008; Abbott

Psoriatic Arthritis The U.S. Food and Drug Administration has a approved **REMICADE®** (infliximab) for inhibiting progression of structural damage and improving physical function in patients with psoriatic arthritis, in addition to reducing signs and symptoms of active arthritis.

An immune-mediated inflammatory disease, psoriatic arthritis affects approximately one million men and women in the U.S. and is often characterized by symptoms of joint inflammation and skin lesions. Psoriasis affects an estimated two to three percent of the world's population, and approximately one out of three patients affected by psoriasis may develop psoriatic arthritis. Both men and women are equally affected by psoriatic arthritis, most commonly between the ages of 30 and 50, in the peak of their productive years. August 2006; Johnson & Johnson

Schizophrenia The U.S. Food and Drug Administration has approved **INVEGA™** (paliperidone) Extended-Release Tablets, a new atypical antipsychotic, for the treatment of schizophrenia. December 2006; Johnson & Johnson

Smoking Cessation The U.S. Food and Drug Administration has approved **CHANTIX®** (varenicline) for smoking cessation. CHANTIX® is specifically designed to partially activate the nicotinic receptor and reduces the urge to smoke. Smoking harms nearly every organ in the body. Smoking is responsible for approximately one in five deaths in the U.S. and costs the U.S. health care system about \$167 billion annually. May 2006; Pfizer Inc.

Ulcerative Colitis The U.S. Food and Drug Administration has a approved **REMICADE®** (infliximab) for maintaining clinical remission and mucosal healing in patients with moderately to severely active ulcerative colitis (UC), who have had an inadequate response to conventional therapy.

An immune-mediated inflammatory disease (I.M.I.D.), ulcerative colitis affects more than 500,000 Americans and is characterized by inflammation and ulceration of the inner lining of the colon. UC symptoms can often include unwanted weight loss; severe, sometimes uncontrollable, bloody diarrhea; fatigue and frequent abdominal pain. For some patients, symptoms may lead to surgical removal of the colon or to secondary complications such as colorectal cancer. *October 2006; Johnson & Johnson*

For further information contact member companies through their websites:

GlaxoSmithKline – www.gsk.com
Johnson & Johnson – www.jnj.com
Pfizer Inc. – www.pfizer.com
Amgen – www.amgen.com
Abbott – www.abbott.com
Wyeth – www.wyeth.com