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**Pharmaceutical research yields results that offer better options to patients.
The New York Health Products Council announces the latest advances in medicine with FDA approval on thirteen new and innovative drugs that improve the outcome and quality of life for patients suffering from chronic disease and ailments.**

Seven members of the New York Health Products Council have announced the approval of thirteen new drugs by the U.S. Food and Drug Administration. Through the research efforts of these companies, physicians can better treat illnesses and increase the quality of life of patients suffering from pain and debilitating side effects of chronic disease. These new drugs will help reduce the signs and symptoms of arthritis and asthma, lower cholesterol, treat depression, control epilepsy in children, and improve sexual response in men with ED. They have also developed drugs that better treat the effects of heart disease, give new hope to patients with HIV, offer better options to women needing hormone therapy or severe PMS relief, and provide last chance options to patients afflicted with lung cancer or Parkinson's Disease.

Each of these companies, along with the other nine member companies, has devoted great amounts of money and time into discovering these new and innovative medicines, investing more than \$12 billion annually into research and development. The latest estimated costs for taking a drug from inception to market was placed at \$801 million in a 2001 study by Tufts University, and out of 5000 new drugs that go into research only one comes out as an FDA approved new product.

The following is a list of new medications and advances for your review. For more information, please visit the web sites listed at the end of this release.

ARTHRITIS

The U.S. Food and Drug Administration has approved Amgen and Wyeth's **ENBREL**® (etanercept) for the treatment of patients with rheumatoid arthritis (RA), psoriatic arthritis and active ankylosing spondylitis (AS). ENBREL is the only fully human anti-TNF receptor approved to reduce signs and symptoms of AS, improve physical function in patients with moderately to severely active rheumatoid arthritis, and to reduce the signs and symptoms and inhibit the progression of structural damage in patients with active psoriatic arthritis.

Rheumatoid arthritis is a chronic and progressively disabling disease that affects more than two million Americans. Patients can become disabled from irreversible joint damage caused by the disease, limiting their ability to function.

Psoriatic arthritis, affecting up to one million people in the U.S., is a chronic inflammatory disease of the joints and connective tissue. The disease combines joint pain and swelling that can lead to crippling debilitation with inflamed and irritated scaly red patches of skin on the body.

Ankylosing spondylitis, which affects approximately 350,000 Americans, is a painful and potentially progressive inflammatory disease affecting joints and ligaments that normally allow a person's back to move and flex. Unlike some other forms of arthritis, AS frequently strikes between the ages of 16 and 30, affecting more men than women. *July 21, 2003, July 24, 2003, August 25, 2003; Amgen and Wyeth Pharmaceuticals*

ASTHMA

The novel IgE-blocker **XOLAIR**[®], developed jointly under an agreement among Novartis Pharma AG, Genetech, Inc., and Tanox, Inc., has been approved by the U.S. Food and Drug Administration for the treatment of moderate-to-severe persistent asthma in adults and adolescents. XOLAIR[®] is the first humanized therapeutic antibody for the treatment of asthma and the first approved therapy designed to target the antibody IgE, a key underlying cause of the symptoms of asthma that has an allergic component.

XOLAIR[®] is indicated for adults and adolescents (12 years of age and above) with moderate to severe persistent asthma who have positive skin test or in vitro reactivity to a perennial aeroallergen, and whose symptoms are inadequately controlled with inhaled corticosteroids. When used as an add-on therapy to inhaled corticosteroids, XOLAIR[®] reduced mean asthma exacerbations ("asthma attacks") per patient by 33% - 75% during the stable-steroid phase and 33% - 50% during the steroid-reduction phase.

Asthma with an allergic component is a chronic inflammatory disorder of the airways, in which exposure to an aeroallergen triggers an allergic cascade that may result in airway inflammation and obstruction. According to the National Institutes of Health, direct and indirect financial costs of all forms of asthma totaled \$14 billion in 1998. In addition, asthma leads to at least two million emergency room visits and more than 5,000 deaths in the U.S. each year. *June 20, 2003; Novartis Pharmaceuticals Corporation and Tanix, Inc.*

CHOLESTEROL

AstraZeneca has received approval for its new cholesterol-lowering medication, **CRESTOR**[®] (rosuvastatin calcium) from the U.S. Food and Drug Administration as an adjunct to diet for the treatment of various lipid disorders including primary hypercholesterolemia, mixed dyslipidemia and isolated hypertriglyceridemia.

CRESTOR[®] is the newest member of the cholesterol-lowering statin class of drug therapy.

Cholesterol is a soft waxy substance found among lipids (fats) in the bloodstream cells and plays a key role in forming cell membranes, some hormones and other necessary tissues. Guidelines issued by the National Cholesterol Education Program's Adult Treatment Panel III have substantially expanded the number of Americans eligible for drug therapy, including raising the number of people on dietary treatment from approximately 52 million to 65 million, and increasing the number of patients eligible

for cholesterol-lowering drug therapy from approximately 13 million to 36 million. Recent data from the national Health and Nutrition Examination Survey suggests that only 35 percent of people with high cholesterol are aware of their condition and only 12 percent are being treated for it.

August 12, 2003; AstraZeneca Pharmaceuticals

DEPRESSION

GlaxoSmithKline's **WELLBUTRIN XL**[®] (bupropion hydrochloride extended-release tablets), the first once-daily norepinephrine and dopamine reuptake inhibitor (NDRI), has been approved by the U.S. Food and Drug Administration for the treatment of major depressive disorder in patients 18 years and older.

Depressive illness affects approximately 4 million adults, or 6.6% of the U.S. population, in a given year. In the U.S. there is more than a 16% percent chance for an adult to develop a major depressive disorder in his or her lifetime. Nearly two-thirds of people fail to get help for their depression, yet treatment can alleviate symptoms in more than 80% of cases. *August 29, 2003; GlaxoSmithKline*

EPILEPSY

The U.S. Food and Drug Administration (FDA) has granted marketing clearance to **TRILEPTAL**[®] (oxcarbazepine) tablets and oral suspension for use as monotherapy in children with partial seizures, four years of age and older. **TRILEPTAL**[®] is the first anti-epileptic drug (AED) to be approved as a monotherapy for children since 1978.

TRILEPTAL[®] has a proven track record of effective seizure control with favorable safety and tolerability as a monotherapy in adults and is currently approved in more than 60 countries worldwide for use as monotherapy and adjunctive therapy in children and adults.

In addition, the FDA has approved a supplemental NDA to expand the indications for Abbott Laboratories' **DEPAKOTE**[®] **ER** (divalproex) to include use in pediatric patients, ages 10 years and older, for epilepsy. **DEPAKOTE**[®] **ER** was previously indicated only for prophylaxis of migraine headache in adult patients.

More than 500,000 children under the age of 18 have epilepsy. On average, children with seizure disorders are one year behind their peers in reading abilities, repeat grades more often, and drop out of school at higher rates. The availability of **TRILEPTAL**[®] as a monotherapy should help simplify dosing for many patients and make compliance easier for many families. *August 7, 2003; Novartis Pharmaceutical Corporation / August 15, 2003; Abbott Laboratories*

ERECTILE DYSFUNCTION

LEVITRA[®] (vardenafil HCl) has been approved by the U.S. Food and Drug Administration for the treatment of erectile dysfunction (ED). Co-developed and co-promoted by Bayer AG and GlaxoSmithKline, **LEVITRA**[®] provides men with their first new ED treatment choice in five years. The drug was shown to improve sexual response for the majority of men the first time they took it, and it worked consistently over time.

Erectile dysfunction, the consistent or recurrent inability of a man to attain and/or maintain a penile erection sufficient for sexual performance, is a common health condition among men that is largely untreated. It is estimated that some degree of ED affects more than one half of all men over the age of forty, 152 million men worldwide and 30 million men in the U.S. alone. Despite the high prevalence of sexual problems, nine out of ten men in the U.S. have not yet sought treatment from a physician. *August, 19, 2003; Bayer Pharmaceuticals Corporation & GlaxoSmithKline*

HEART DISEASE

Novartis Pharmaceuticals has received approval from the U.S. Food and Drug Administration for **LESCOL**[®] (fluvastatin sodium) and **LESCOL**[®] **XL** (fluvastatin sodium) 80mg extended-release tablets to reduce the risk of undergoing coronary revascularization procedures in patients with coronary heart disease.

Treatment with LESCOL 80mg (40mg twice daily), routinely initiated shortly after a first PCI procedure, significantly reduced the chances of a recurrent cardiac event by 22%.

In addition to the new indication, LESCOL[®] and LESCOL[®] XL are also indicated to reduce elevated total cholesterol, LDL-C, TG and apolipoprotein B (Apo B) levels and to increase HDL-C in patients with primary hypercholesterolemia and mixed dyslipidemia. Both drugs are also indicated to slow the progression of atherosclerosis in patients with coronary heart disease.

Each year approximately one million patients in the U.S. undergo percutaneous coronary intervention (PCI) procedures, such as angioplasty and stenting, to open blocked arteries. Of those patients, nearly 40% will undergo a second procedure or have a heart attack within five years. *May 28, 2003; Novartis Pharmaceuticals Corporation*

HIV

The U.S. Food and Drug Administration has granted approval to **FUZEON**[™] (enfuvirtide), a novel treatment for HIV-1 developed by Roche and Trimeris, Inc. FUZEON[™] is the first fusion inhibitor, representing the first new class of anti-HIV treatments in seven years. When used in combination with antiretroviral agents is indicated for the treatment of HIV-1 infection in treatment-experienced patients with evidence of HIV-1 replication despite ongoing antiretroviral therapy.

Unlike currently approved anti-HIV drugs, FUZEON[™] blocks HIV's ability to infect healthy immune (CD4) cells. When used with other anti-HIV medicines, FUZEON[™] can reduce the amount of HIV in the blood and increase the number of CD4 cells, which has been shown to slow HIV progression in patients who have developed resistance to currently available medications.

FUZEON[™] is a significant breakthrough and its approval is a milestone event in the HIV epidemic. Patients are becoming resistant to our best, current therapies and this drug attacks the virus in a new way so it can work for patients whose virus is resistant to other therapies. However, as with any anti-HIV drug, patients can also develop a resistance to FUZEON[™]. Almost one million people in the U.S. are living with HIV/AIDS. *March 13, 2003; Hoffman-la Roche and Trimeris, Inc.*

HORMONE THERAPY

Wyeth Pharmaceuticals has received U.S. Food and Drug Administration approval for their new lower dose of **PREMPRO™** (conjugated estrogens [CE]/ medroxyprogesterone acetate [MPA] tablets), the most commonly prescribed brand of combination estrogen plus progestin therapy (also known as hormone therapy, or HT.) Low dose PREMPRO™ 0.45/1.5 is indicated for use by women with a uterus for the treatment of moderate to severe vasomotor symptoms associated with menopause.

Recent data from the Women's Health Initiative was released which led the FDA and other health experts to recommend that women take the lowest dose of postmenopausal hormone therapy for the shortest duration consistent with treatment goals and risks for the individual woman.

Earlier this year, the FDA also approved other lower doses of Wyeth's hormone therapies, including **PREMARIN®** (conjugated estrogen tablets, USP) for the prevention of postmenopausal osteoporosis and for the treatment of severe vasomotor symptoms associated with menopause and vulvar and vaginal atrophy.

In the U.S. alone, nearly 5,000 women a day enter menopause. A very important health issue for many women, symptoms can disrupt a woman's daily activities at home or work, disrupt sleep, contribute to fatigue and interfere with intimacy. Postmenopausal hormone therapy is the only FDA-approved treatment for the relief of menopausal symptoms. *March 13, 2003, July 1 & 17, 2003; Wyeth Pharmaceuticals*

LUNG CANCER

The U.S. Food and Drug Administration has granted approval for **IRESSA®** (gefitinib) to AstraZeneca Pharmaceuticals for the treatment of advanced non-small cell lung cancer (NSCLC). The drug provides meaningful therapeutic benefits where no approved treatment currently exists. IRESSA® is indicated as a monotherapy for the treatment of patients with locally advanced or metastatic NSCLC after failure of both platinum-based and docetaxel chemotherapies.

Lung cancer is the leading cause of cancer deaths in the United States, estimated to account for approximately 157,000 deaths in 2003, killing more Americans than breast, prostate and colorectal cancers combined. NSCLC is the most common form of lung cancer, accounting for 80 percent of all lung cancer cases. Most people diagnosed with lung cancer can not be treated with surgery and new drugs like IRESSA® provide alternatives to patients when chemotherapy fails. *May 5, 2003; AstraZeneca Pharmaceuticals*

PARKINSON'S DISEASE

Novartis Pharmaceuticals Corporation received approval for **STALEVO™** (carbidopa, levodopa and entacapone) tablets by the U.S. Food and Drug Administration for the treatment of patients with idiopathic Parkinson's disease. It is indicated for treatment of patients receiving levodopa therapy who experience signs and symptoms of end-of-dose "wearing-off," a condition where the levodopa lasts for shorter and shorter periods of time. In about 15 to 20 percent of patients "wearing-off" becomes extreme and disabling.

Parkinson's disease is a chronic and progressive neurological condition that affects approximately 1.5 million Americans. While its cause is unknown, symptoms include limbs that tremble, slowness of movement, stiffness and rigidity of limbs, and gait or balance problems. As the disease progresses, these symptoms usually increase and impact a person's ability to work and function. *June 13, 2003; Novartis Pharmaceuticals Corporation*

PMS

Approval has been granted by the U.S. Food and Drug Administration to GlaxoSmithKline for **PAXIL® CR** (paroxetine HCl), the first controlled-release medication for the treatment of premenstrual dysphoric disorder (PMDD).

Affecting over 5 million women of reproductive age in the U.S., PMDD is a severe form of PMS that can significantly impair a woman's ability to carry out daily activities both professionally and personally. PMDD is characterized by intense emotional symptoms including irritability, tension, and depressed mood, as well as physical symptoms associated with the menstrual cycle. PAXIL® CR is also indicated for the treatment of depression and panic disorder. *September 2, 2003; GlaxoSmithKline*

For further information, contact member companies through their web sites:

Abbott Laboratories – www.abbott.com

Wyeth Pharmaceuticals – www.wyeth.com

www.enbrel.com or toll free at 1-888-4ENBREL

AstraZeneca Pharmaceuticals – www.astrazeneca-us.com or toll free at 1-800-236-9933

Bayer Pharmaceuticals Corporation – www.bayer.com

GlaxoSmithKline – www.gsk.com

Hoffman-La Roche – www.rocheusa.com

Novartis Pharmaceuticals Corporation – www.us.novartis.com

www.Xolair.com or toll free at 1-866-4XOLAIR

www.Trileptal.com or toll free at 1-888-778-7336

www.Stalevo.com