NEW DRUGS

A Single Injection (Synvisc-One) for Knee Pain

Genzyme Corporation has announced the FDA’s approval of Synvisc-One (Hylan G-F 20), which relieves pain associated with osteoarthritis of the knee. This agent has the potential to reduce the cost and burden of multiple injections. With one visit, patients have found relief for up to six months and may be able to delay a total knee replacement.

As an intra-articular injection, Synvisc-One contains the same material and volume as Synvisc, but it supplies 6 mL of Hylan G-F 20 at one time. Relief is possible without the systemic adverse effects associated with such medications as steroids and anti-inflammatory medications.

Caution must be used in patients who are allergic to avian proteins, feathers, or egg products; with venous or lymphatic stasis in the leg to be treated; or with severe inflammation in the knee to be treated. Patients should avoid prolonged weight-bearing activities for 48 hours after treatment.

For more information about Synvisc-One, please see this month’s Pharmaceutical Approval Update feature on page 200.

Source: Genzyme, www.synvisc.com

NEW INDICATIONS

Symbicort in Chronic Obstructive Pulmonary Disease

The FDA has approved AstraZeneca’s Symbicort (budesonide/formoterol fumarate dihydrate, 160/4.5 mcg) for the maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. Two inhalations twice daily are recommended for patients with COPD.

The approval of this metered-dose inhaler was based on results from two pivotal phase 3 clinical trials of patients 40 years of age and older—the six-month SHINE study and the 12-month SUN study. In both trials, an inhaled corticosteroid (budesonide) plus a rapid and long-acting beta2-agonist (formoterol) significantly improved lung function within five minutes of the first dose. The effect was maintained for the duration of the trial period.

Symbicort is also indicated for the long-term maintenance treatment of asthma in patients 12 years of age and older.

Sources: Medscape, March 5, 2009, www.medscape.com; AstraZeneca, February 27, 2009

Glatiramer (Copaxone) For Early Multiple Sclerosis

Glatiramer acetate (Copaxone, Teva) is now approved to include the treatment of patients who have experienced a first clinical episode and have features on magnetic resonance imaging (MRI) that are consistent with multiple sclerosis (MS).

Up to 85% of MS patients initially experience a single neurological event suggestive of MS. Early treatment can help delay the conversion from the clinically isolated syndrome (CIS) to clinically definite MS.

The FDA approved the new indication after reviewing the phase 3 PreCISe study, which was conducted at 80 centers throughout the world. Long-term data showed that 80% of patients were able to walk unassisted after 15 years of adhering to therapy and after an average of 22 years of living with MS.

Glatiramer acetate was originally indicated for reducing the frequency of relapses in relapsing-remitting MS.


Peginteron/Ribavirin Offers Second Chance for Patients With Hepatitis C

The FDA has approved new labeling for Schering-Plough’s peginterferon alfa-2b/ribavirin (Peg-Intron/Rebetol) combination in treating chronic hepatitis C virus (HCV) infection in patients three years of age and older with compensated liver disease. The new indication includes patients who received previous therapy for HCV infection. This is the first pegylated interferon combination approved in the U.S. that is not restricted to treatment-naive patients.

This approval was based on the results of a noncomparative clinical study involving 2,293 adults with moderate-to-severe fibrosis or cirrhosis who had not responded to previous treatment with interferon-alpha/ribavirin. After patients were re-treated with combination Peg-Intron/Rebetol therapy, the overall study response rate was 22%. The results helped to define patients most likely to respond to retreatment.


Zoledronic Acid (Reclast) For Steroid-Induced Osteoporosis

Once-yearly zoledronic acid (Reclast, Novartis) Injection is now approved to treat and prevent osteoporosis caused by glucocorticoids for patients expecting to be taking steroids for at least 12 months. A single 5-mg, 15-minute infusion can prevent bone loss for a full year.

Glucocorticoids are widely used to treat inflammatory diseases, such as asthma and rheumatoid arthritis, and are the primary cause of secondary osteoporosis. Up to 50% of patients receiving long-term glucocorticoid therapy are at increased risk of fracturing a bone as a
result of osteoporosis.

This is the fourth indication for Reclast in the U.S. Reclast was approved in the U.S. in 2007 for treating patients with postmenopausal osteoporosis and in 2008 to increase bone mass in men with osteoporosis. In June 2008, the indication for treating osteoporosis was broadened to include the reduction of new clinical fractures in men and women after they experienced a recent low trauma hip fracture. In April 2007, Reclast was approved to treat Paget’s disease of bone in men and women.

Patients should not take Reclast if they are taking Zometa, which contains the same ingredient, and they should drink fluids before receiving the injection to help prevent kidney problems.

Common adverse effects include flu-like symptoms, fever, muscle or joint pain, and headache.


**NEW DRUGS**

**Warning about Glucose Updated for Quetiapine (Seroquel)**

AstraZeneca is strengthening warnings for its antipsychotic drug quetiapine fumarate (Seroquel) at the request of the FDA. The company agreed to move a statement on the risk of increased blood glucose levels to the warnings and precautions section of the label.

AstraZeneca made the label change in January 2009.

The FDA originally approved Seroquel to treat schizophrenia and depression, but AstraZeneca applied for approval of an extended-release formulation to treat depression and anxiety.

More than 15,000 patients have sued AstraZeneca, claiming that the company did not inform doctors and patients about a relationship between the drug and diabetes and weight gain associated with quetiapine by publishing only selective data. Many lawsuits also claimed that AstraZeneca promoted quetiapine for unapproved uses. In 2003, the FDA did warn doctors about a possible link between diabetes and atypical antipsychotic agents.

In March 2009, hearings were held in Delaware to determine whether to allow testimony from three physicians in the case of a patient who claimed that using the drug caused diabetes.


**Wearing Medicated Patches During MRIs Can Be Risky**

Some adhesive transdermal patches may pose a risk to patient safety. Patients who wear the patches while undergoing MRI scans may experience skin burns, says the FDA. The patches of concern include brand-name, generic, and non-prescription products.

The FDA issued a Public Health Advisory after learning that a warning was missing on some skin patches that contain aluminum or other metals in their non-adhesive backing. Although the metal is not attracted to the magnetic field during the MRI procedure, it can conduct electricity and generate heat. The metal might not be visible, and the product’s labeling might not disclose the presence of metal.

The FDA was alerted to the missing warning on Teva Pharmaceutical’s fentanyl transdermal system in January. It is reviewing all medicated patches to ensure that those containing metal provide a warning to patients undergoing MRI.

The FDA recommends that patients inform their physician or health care professional that they are wearing a medicated skin patch when they are referred for the MRI.

Source: FDA, March 5, 2009

**Boxed Warning Added For Metoclopramide**

Manufacturers of metoclopramide, a drug used to treat gastrointestinal (GI) tract disorders, must add a boxed warning to the drug labeling about the risk of tardive dyskinesia when the product is used for a long time and when it is given in a high dose. These involuntary, repetitive movements can persist even after the patient stops taking the drug.

Companies will be required to implement a Risk Evaluation and Mitigation Strategy (REMS) to ensure that patients using metoclopramide receive a medication guide. Patients at high risk include the elderly, especially older women. Symptoms of tardive kinesia are usually irreversible, and there is no known cure, although symptoms may diminish after metoclopramide is discontinued.

Metoclopramide is available in the form of tablets, syrups, and injections. Reglan Tablets (Schwarz), for example, are used to treat gastroesophageal reflux disease (GERD), emesis, and diabetic gastroparesis (slowed emptying of the stomach’s contents).

Metoclopramide appears to be the most common cause of drug-induced movement disorders. Chronic metoclopramide therapy should be avoided except when the benefits are believed to outweigh the risks. It is recommended that treatment not exceed three months.

Source: FDA, February 26, 2009; www.fda.gov

**FDA Alert for a Facility in India**

Paonta Sahib, a facility owned by Ranbaxy Laboratories in India, has been under an FDA import alert since September 2008 because it falsified data and test results in approved and pending drug applications.

The FDA is still investigating to ensure the safety and efficacy of marketed drugs associated with the site. However,
the agency has not identified any health risks associated with currently marketed Ranbaxy products. For now, the FDA recommends that patients not disrupt their drug therapy.

The affected applications are for approved drugs made at the Paonta Sahib site for the U.S. market; drugs pending approval at the FDA that are not yet marketed; and drugs manufactured in the U.S. that relied on data from the Paonta Sahib facility.

The FDA has invoked its Application Integrity Policy (AIP) against the facility and has asked Ranbaxy to cooperate. On September 16, 2008, the FDA issued two warning letters and instituted an alert barring the entry of all finished drug products and active pharmaceutical ingredients from Ranbaxy’s Dewas, Paonta Sahib, and Batamandi Unit facilities because of violations of current Good Manufacturing Practices requirements. That action barred the commercial importation of 30 generic drugs into the U.S., and as of this writing, it remains in effect.

Source: FDA, February 26, 2009

**Appearance of Topiramate (Topamax) Tablets To Change**

Ortho-McNeil Neurologics is changing the appearance of its topiramate (Topamax) tablets to help reduce medication errors and confusion with AstraZeneca’s Toprol XL (metoprolol succinate extended-release tablets).

Topamax, an anticonvulsant, is indicated for patients with partial-onset or primary generalized tonic-clonic seizures, as adjunctive therapy in Lennox-Gastaut syndrome, and for migraine prophylaxis.

The color of Topamax 25-mg tablets will be changed from white to cream, and the imprint code for all tablet strengths will be changed from “Top” or “Topamax” to “Omn.” The appearance of Topamax sprinkle capsules will also be modified, but the National Drug Code (NDC) numbers for both Topamax tablets and sprinkle capsules will be changed.

**Dr. Hamburg Nominated For FDA Commissioner**

Margaret Hamburg, MD, has been nominated by President Obama to lead the FDA.

Currently a Senior Scientist for the Global Health and Security Initiative, Dr. Hamburg was previously Assistant Secretary for Planning and Evaluation at the U.S. Department of Health and Human Services in the Clinton administration; Commissioner of Health for the City of New York; and Assistant Director of the National Institute of Allergy and Infectious Diseases of the National Institutes of Health.

She also worked in the Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary of Health and has held academic appointments at Cornell University Medical Center, Columbia University School of Public Health, Rockefeller University, and Georgetown University School of Medicine.

A graduate of Harvard College and Harvard Medical School, she completed her internship and residency in Internal Medicine at the New York Hospital/Cornell University Medical Center. She is a member of the Institute of Medicine, the New York Academy of Medicine, and the Council on Foreign Relations, and she is a Fellow of the American Association for the Advancement of Science.

She has served on the editorial boards of *Current Reviews in Public Health* and *The Bulletin* of the New York Academy of Medicine. Her research covers the biology of addictions, AIDS, the behavioral sciences, and child development. She has published many articles and has won awards for public service and outstanding achievement.

Source: Center for Biosecurity/University of Pittsburgh, www.upmc-biosecurity.org

**No Protection from Lawsuits—Even When Companies Comply With FDA Rules**

On March 4, the U.S. Supreme Court decided that state juries may award damages for harm from unsafe drugs even though their manufacturers had satisfied federal regulators. Many drug companies had sought tighter federal regulation to protect themselves against litigation.

The Court, voting 6 to 3, upheld a jury verdict of $6.7 million in favor of Diana Levine, whose arm had to be amputated after she received a promethazine (Phenergan) injection. (See this month’s Medication Errors column on page 175.)

Wyeth argued that it had complied with FDA’s labeling requirements and thus should be exempt from lawsuits. Many drug firms, upset by the decision, suggested that laypersons on juries should not be second-guessing physicians and scientists at the FDA.

Drug companies had hoped the Vermont case would establish broader protections. A lawyer representing Wyeth said the company had fully complied with federal law in its labeling of Phenergan.

Supreme Court Justice Alito said Wyeth had provided ample notice about the risk of gangrene in six separate warnings, prominently displayed on the approved drug label. He wrote that juries see only the “tragic accident” before them. The FDA, he wrote, “has the benefit of the long view” and “conveys its warnings with one voice.”

Source: *The New York Times*, March 5, 2009

continued on page 183
FDA Allows Patients Access To Rare Drug (Iplex) for ALS

The FDA has decided to allow patients with the fatal neurodegenerative disease amyotrophic lateral sclerosis (ALS, or Lou Gehrig’s disease) to have access to a medication that is under an Investigational New Drug (IND) application.

Mecasermin rinfabate (recombinant DNA origin) injection (Iplex, Insmed) combines human insulin-like growth factor-1 (IGF-1) and human IGF-binding protein-3 (rhIGFBP-3). Iplex is approved by the FDA only for the treatment of growth failure in children with severe primary IGF-1 deficiency or with growth hormone (GH) gene deletion who have neutralizing antibodies to GH. It is not available for sale because of a court order related to patent infringement.

Access is being granted in two ways:

• INDs requesting “compassionate use” for an individual may proceed (that deadline was March 6, 2009).
• For the remaining limited supply, patients would receive the drug by lottery in a clinical trial.

The FDA realized that granting access to individual patients would rapidly deplete the supply and make it almost impossible to conduct a controlled clinical trial. Insmed does not have enough of the drug for every patient. The FDA learned that Iplex was being made available in Italy under a court order and that more than 100 patients with ALS had received treatment there. Insmed has learned that Iplex was being made available in Italy under a court order and that more than 100 patients with ALS had received treatment there. Insmed has agreed to allow the FDA to make a summary of Italian data available to the public.

Source: FDA, March 11, 2009

Heated Form of Doxorubicin (ThermoDox) in Liver Cancer

The FDA has granted orphan drug designation for ThermoDox (Celsion), a heat-activated liposomal encapsulation of doxorubicin, for treating patients with inoperable hepatocellular carcinoma.

ThermoDox is being evaluated under a Special Protocol Assessment with the FDA in a 600-patient, global phase 3 trial. The technology enables high levels of doxorubicin to be deposited in a targeted tumor.

Primary liver cancer is the fifth most common solid tumor cancer, affecting approximately 20,000 patients per year in the U.S. The rate is rapidly growing worldwide at approximately one million cases per year because of the high prevalence of hepatitis B and C in developing countries.

The standard first-line treatment is surgical resection of the tumor, but most patients are ineligible for surgery. Radiofrequency ablation is also used for non-resectable liver tumors, but it is less effective for larger tumors. Chemotherapy is largely ineffective.

Along with hyperthermia, ThermoDox has the potential to provide local tumor control and improve quality of life.


Fenofibrate Meets Challenge Of Metabolic Syndrome

A five-year study of 9,795 patients with type-2 diabetes reveals that fenofibrate significantly reduces the risk of cardiovascular disease (CVD) in all subgroups, but the absolute benefits are likely to be greater in the context of metabolic syndrome.

Fenofibrate reduced total CVD events by 11%, and the effect on patients with metabolic syndrome was nearly independently significant. The largest effect was seen in patients with marked dyslipidemia; in that group, fenofibrate reduced CVD rates by 30% in women and by 24% in men. Among patients with metabolic syndrome, fenofibrate reduced the proportional risk of CVD by 18% in women and by 7% in men.

Source: Diabetes Care 2009;32:493–498

Lipid Lowering Is Possible In Patients with HIV Infection

Antiretroviral therapy (ART) may adversely affect lipid levels in patients with HIV infection, but is the dyslipidemia more difficult to treat?

A study by researchers at Kaiser Permanente Northern California in Oakland and at the University of California, San Francisco, suggests that it isn’t HIV infection as much as it is the antiretroviral agent itself that may cause the difficulty.

Observing 7,776 patients who began lipid-lowering therapy, the researchers measured changes in lipid levels within 12 months. Patients with HIV infection showed smaller decreases in low-density lipoprotein-cholesterol (LDL) (25.6% vs. 28.3%) and triglyceride levels (44.2% vs. 59.3%). However, because LDL cholesterol is the primary therapeutic target in managing lipids, the researchers were encouraged that differences in response according to HIV status were modest.

Responses varied according to the antiretroviral medication used. Patients with HIV infection who were receiving ART with protease inhibitors had the smallest reductions in triglyceride levels (26.4%), compared with 44% among those receiving protease inhibitors alone and 60.3% among those receiving ART with non-nucleoside reverse transcriptase inhibitors (NNRTIs). The patients who received NNRTI-based ART experienced decreases similar to those of patients without HIV infection, even after the investigators adjusted for confounders.

Although the HIV patients tolerated lipid-lowering therapy well, they had a six-times-higher risk of rhabdomyolysis.
Reducing Blood Pressure Safely With Combination Therapy

One medication often helps in lowering blood pressure (BP), but combining two or more drugs from different classes has additive effects.

Researchers from England found that combination therapy had almost five times the effect of simply doubling the dose of one drug. Analyzing data from 42 trials, they quantified the incremental effects of combining drugs from any two classes of thiazides, beta blockers, angiotensin-converting enzyme (ACE)–inhibitors, and calcium-channel blockers over one drug alone.

A single blood pressure-lowering drug at the standard dose reduced diastolic BP by 5 mm Hg, equivalent to a 25% reduction in risk of coronary heart disease (CHD) events and a 35% reduction in stroke, the researchers say. Doubling the dose of a single drug would change the reduction in BP to 6 mm Hg instead of 5 mm Hg, in turn reducing CHD events by 29% and stroke by 40%. Combining two drugs from different classes would change the reduction in BP to 9 mm Hg instead of 5 mm Hg, reducing CHD events by 40% and stroke by 54%. Thus, for every one incremental CHD event or stroke prevented by doubling the dose of a single drug, combination therapy would prevent four events.

The researchers suggest that combination low-dose therapy is more effective and also less toxic than a higher dose of a single drug. Low-dose therapy can also reduce some adverse effects that are strongly dose-related. Combining two drugs at the half of the standard dose, therefore, causes fewer adverse events than would one drug at a standard dose.


American Psychiatric Association Changes Funding Policy

The American Psychiatric Association Board of Trustees has voted to eliminate drug industry–supported symposia and meals at its annual medical meetings. With this move, the APA is striving to increase transparency and reduce potential financial conflicts of interest. Symposia at meetings that supply doctors with continuing medical education credits are sometimes funded by drug firms, a practice that can raise concerns that sessions might be biased in favor of the sponsoring company’s products.

APA President Nada L. Stotland, MD, MPH, claims that the organization has always taken care to avoid biased reporting at its symposia but decided that the only way to eliminate the risk was to have the symposia supported by the APA alone.


Few Hospitals Have Electronic Health Records

Even with a stimulus bill including billions of dollars for promoting electronic health records (EHRs), few hospitals in the U.S. have adopted the technology thus far. A large obstacle is cost (which can be as high as $100 million per institution) as well as the reluctance of health care providers to adapt to change.

In a survey of 3,049 hospitals, only 1.5% had comprehensive systems. Larger urban and teaching hospitals tended to have EHRs. Federal hospitals were not surveyed because Veterans Affairs hospitals already have EHRs.

Sources: N Engl J Med online; and Business Week, March 25, 2009; Medscape, March 26, 2009

Disposable Insulin Pen (Apidra SoloStar) for Diabetes

A prefilled disposable pen, the Apidra SoloStar (Sanofi-Aventis), is now available. The pen contains insulin glulisine of recombinant DNA origin. Apidra, an insulin analogue, is indicated for improving glycemic control in adults and children (four years of age and older) with type-1 diabetes or adults with type-2 diabetes.

The approval follows the launch of Lan- tus SoloStar (insulin glargine of rDNA origin) in 2007. Apidra SoloStar delivers rapid-acting insulin, and Lantus SoloStar delivers long-acting insulin.

Source: Sanofi-Aventis, February 26, 2009

Barrier (Repel CV) for Children After Open-Heart Surgery

Repel-CV (SyntheMed) has been approved to reduce the severity of adhesions in children undergoing open-heart surgery. This synthetic cardiac film barrier is inserted over the heart just before the chest is closed following an open-heart procedure. In the early healing stages, the temporary, absorbable barrier helps to decrease the severity of scar tissue. Bands of scar tissue are often found in the abdomen, pelvis, or chest; however, cardiac adhesions bind the outer membrane of the heart to surrounding tissue and may restrict heart activity and complicate additional procedures. Scar tissue is a result of natural healing, but adhesions can become densely fibrous and difficult to navigate surgically. This can pose problems for patients who need repeated operations.

Repel-CVs is indicated for children who are likely to require more than one heart operation. In one study, patients who received Repel-CV had adhesions occupying 21% of the surgical site; controls had adhesions that occupied 47% of the site.

Source: FDA, March 6, 2009
DNA Tests Detect Human Papillomavirus

A new DNA test can identify the two types of human papillomavirus (HPV) that cause most cervical cancers among women in the U.S.

Cervista HPV 16/18 (Hologic/Third Wave Technologies) detects the DNA sequences for HPV type 16 and HPV type 18 in cervical cells. Differentiating these HPV types gives more information on the risk of subsequent development of cervical cancer. A positive result indicates whether HPV type 16, 18, or both types are present in the cervical sample.

The FDA also approved Cervista HPV HR (High Risk), which is used to detect the DNA sequences of these HPV types. In women 30 years of age and older with borderline cytologic findings, Cervista HPV 16/18 can be used together with cytology and Cervista HPV HR to assess risk of cervical disease.

Hologic acquired the Cervista tests last year when it bought Third Wave Technologies.


Patients Should Not Share Insulin Pens and Cartridges

The FDA has issued an alert to remind health care professionals that single-patient insulin pens and insulin cartridges should not be used to administer medication to more than one patient because of the potential risk of transmitting blood-borne pathogens such as human immunodeficiency virus (HIV) and hepatitis virus infection.

These pen-shaped injector devices contain a disposable needle with an insulin reservoir or an insulin cartridge.

The FDA has learned of incidents at two hospitals involving more than 2,000 people in which the cartridge component was used for more than one patient, although the disposable needles were reportedly changed. The pens are not safe even if needles are changed.

Patients exposed to shared insulin pens are being contacted by the two hospitals and are being offered testing for hepatitis and HIV infection.

Source: FDA, March 19, 2009

Patients Might Be Able to Sue Medical Device Makers

A day after the Supreme Court decided that federal rules did not protect drug makers from state lawsuits, Democrats in Congress moved to overturn a decision that has protected medical device companies from similar legal actions.

On March 4, the Supreme Court rejected Wyeth’s claim that it was not subject to lawsuits in state courts for its antiemetic drug promethazine (Phenergan), because the FDA had already approved it. On March 5, Democrats reintroduced the Medical Device Safety Act, a bill that would allow similar lawsuits. Patients would have the right to sue if they are injured by a medical device. The device industry’s chief lobbying group criticized the bill and said it would inhibit innovation and result in higher health care costs.

However, the bill enjoys support from consumer advocates, trial lawyers, and the American Association for Retired Persons (AARP). Senator Edward M. Kennedy (D-Mass.) introduced the companion legislation.

Source: Associated Press, March 6, 2009

Controversy Surrounds Knee Device (Menaflex)

The approval of a knee device, Menaflex (ReGen Biologics) may have been a result of political pressure. Scientists at the FDA had repeatedly rejected the device, but lobbying appears to have played a role in the device’s approval.

Menaflex is a collagen scaffold implant designed to repair a torn medial meniscus and promote the growth of new tissue. The device was approved under the FDA’s 501(K) rules, which allow for a “fast-track” approval and obviate the need for clinical trials.

When ReGen first sought approval for Menaflex, it did so under the FDA’s normal process and began a clinical trial. However, the FDA cited record-keeping violations in the trial. In December 2005, the company decided to apply for the fast-track approval.

In July 2008, the FDA rejected the Menaflex fast-track bids in August 2006 and September 2007. A second rejection of the fast-track application prompted the company to appeal to members of New Jersey’s Congress. The company also asked that FDA staffers who previously had opposed Menaflex be excluded from decision making.

FDA scientists recommended that the company’s third fast-track bid for Menaflex be rejected. Instead, a special panel was invited to look at Menaflex, and according to the FDA, ReGen tried to influence the selection of panel members.

The panel included five outside sports medicine experts, and Menaflex was eventually approved. Andrew von Eschenbach, former FDA chairman, is calling for an overhaul of the way in which medical devices are approved.

Sources: The Wall Street Journal; News Inferno.com, March 6, 2009; ReGen, www.regenbio.com

NIH NEWS

Stem Cells Help Heal Ulcers In Patients with Scleroderma

Scleroderma, an autoimmune disease, leads to thickening and severe scarring of skin as well as thickening and failure of internal organs. The disease can be fatal, and there is no cure. A major com-
plication is the development of ulcers on patients’ fingers and toes that are difficult to heal.

At the 67th Annual Meeting of the American Academy of Dermatology in San Francisco in March, Vincent Falanga, MD, described the research taking place at the Roger Williams Medical Center, in Providence, Rhode Island. He explained how the stem cells are “instructed” to stimulate healing in a difficult wound.

A fibrin spray was used to apply stem cells to the wounds of three patients. After the stem cells were delivered to the affected finger, the wound was covered and treated with substitute skin. Pain relief was rapid, with healing seen at four and eight weeks.

Treatment was limited by the study protocol to three cycles of stem cells. Research was funded by the National Institutes of Health.


**RESEARCH NEWS**

**Sugar-Coated ‘Quantum Dots’ Deliver Anticancer Drugs**

Scientists in Switzerland are reporting an advance that could help tap the much-heralded potential of “quantum dots.” These nanocrystals glow when they are exposed to ultraviolet light in the treatment of cancer and other diseases.

In a new study, giving quantum dots an icing-like cap of certain sugars made these nanoparticles accumulate in the liver but not in other parts of the body. This selective targeting might be used to deliver anticancer drugs to one organ, without causing the systemic adverse effects from existing cancer drugs.

Quantum dots are about 1/5,000th the width of a human hair and are used in solar cells, medical diagnostic imaging, and electronics. Although these particles also show promise for delivering drugs to treat cancer and other diseases, researchers have not yet found the best way to target these dots to specific tissues or organs in order to maximize their effectiveness and limit toxicity.


**The $1,000 Genome And Personalized Medicine**

A new, economical technique for decoding genes is ushering in the long-awaited era of personalized medicine when doctors may be able to tailor prevention and treatment for each patient’s genetic profile.

Scientists have made a key advance toward an inexpensive DNA nanopore sequencer. The device can determine the chemical instructions in the famed double-helix molecule. This sequencer may be able to replace higher-priced techniques currently in use.

The nanopore device identifies the four DNA building blocks (adenine, thymine, guanine, and cytosine) based on the amount of electric current that is blocked by these nucleotides as they squeeze through the pore. Nanopores can cost only $1,000 for an individual’s genome, or one’s complete genetic endowment, compared with the present sum of $100,000 to $1 million for sequencing an entire genome with conventional techniques.


**Cethromycin, An Antibiotic To Fight Bioterror Agents**

Advanced Life Sciences Holdings, Inc., has been awarded $2 million from the Department of Defense (DoD) to develop cethromycin as a new broad-spectrum medical countermeasure. Cethromycin is designed to treat patients with respiratory tract infections and to combat bioterror agents. Studies are planned to assess the drug’s efficacy in combating *Francisella tularensis* (tularemia), *Ves- sinia pestis* (plague), and *Burkholderia pseudomallei* (melioidosis).

A mouse study conducted by the U.S. Army Medical Research Institute of Infectious Disease suggested that cethromycin at a dose of 75 mg/kg over 21 days offered 100% protection from tularemia infection.

Cethromycin is a once-daily oral ketolide under FDA review for approval for the treatment of mild-to-moderate community-acquired pneumonia (CAP).

A 30-day course of oral cethromycin was 100% protective against a lethal dose of inhaled anthrax, compared with the standard of care—Bayer’s ciprofloxacin (Cipro), which provided 90% protection.

The FDA has designated cethromycin as an orphan drug for the prophylactic treatment of post-exposure inhalation anthrax, but the FDA has not approved it for marketing in this or any other indication.

*F. tularensis* is the causative agent of tularemia in humans. The spectrum of illness ranges from a mild flu-like syndrome to a life-threatening infection. Tularemia is a CDC Category A biologic threat agent because of its high infectivity, ease of spread by aerosol, and its potential to cause morbidity and mortality. (An infectious dose can contain as few as one to 10 organisms.)

Source: Advanced Life Sciences Holdings, Inc, March 19, 2009

**NEW MEDICAL DEVICES**

Marvin M. Goldenberg, PhD, RPh, MS

Name: Tecnis Multifocal Posterior Chamber Intraocular Lens, Models ZM900 (silicone) and ZMA00 (acrylic)

Manufacturer: Advanced Medical Optics, Inc., Santa Ana, Calif.

Approval Date: January 16, 2009

Use Classification: A foldable intraocular (IOL) lens is used to restore vision
in adults who have had a cataract removed. Cataracts cause the lens of the eye to gradually thicken, resulting in loss of vision.

**Description:** The Tecnis plastic lens is made of the same materials and design as many multifocal IOLs, such as silicone and acrylic.

**Purpose:** The lens restores vision after cataract surgery.

**Benefit:** The Tecnis IOL decreases the need for eyeglasses for both distant and near tasks, although sharpness of vision might be decreased. In clinical studies, fewer than 1% of patients in clinical studies requested removal of the multifocal IOL. This lens provides good distance vision as well as useful intermediate vision (at two to five feet).

**Precautions:** Halos and glare from lights at night are more common with this lens than with a monofocal IOL. Under poor visibility conditions, vision might be reduced more than it would be with a monofocal IOL. When driving, patients may have difficulty in recognizing traffic signs and objects in the road and should take extra care, especially in poor light conditions. In rare instances, multifocal IOLs may make some types of retinal surgery more difficult.

**Source:** FDA, www.fda.gov

**Name:** Spectral Oct Slo Combination Imaging System

**Manufacturer:** Opko Health, Inc., Miami, Fla.

**Approval Date:** January 26, 2009

**Use Classification:** The Spectral Oct Slo diagnostic device produces high-resolution images of the inner retinal choroid and vitreous humor of the eye to detect and manage diseases affecting the rear segment of the eye.

**Description:** This noninvasive tomographic and confocal device is indicated for in vivo viewing, and measuring posterior ocular structures (i.e., the retina, macula, retina nerve fiber layer, and optic disk).

**Purpose:** The device helps to detect and treat diseases affecting the posterior part of the eye. The cornea, sclera, and conjunctiva can also be visualized if the focal position is changed.

**Benefit:** High image quality offers clinicians a valuable tool for detecting ocular pathology and facilitates monitoring of disease progression or regression.

**Source:** Medical News Today, www.medicalnewstoday.com

**Name:** NaviStar ThermoCool Irrigated Tip Catheter

**Manufacturer:** Biosense Webster/J&J, Diamond Bar, Calif.

**Approval Date:** February 6, 2009

**Use Classification:** The catheter is used to treat recurrent symptomatic paroxysmal atrial fibrillation (AFib) when patients have not responded to drug therapy.

**Description:** The luminal catheter has a deflectable tip designed to facilitate mapping of the heart and to transmit radiofrequency current to the catheter tip electrode for ablation. Saline, delivered by the CoolFlow Pump, passes through the lumen of this catheter to maintain lower tip-to-tissue temperature at the ablation site. The catheter is available in five curve shapes.

**Purpose:** This is the only ablation catheter to be approved for the treatment of AFib, which is characterized by fast and disorderly beating in the heart’s upper chambers. The catheter is also approved for patients with two types of arrhythmias: type 1 atrial flutter, and recurrent, refractory ventricular tachycardia resulting from prior myocardial infarction (MI).

**Benefit:** AFib is a common rhythm disorder that affects more than two million Americans. It can raise the risk of stroke, heart failure, and other complications. Cardiac ablation offers an option for patients whose debilitating symptoms are not effectively managed with drugs. Patients receiving cardiac ablation with this catheter were significantly more likely to be free of recurring AFib and to experience fewer serious adverse events compared with patients receiving antiarrhythmic agents.

**Source:** www.biosensewebster.com

**New Device Designation For Humanitarian Use**

Although medical devices are not eligible for orphan designation, the FDA has made it easier and less expensive, through a two-step process, for manufacturers to obtain approval for devices used to treat rare diseases.

The FDA grants approval for the Humanitarian Use Device, then grants approval for the device to be marketed under Humanitarian Device Exemption (HDE) provisions of the Safe Medical Devices Act of 1990. This Act allows a medical device to be approved if manufacturers show that the probable benefits outweigh the risks for patients with a rare condition (affecting fewer than 4,000 persons in the U. S. per year). The provision requires only that the probable health benefit of the device is greater than the risk of using it. This standard is less costly compared with the level of safety and effectiveness required for other marketing approvals.

The FDA's Office of Orphan Products Development has designated 133 humanitarian use devices, and 44 of those were approved as HDEs. Two of the devices include a stent to treat urinary tract obstruction in unborn babies and a titanium rib for children who have been born with an inadequate rib cage. Neither device would have been available without the exemption.

**Source:** Source: FDA, February 27, 2009, www.fda.gov