NEW DRUGS

First-in-Class Antibiotic for Respiratory Infections

The U.S. Food and Drug Administration (FDA) has approved telithromycin tablets (Ketek™, Aventis) in the U.S. to treat acute exacerbation of chronic bronchitis, acute bacterial sinusitis, and mild-to-moderate community-acquired pneumonia, including infections caused by multidrug-resistant *Streptococcus pneumoniae*, in patients aged 18 years and older. As the first in a new class of antibiotics known as the ketolides, Ketek™ is designed to treat community-acquired respiratory tract infections.

More than seven million patients have used Ketek™ since its introduction in Europe, Latin America, and Asia. It has also been widely used in Japan and France.

(Source: Aventis, April 1, 2004, www.aventis-us.com.)

Generic SSRI for Depression

Synthon Pharmaceuticals, Ltd., has announced its launch of paroxetine mesylate tablets (Pexeva™) in strengths of 10, 20, 30, and 40 mg for the treatment of depression, obsessive–compulsive disorder, and panic disorder. This drug provides an alternative for patients who need or are currently taking selective serotonin reuptake inhibitors (SSRIs).

Pexeva™ is the bioequivalent to GlaxoSmithKline's Paxil®.

(Source: Synthon, March 24, 2004; www. synthon-usa.com.)

Generic Oxycontin for Pain

Teva Pharmaceutical Industries, Ltd., has announced that subsequent to the approval of its Abbreviated New Drug Application (ANDA), dated March 24, 2004, the FDA now regards the company's voluntary risk-management program (RMP) for oxycodone HCI extended-release tablets, 80 mg, as operational.

The tablets are the AB-rated generic equivalent of OxyContin® (Purdue Pharma) and are indicated for patients with moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time.

The FDA recognizes that despite the advantages of the product, the tablets present a potential for abuse and misuse.

(Sources: Teva, March 30, 2004; FDA, March 24, 2004.)

Ribavirin for Hepatitis C

The FDA has granted marketing approval to Three Rivers Pharmaceuticals for its ribavirin capsules (Ribasphere™), 200 mg, in combination with interferon alfa-2b for the treatment of chronic hepatitis C (HCV) infection.

The company had to battle multiple patent infringement lawsuits and overcome significant regulatory obstacles that delayed and complicated the entry of Ribasphere™ into the marketplace.

HCV infection is the primary cause of the need for liver transplantation. It can also lead to cirrhosis, end-stage liver disease, and liver cancer.

(Source: Three Rivers, April 7, 2004.)

NEW INDICATION

Diltiazem for Angina

The FDA has approved diltiazem HCI (Cardizem® LA, Biovail), a calcium-channel blocker, to treat chronic, stable angina pectoris (chest pain). The drug is already approved for the treatment of high blood pressure, or hypertension. Angina occurs when a part of the heart does not receive enough blood.

The new formulation provides 24-hour blood pressure control with a single daily dose and may minimize a rise in blood pressure in the early morning, when the risk of an ischemia-associated cardiovascular event is highest.

In a trial of 311 patients with chronic stable angina, all of the Cardizem® LA doses that were administered at night increased the patients' exercise tolerance, compared with placebo, after 21 hours. When patients took 360 mg of the drug in the morning, exercise tolerance also improved when measured 25 hours later.

(Source: Reuters Health Information, April 5, 2004; www.biovail.com.)

NEW FORMULATIONS

Injectable Olanzapine for Acute Agitation

Physicians have a new, fast-acting option for controlling the potentially crippling effects of acute agitation in patients with schizophrenia and bipolar mania. Olanzapine for injection (Zyprexa® IntraMuscular, Eli Lilly) enables quick relief of acute agitation without oversedation and without many of the debilitating side effects of conventional injectable therapies.

Sixty percent of hospital-based psychiatrists or emergency room physicians say that currently available intramuscular (IM) treatments are not adequate for rapidly calming agitated patients.

Acute agitation is a behavioral syndrome that includes hostility, extreme excitement, poor impulse control, tension, and uncooperativeness.

In two studies in agitated patients with schizophrenia, IM Zyprexa® was compared with IM haloperidol (Haldol®, Ortho-McNeil) and with placebo. The injectable formation of haloperidol, a first-generation, or "typical," antipsychotic, drug has been the standard of care for acutely agitated patients for many years. Both IM Zyprexa® and IM haloperidol were superior to placebo. Painful muscle contractions (dystonia) occurred in 6.6% of the IM haloperidol patients but not in the IM Zyprexa® patients.

All patients with schizophrenia should be monitored for symptoms of hyperglycemia. The Zyprexa® label includes a

warning for elderly patients with dementia.

(Source: Eli Lilly, March 30, 2004; www.zyprexa.com.)

Injectable Pantoprazole for Acid Suppression

The FDA has approved the reformulation of the acid suppressant pantoprazole (Protonix®, Wyeth). The injectable product eliminates the need for an in-line filter and allows wholesalers to purchase the product directly from the manufacturer.

The new intravenous (IV) formulation is approved for two-minute or 15-minute infusion regimens. These approaches should reduce drug-preparation time and administration costs in hospitals, because the IV admixture bag can be replaced with a less expensive syringe.

The only proton pump inhibitor (PPI) currently available in the U.S. in IV form, this drug received expedited FDA approval in October 2001 for patients with pathological hypersecretory conditions associated with Zollinger–Ellison syndrome or other neoplastic conditions.

IV Protonix® should be discontinued as soon as patients can take the delayed-release tablets.

(Source: Wyeth, April 12, 2004.)

DRUG NEWS

Irbesartan: What Happens After the Research?

A postmarketing surveillance study is one way to find out how a drug actually behaves after the researchers are no longer involved in the day-to-day monitoring of patients.

Irbesartan (Karvea®, Sanofi-Synthelabo), an antihypertensive agent, was first introduced in Spain in 1998. In the KARTAN (Karvea irbesartan) study, which was designed to confirm findings from previous clinical trials, 852 primary care physicians monitored 4,887 patients for up to six months. The goal was to assess the types and frequency of adverse drug reactions (ADRs) resulting from irbesartan and whether it interacted with other agents that were commonly used in the primary care setting.

Of the patients studied, 108 (2.2%) experienced ADRs during the six months. In most cases, the ADRs were mild to moderate; only two were classified as serious and warranted hospitalization: an allergic reaction and syncope attributable to hypotension. In both of these cases, elderly patients were affected.

The efficacy of irbesartan had already been established in earlier clinical trials. In this study, irbesartan reduced blood pressure to statistically significant levels by one month.

The value of postmarketing studies such as this, say the researchers, is not in the design but in the larger number of patients who can be enrolled, including patients who might have been excluded from the more rigorously designed clinical trials.

The researchers felt confident that their study captured enough information to reassure practitioners about the safety and tolerability of this drug for most patients.

(Source: *Clin Ther* 2004;26:232–244.)

Fewer Falls with Alfacalcidol

Alfacalcidol, a prodrug of the D-hormone calcitriol and a calcium regulator, can restore stability in the lives of older people who are at risk for falling. A 36-week, placebo-controlled study from Switzerland found that the drug safely reduced the number of falls among 321 men and women aged 70 and older.

Although most of the participants had normal vitamin D and D-hormone serum levels, older adults are often at risk for vitamin D deficiency because they receive insufficient sunlight and consume inadequate amounts of dietary vitamin D. Even people with normal vitamin D serum levels may have D-hormone deficiency because of age-related reduced activity of renal 1-hydroxylase, drug interactions, and other factors.

Alfacalcidol was judged to be preferable to vitamin D supplements because (1) its mechanism of action is independent of renal 1-hydroxylase, (2) it is effective in the presence of resistance to the vitamin D receptor, and (3) the risk of hypercalcemia appears to be lower than with calcitriol.

Serum intact parathyroid hormone (iPTH) levels have been shown to be inversely related to muscle strength and endurance. Various researchers have suggested that PTH is an independent risk factor for reduced muscle strength and falls. After 12 weeks, iPTH levels declined by an average of 32.5% in all participants who took alfacalcidol, followed by another 5.4% decrease over the next 12 weeks. In contrast, iPTH levels rose in the placebo group by 5.4% over the 24 weeks.

The decline of iPTH in the patients taking alfacalcidol was observed regardless of calcium intake. Alfacalcidol therapy also raised serum calcium levels significantly, but calcium levels did not change in the placebo group.

Fewer alfacacidol patients experienced falls during the study. In patients who took in more than 512 mg of calcium daily, alfacacidol was associated with significantly fewer falls. At least 512 mg/day of calcium was required for vitamin D or D-hormone analogues to be effective.

(Source: *J Am Geriatr Soc* 2004;52: 230–236.)

Tuberculosis Therapy and Hypokalemia

While receiving treatment for multidrug-resistant tuberculosis (TB), one third of screened patients were found to

have abnormally low levels of potassium. In a study from Brigham and Women's Hospital and Partners in Health in Boston, Massachusetts, and from Socios En Salud and the Peruvian National Tuberculosis Program in Lima, Peru.

The use of capreomycin (Capastat®, Eli Lilly) and a low initial body weight raised the risk of hypokalemia. Patients often had low magnesium levels, which were probably induced by the same mechanism of electrolyte wasting. Hypokalemia was diagnosed, on average, five months after treatment started.

For 86% of 125 patients, potassium levels were normalized, but hypokalemia significantly increased the risk of death. The average time from diagnosis to death was four months, and it was unlikely that those eight patients died too quickly for electrolyte disorders to be corrected, the researchers say. Given the subtle symptoms and significant morbidity associated with electrolyte disturbance, close monitoring and aggressive management are essential.

(Source: *Chest* 2004;125:974–980.)

Hypochondriacs Unlikely to Seek Psychotherapy

Although psychotherapy sometimes helps patients with hypochondria (persistent, unfounded fears about having a serious disease), 25% of patients quit after being told that their problem is mental, not physical. Most hypochondriacs do not visit psychiatrists; they do not think that talking helps, and they hope that a medical procedure will take care of their problems.

Among patients who completed six therapy sessions, almost 57% showed significant improvement in symptoms and quality of life after a year, compared with 32% of the patients who did not finish therapy; the treatment did not fit with their belief that their illnesses were real.

In the study, therapists encouraged patients to break certain habits, such as seeking medical information on the Internet and reading obituaries; they taught the patients how to understand their symptoms better and to use distraction techniques.

Hypochondria is difficult to treat, in part because patients often switch doctors repeatedly until they get tests or a diagnosis they can accept. Scientists think that the disorder might be genetic or learned from parents who overreact to illness. It often starts in childhood or early adulthood and can last a lifetime.

For some, accepting mental health treatment still carries a stigma; in fact, some psychiatrists and patients call the condition "health anxiety."

(Sources: *JAMA* 2004;29(12):1464– 1470; *The New York Times*, Associated Press, March 25, 2004.)

Galantamine May Improve Alzheimer's Disease . . .

Although cholestinerase inhibitors have demonstrated efficacy against Alzheimer's disease (AD) over three to six months, little is known about long-term therapy. Thus, findings from a 36-month trial of galantamine (Reminyl®, Janssen) showed that the drug appears to slow the clinical progression of AD and to offer sustained benefits.

Researchers monitored 194 patients with mild-to-moderate AD from two earlier double-blind, placebo-controlled trials and compared the rate of cognitive decline in patients who completed the entire 36-month study with that of 75 patients who withdrew during the long-term, open-label extension.

Patients who received galantamine continuously for 36 months gained a mean of 10.2 points on the Alzheimer's Disease Assessment Scale. Almost 80% of the patients taking galantamine showed continuous cognitive benefits. On average, patients taking galantamine 24 mg/day maintained cognitive function at pretreatment baseline levels for the first 12 months of therapy. At the endpoint, cognitive decline was delayed by approximately 18 months; as predicted, the untreated patients experienced decline. Almost 20% of the galantamine patients had cognitive function at or above prerandomization levels by the end of the 36 months of treatment, and more than 50% demonstrated improved cognition, compared with that predicted for the untreated patients.

Most adverse drug events (ADEs) were transient and mild to moderate. The most commonly observed ADEs were psychiatric disorders, such as agitation, insomnia, and depression, all of which were characteristic of an elderly AD population followed for three years.

(Source: *Arch Neurol* 2004;61:252–256.)

. . . But Researchers Question Benefits of Drugs for AD

According to some experts who attended a meeting at Johns Hopkins University in March 2004, the drugs currently prescribed to treat the memory and thinking problems of patients with Alzheimer's disease offer such modest benefits that doctors are unsure about whether to prescribe them; they think that it might be decades before real progress is made. Some have expressed disappointment because of earlier hopes that they would stop or slow disease progression.

Patients usually take one drug at a time, which costs approximately $120 a month. The medications are meant to aid thinking and memory, but they do not change the underlying course of the illness. A million Americans take these drugs, at an overall cost of $1.2 billion a year.

Although the drugs do seem to bring about improvements on tests that measure thinking and memory, they might not be enough to help patients function in the real world.

Donepezil (Aricept®, Eisai/Pfizer), rivastigmine (Exelon®, Novartis), galantamine (Reminyl®, Janssen) and tacrine (Cognex®, Parke-Davis) are approved to treat the mild to moderate symptoms. Memantine (Namenda™, Forest) was approved in 2003 for moderate to severe cases.

Physicians said that they felt that they had to do something for their patients even if they thought that the drugs would not help. Some drugs were described as "mildly effective," but they did not restore memory to its previous state.

Despite the short-term benefits of the drugs, patients and their relatives said that they were pleased to have them.

On a more hopeful note, some researchers think that statin drugs, which can reduce high cholesterol levels, might offer a protective effect on the brain, but much more study is needed.

(Sources: *The New York Times*, April 7, 2004; *Arch Neurol* 2000;57[10]:1439–1443; *Ann Pharmacother* 2004;38[1]:91–98.)

Skin Reactions and Paclitaxel

Although generalized dermatological reactions to the antineoplastic agent paclitaxel (Taxol® Injection, Bristol-Myers Squibb) are rare, they might become more common as the drug is more widely used. Researchers at the University of Illinois in Chicago suggest that physicians watch for skin reactions even weeks after the first infusion. They reported on the development of erythematous patches that became necrotic.

Paclitaxel is classified as an irritant, not a vesicant, the authors say. It is debatable whether the classification is appropriate, given reports of severe edema, cellulitis, blister formation, and necrosis following extravasation of paclitaxel. They also note that some patients have had reactions such as "paclitaxel recall," or recurrent cutaneous injury at the site of previous extravasation after receiving subsequent doses, even at different injection sites.

(Source: *Ann Pharmacother* 2004;38:238–241.)

Antibiotic Use Decreasing

Doctors and patients seem to be curbing their use of antibiotics as a result of educational programs, say federal health officials. The inappropriate use of antibiotics has led to drug-resistant microbes. Antibiotic resistance is a major health problem throughout the world and is common among the bacteria that cause ear and respiratory infections. Antibiotics are often prescribed for otitis media, an inner ear infection in children.

At the Fourth International Conference on Emerging Infections in Atlanta

this past winter, it was anticipated that antibiotic usage might become even less widespread after pediatric and family practice organizations issue new guidelines that will encourage physicians to avoid prescribing antibiotics for ear infections in children.

The proposed guidelines emphasize the need for stricter criteria when doctors diagnose infections and also advise doctors that observing children without prescribing antibiotics is acceptable therapy. In Europe, 80% of children get better without the drugs.

(Sources: *The New York Times*, March 4, 2004; www.cdc.gov.)

New Options to Prevent Breast Cancer Recurrence

For more than 25 years, the standard treatment used to avert breast cancer recurrences after a lumpectomy or a mastectomy was tamoxifen (Nolvadex®, AstraZeneca), a powerful medication but one that sometimes loses effectiveness with long-term use. Now a new class of drugs, the aromatase inhibitors, is expanding the options. One such next-generation drug, called exemestane (Aromasin®, Pfizer), appears to keep breast cancer at bay more effectively than tamoxifen does.

The new hormonal therapies, as well as tamoxifen, can be used to treat about two-thirds of breast cancers.

In a study of 4,700 postmenopausal women, switching to Aromasin® after two or three years of tamoxifen therapy reduced the risk of recurring cancer in either breast, or death from any cause, by 32%, compared with the rate for women who took tamoxifen for five years.

Aromatase inhibitors (e.g., Femara®, Novartis; Arimidex®, AstraZeneca) inhibit the conversion of naturally produced hormones (steroids) into estrogen. Estrogen is believed to stimulate the growth of breast cancer cells.

Researchers have not yet analyzed the effect of Aromasin® on bone density or the risk of uterine cancer or other gynecological problems. Approved in the U.S. in 1999, Aromasin® has been used to treat women with breast cancer that has progressed after tamoxifen treatment.

During the mid-1970s, tamoxifen was found to reduce the recurrence of cancer after surgery. Unfortunately, tamoxifen therapy is generally limited to five years because it tends to increase the risk of endometrial cancer, blood clots, and stroke.

Arimidex® is approved to treat early-stage breast cancer but carries a higher risk of joint pain and bone fractures.

Femara® is an excellent alternative for bridging the gap after five years of tamoxifen. In one trial, it lowered the risk of cancer recurrence by 43%, compared with placebo. In this study, the patients who took tamoxifen had a higher rate of new non-breast cancers than women switching to Aromasin®, but the reasons are not yet understood.

(Sources: *N Engl J Med* 2004;350[11]: 1140–1142; *The Wall Street Journal*, March 11, 2004.)

Early Test for Ovarian Cancer

Two newly discovered rare substances might some day help to prevent thousand of deaths each year from ovarian cancer. A molecular biologist at the University of Washington in Seattle has found biomarkers that might be the basis of a new cancer-detection test.

Much work remains before the discovery results in a blood test to spot ovarian tumors before they turn lethal and spread, but a prototype of the test already has passed some crucial hurdles. In preliminary studies, researchers detected the proteins in blood taken from women known to have cancer but found no evidence of the proteins in the blood of women without the disease. Encouraged, Japanese scientists from Fujirebio, Inc., licensed the technology last year, hoping to develop a commercial screening test.

(Source: *The Wall Street Journal*, March 12, 2004.)

Long-Term Alendronate for Osteoporosis Found Safe

For many patients with the bone-thinning disease osteoporosis, alendronate sodium (Fosamax® Merck) can be taken safely and effectively for 10 years.

A 10-year study found that alendronate enabled women to maintain or increase their bone density, with no apparent ill effects. The improved bone density persisted even after the drug was stopped, and it diminished only gradually.

Although alendronate can be used for 10 years, it is not clear whether patients need to take it for that long or when they should start. Earlier studies proved that the drug could halve the risk of breaking a bone, but the study relied on bone density measurements, not fractures, as a measure of success.

High bone density usually protects against fractures, but not always. The study was not large enough to compare the effects of different doses and treatment schedules on fracture risk or to prove that the full protection against fracture lasted. The optimal duration of treatment had not been established.

Although trials in people showed no adverse effects from bisphosphonates, some animal studies suggested that high doses might actually weaken bone, cause brittleness, or delay the healing of fractures.

Some doctors prescribe bisphosphonates only for women with a serious risk of breaking a bone and hesitate to use them in younger women.

Many surgeons suggest stopping bisphosphonates for a year or so after five years because their long-term effects on the integrity of bone are not clear.

(Sources: *N Engl J Med* 2004;250[12]: 1189–1199; *The New York Times*, March 18, 2004.)

Test Drug May Raise "Good" Cholesterol Levels

An experimental drug seems to sharply increase levels of high-density lipoprotein-cholesterol (HDL-C, or the "good" cholesterol) and may offer a new way to help prevent heart attacks.

Researchers at the University of Pennsylvania and Tufts University found that torcetrapib (Pfizer) doubled HDL-C in people with very low levels and reduced low-density lipoprotein-cholesterol (LDL-C, or "bad" choles- terol).

Until now, doctors have concentrated largely on lowering LDL-C by prescribing statins. Many experts hope to decrease heart disease by raising HDL-C. The only available product that raises HDL-C levels is the vitamin niacin; however, its effects are modest, and itching and hot flashes bother many patients.

The new study included only 19 patients, but torcetrapib had a powerful effect. The drug is expected to be available in a few years.

(Sources: *N Engl J Med* 2004;350:1491–1494; *The New York Times,* Associated Press, April 8, 2004.)

Fentanyl Skin Patch Recalled

Janssen has expanded its U.S. recall of fentanyl transdermal system (Duragesic®) 75-mcg/hour patches to include five manufacturing lots with control numbers 0327192, 0327193, 0327294, 0327295, and 0330362. No other dosage strengths or control numbers are affected.

The company recalled one lot (number 0327192) in February 2004 after determining that some patches might leak medication along one edge. Since then, patches with the same problem have been identified in an additional lot.

The patches contain a potent opiate gel. If the gel leaks from the patch, patients can be exposed to either too much or too little medication. Exposure to too much medication can occur if the gel leaks directly onto the skin and the body absorbs a higher than intended amount or if any of the medication is swallowed accidentally. Overexposure may cause potentially life-threatening complications. If the drug leaks out, there might not be enough medicine to achieve the desired effect and the patient may experience withdrawal symptoms.

If patients or their caregivers have

unintended contact with the gel, they should immediately wash the affected area with large amounts of water only, but not soap, and seek further instructions.

"Atypical" Antipsychotic Agents May Reduce Violence

Researchers at Duke University in Durham, North Carolina, believe that the newest generation of antipsychotic medications appear to lower the risk of violent behavior in people with schizophrenia who are being treated in community-based centers.

In a two-year study, patients who consistently took one of the newer medications had less than one-third the incidence of engaging in violent actions toward others, compared with those who consistently took one of the older antipsychotic medications (neuroleptics).

Examples of drugs in this newer class include clozapine (clozaril®, Novartis), risperidone (Risperdal®, Janssen), and olanzapine (Zyprexa®, Eli Lilly).

Slightly more than half of the participants were males, from 18 to 71 years old. They were observed at six-month intervals to assess treatment, their social and demographic characteristics, recent psychiatric hospitalizations, substance abuse, and violent episodes. The reduction in violence for those taking the newer medications remained statistically significant.

The new medications are easier to tolerate because there are fewer side effects. Greater tolerability makes it easier to control symptoms more consistently and may also help patients avoid substance abuse and situations that otherwise can lead to violence. Older medications, although less expensive, produce uncomfortable side effects, making it more difficult to adhere to therapy.

(Sources: *Schizoph Bull* 2004;30[1]; Duke University Medical Center, April 12, 2004; www.dukemednews.org.)

NEW MEDICAL DEVICES

By Marvin M. Goldenberg, PhD, RPh, MS

Name: OraSure® HIV-1 Oral Fluid Specimen Collection Device

Manufacturer: OraSure Technologies, Inc., Bethlehem, PA

Approval Date: March 26, 2004

Use Classification: This is the only FDA-approved device that collects oral fluid to test for antibodies to the human immunodeficiency virus (HIV).

Description: A noninvasive HIV antibody test, this device extracts antibodies from the blood vessels in the mucous membranes in the patient's mouth but is not a saliva test. Like a blood test, it looks for antibodies to HIV, not the virus itself.

The subject takes the device, which has an exposed absorbent pad at one end; places the pad above the teeth and against the outer gum; and gently swabs completely around the outer gums, both upper and lower, one time around. The tester then takes the device and inserts it into a vial containing a solution. In as little as 20 minutes, the device indicates whether HIV-1 antibodies are present in the solution.

The FDA approved the OraSure® enzyme-linked immunosorbent assay (ELISA) in 1994 and the Western blot confirmatory test in 1996.

Purpose: The company's original version of this rapid test—the OraQuick Rapid HIV-1/2 Antibody Test—was approved November 7, 2002, to detect antibodies to HIV-1 in blood. On March 19, 2004, the FDA approved the test for the detection of HIV-2 (a variant of HIV that is prevalent in parts of Africa but rarely found in the U.S.) in blood.

Benefit: Results are available in 20 minutes. A correctly performed antibody test is an alternative to blood testing for HIV-1 infection in public health and clinical settings. The rapid oral test may result in greater numbers of high-risk people being tested because needle-free testing is safer for both subjects and health care workers. Oral conditions, disease, medications, and non–HIV-related medical conditions do not affect the accuracy of the OraSure® HIV-1 test.

Caution: Collection devices (both unused and collected samples) should never be stored at temperatures above 98° F. If temperatures higher than 98° F are anticipated, insulated coolers or cold packs should be used. If a specimen is sent by U.S. mail, it should not be left in a hot mailbox for an extended period, such as over a weekend.

Sources: www.orasure.com; www.fda.gov.

Name: Oncotype DX™

Manufacturer: Genomic Health, Redwood City, CA

Approval Date: April 8, 2004

Use Classification: This clinically validated diagnostic assay provides a quantitative evaluation of the likelihood of distant breast cancer recurrence.

Description: The device quantifies the likelihood of recurrence in women with newly diagnosed, stage 1 or 2, node-negative, or estrogen receptor—positive breast cancer that is to be treated with tamoxifen. Formalin-fixed, paraffin-embedded tissue is used to analyze the expression of a panel of 21 genes. The gene panel, containing 16 breast cancer-related genes and five reference genes, and the Recurrence Score™ algorithm were developed from extensive laboratory testing and three independent clinical trials of 447 patients.

Purpose: To measure gene expression using real-time reverse transcription–polymerase chain reaction (known as RT– PCR).

Benefit: The assay offers accurate predictions of recurrent breast cancer risk. Its performance exceeds standard measures such as tumor size, tumor grade, and patient age. If this technique

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proves useful, researchers will be able, for the first time, to correlate archived tumor tissue with known patient outcomes from studies initiated and completed years ago, thus avoiding lengthy and costly "prospective" clinical trials.

Sources: Steven Shak, MD, Genomic Health, Inc., 2004; Mayer M., Impressions from the 26th San Antonio Breast Cancer Symposium, Breast Cancer Action, Newsletter No. 80, February/March 2004.

Name: On-Board Imager™ Accessory for the Clinac® and Trilogy™ Medical Linear Accelerators

Manufacturer: Varian Medical Systems, Inc., Palo Alto, CA

Approval Date: April 4, 2004

Use Classification: The imaging accessory is designed to improve the precision and effectiveness of cancer treatments by enabling clinicians to target and track tumors accurately.

Description: The imager is mounted on the treatment machine via robotically controlled arms that operate along three axes of motion so that they can be positioned for the best possible view of the tumor. An amorphous silicon flat-panel x-ray image detector yields digital images showing internal anatomical landmarks with a high degree of precision. The image detector can track anatomical motion and thus provide doctors with a clear indication of exactly how a tumor moves during treatment as a result of respiration or other normal physiological processes.

A unique 150-kilovolt x-ray tube generates precise, high-resolution computed tomography–quality images from a moving gantry. The total system offers the automation, speed, and flexibility needed to make image-guided radiation therapy (IGRT) clinically practical for cancer patients.

Purpose: To improve the precision and effectiveness of cancer treatments.

Benefit: Until now, radiation oncologists have had to contend with variations in patient positioning and with respiratory motion by treating a margin of healthy tissue around the tumor. IGRT enables doctors to locate the tumor while the patient is in the treatment position and to minimize the volume of healthy tissue that is exposed to radiation. This automated system enables clinicians to obtain high-resolution x-ray images to pinpoint tumor sites, to adjust patient positioning when necessary, and to complete a treatment, all within the standard time slot.

Source: PharmacyOneSource.com, March 31, 2004

Name: Gemini™ Dual-Wavelength Laser System ™

Manufacturer: Laserscope Inc, San Jose, CA

Approval Date: April 6, 2004

Use Classification: The laser system is indicated for 17 clinical applications and has received clearance for the treatment of acne, wrinkle reduction, and permanent hair reduction on all skin types.

Description: The Gemini system combines both the wavelengths and pulsing characteristics of the company's two leading aesthetic products (the Aura™ and Lyra™) laser systems, into a single, higher-power product platform. It incorporates computer-controlled, continuously adjustable spot sizes, patented cooling for patient safety and comfort, a touch-screen interface, and ergonomic handpieces designed to reduce operator fatigue and improve visibility of treated areas. The system has been peer-reviewed, and clinical results validate its effectiveness.

Purpose: To provide precise treatment control of acne, skin rejuvenation, and hair removal on the face, nose, and other contoured areas.

Benefit: The system's continuously adjustable handpiece allows physicians to choose up to 42 different sizes for spot treatment and allows for fast laser coverage of large areas, making treatment less tedious and more cost-effective for physicians and patients.

Source: www.laserscope.com.

Name: The Viewpoint™ Conductive Keratoplasty® (CK®) System for NearVision℠

Manufacturer: Refractec, Inc., Irvine CA

Approval Date: March 26, 2004

Use Classification: This procedure is the only FDA-approved visual technology that improves near vision in people with presbyopia (the inability to focus on near objects), the age-related eye condition that often occurs after age 40.

Description: Radio waves are used to reshape the cornea and bring near vision back into focus.

Purpose: To treat presbyopia. Most patients with presbyopia need reading glasses to see a printed menu or to do other close work. The condition results from the hardening of the eye's lens with advancing age.

Benefit: NearVision CK is laser-free and safe; there is no cutting or removal of tissue. It is typically performed in just one eye, restoring close-up vision without compromising distance vision. CK is minimally invasive and painless and can be performed in less than three minutes in the ophthalmologist's office with only eyedrop anesthesia. The cost ranges from $1,500 to $2,000 per eye.

Caution: Not all patients are candidates for the procedure, especially those with thin corneas. Some people may still need reading glasses after surgery or additional treatments as they grow older and their vision continues to deteriorate.

Source: Refractec, Inc., March 22, 2004; www.refractec.com.