

FDA Approves Antidepressant for Diabetic Neuropathic Pain

Eli Lilly and Company (Minneapolis) announced that the FDA approved its antidepressant duloxetine (Cymbalta) for the management of diabetic peripheral neuropathic pain. Duloxetine is a balanced and potent serotonin reuptake inhibitor, and the company said it is the first and only FDA-approved treatment for this type of pain. More than 18 million Americans have diabetes

and are at risk for developing persistent pain as a result of nerve damage. Duloxetine's safety and efficacy were demonstrated in two randomized, 12-week, double-blind placebo-controlled, fixed-dose studies in nondepressed adults who had pain for at least 6 months. The drug was originally approved August 3 for treatment of major depression in adults.

Exercise Video for Patients with Type 2 Diabetes Available

The Joslin Diabetes Center in Boston has released the exercise video, "Keep Moving! Keep Healthy with Diabetes." According to the center, this is the first video designed specifically for people with diabetes or prediabetes. Created by the center's exercise physiology department, it describes low-impact exercises designed for people with physical limitations or those who are new to exercise programs.



Exercise can delay or prevent the onset of type 2 diabetes as well as to improve the health of people with diabetes. A recent study conducted by the Joslin Diabetes Center showed that obese adults who lost 7% of their body weight and did moderate-intensity physical exercise for 6 months, improved their major blood vessel function by 80%, regardless of whether or not they had type 2 diabetes.

"This is a unique resource, especially for those with type 2 diabetes," said Cathy Mullooly, clinical exercise specialist at Joslin. "It is also beneficial for those struggling with their weight and who either should not or cannot embark on a high-impact exercise routine. This video is a great resource for people who assume that fitness is unattainable." For more information, visit Joslin's online store at www.store.joslin.org.

Alternative Diabetic Foot Treatment Available

Seattle Systems Inc. has introduced a custom orthosis to treat Charcot foot and ankle deterioration. The Sure Step Neuropathic Charcot Restraint Orthotic Walker (CROW), protects the diabetic foot by offloading weight and stabilizing and protecting from trauma.

The CROW is an effective alternative to total Contact Casting, according to a company news release. The walker puts minimal pressure on the foot and evenly distributes weight to provide better mobility. The boot is custom-molded with a bivalve pretibial and posterior shell with rocker bottom sole. The CROW can reduce plantar forefoot and midfoot pressures by about 50%. For more information, visit www.seattlesystems.com.

Exenatide NDA Accepted for Review by FDA

Amylin Pharmaceuticals Inc. (San Diego), and Eli Lilly and Company announced that the NDA for exenatide has been accepted for review by the FDA. Exenatide is the first potential therapy in a new class of drugs, incretin mimetics, under investigation for treating type 2 diabetes.

"This is an important step in the regulatory process as we work to transition exenatide from an investigational agent to the marketplace, providing an additional therapy to people living with type 2 diabetes," said Ginger Graham, president and CEO of Amylin.

The NDA is made up of three components; chemistry and manufacturing, clinical and preclinical. The clinical portion of the submission is based on 30-week data from three blinded pivotal trials of exenatide involving 1,400 patients who were unable to control their blood

sugar on common oral therapies including metformin, sulfonyleurea or a combination of both. The application also includes 52-week open-label data from the extension of these studies and from an additional open-label study.

Subcutaneous Insulin Infusion Set Available

The FDA has approved Smiths Medical ASD Inc.'s (Rockland, Mass.) subcutaneous insulin infusion set product, the Cleo 90.

According to a company news release, infusion sets are a key element of an insulin pump system, delivering insulin in a flow path connection between the pump and its wearer.

The all-in-one canister design of the Cleo 90 infusion set features an automatic needle retraction system designed to reduce unwanted needlesticks, a skin-like adhesive dressing, and a hidden insertion needle aiding insertions with small children and those with needle phobia. The 360-degree site connectivity option provides total tubing direction control, allowing users to wear what they want, when they want. For more information, visit smiths-medical.com.



Ezetimibe/Simvastatin Combo for LDL Cholesterol Reduction Approved

The FDA has approved ezetimibe/simvastatin (Vytorin, Merck & Co. Inc. [Whitehouse Station, NJ]/Schering-Plough Corporation [Kenilworth, NJ]) for the treatment of high LDL cholesterol in patients with primary hypercholesterolemia or mixed hyperlipidemia. The combination treatment is to be used adjunctive to diet when diet alone is not enough. This combination product is the first approved to treat the two sources of cholesterol by inhibiting the production of cholesterol in the liver and blocking the absorption of cholesterol in the intestine, including cholesterol

from food, according to a company news release.

The recommended starting dose of the combination is 10 mg ezetimibe/20 mg simvastatin. "Many patients who continue to have high cholesterol despite diet and other lifestyle modifications may require powerful LDL cholesterol-lowering agents and to do this we frequently look to highly efficacious medicines to provide the reduction they need," said Christie Ballantyne, MD, director of the Center for Cardiovascular Disease Prevention, Methodist DeBakey Heart Center, Houston. For more information, visit www.vytorin.com/ezetimibe_simvastatin/vytorin/consumer/index.jsp.

Phase II Clinical Trial of PVD Treatment Concluded

Endovasc Inc. (Montgomery, Texas) has concluded a phase II clinical trial for Liprostin. The drug is being studied as an alternative to surgery for patients with peripheral vascular disease. According to a company news release, patients taking Liprostin showed a marked improvement in the endpoints of maximum walking distance and pain-free maximum walking distance. Liprostin is a liposome-encapsulated form of prostaglandin E-1. For more information, visit www.endovasc.com.

Analytical Tool Evaluates Accuracy of Continuous Glucose Monitoring

The continuous glucose error-grid analysis (CG-EGA) evaluates clinical accuracy of continuous glucose monitoring in people with diabetes. As reported in *Diabetes Care*, continuous monitoring can provide highly accurate test results. The CG-EGA was developed by the same group from the University of Virginia that developed the Clarke Error-Grid Analysis, the current standard for evaluating the clinical accuracy of fingerstick blood glucose monitoring, according to Abbott Laboratories (Abbott Park, Ill.).

The CG-EGA can monitor the static point accuracy of glucose levels, as well as directional accuracy, which tells patients whether their glucose levels are rising, falling or remaining steady. The *Diabetes Care* report illustrated the applicability of CG-EGA using data collected during a clinical trial of Abbott's Freestyle Navigator System, an investigational device designed to continuously monitor interstitial glucose levels that is under review by the FDA. For more information, visit www.abbott.

FDA Approves Impax's Metformin Extended-Release

The FDA has approved Impax Laboratories Inc.'s (Hayward, Calif.) abbreviated NDA for its generic version of Glucophage XR(R), (metformin HCl) extended-release 500-mg tablets. Bristol-Myers Squibb markets Glucophage for the improvement of glycemic control in patients with type 2 diabetes. According to NDCHealth, U.S. market sales of Glucophage and the other marketed generic versions were approximately \$376 million in the 12 months ended June 30, 2004. For more information, visit www.impaxlabs.com.

FDA Approves OptiClik Pen for Insulin Delivery

The FDA has approved Aventis Pharmaceuticals Inc.'s (Bridgewater, NJ) OptiClik, a new reusable pen for injecting 24-hour insulin glargine (rDNA origin) injection (Lantus) for people with type 1 and type 2 diabetes. Lantus is indicated for once-daily subcutaneous administration in the treatment of adults with type 2 diabetes who require basal insulin for the control of hyperglycemia and for adult and pediatric patients (aged 6 years and older) with type 1 diabetes, according to the company. Lantus demonstrates a consistent slow, prolonged absorption and a relatively constant concentration/time profile over 24 hours. For more information, visit www.lantus.com.

HoMedics Products Help Patients Combat Obesity

HoMedics provides consumers with accurate weight-monitoring tools. Products available to help patients meet their weight loss goals include weight scales that measure up to 400 lbs; weight management scales that feature body mass index and goal weight progress; body fat analyzer scales which measure body fat percentage and weight; and fitness scales that track body fat percentage, body water percentage, and daily calorie intake, in addition to weight.

In additional weight scales, the Salter division of the company has a line of food scales that can calculate nutritional content of food. For more information, visit www.homedics.com.

ADA Launches ClubPed Interactive Online Tool

ClubPed is an interactive online tool from the American Diabetes Association designed to encourage regular physical activity. The Diabetes Prevention Program study found that people who lost as little as 10 to 15 lbs and exercised 30 minutes a day at least 5 times a week reduced the risk of developing diabetes by close to 60%. For those who already have diabetes, exercise helps manage the disease and reduce complications.



ClubPed is one of several tools the ADA is developing to help patients set exercise goals and stay motivated. "The [ADA] is committed to enhancing our online tools and technology to help constituents prevent or delay the onset of diabetes or, for those with diabetes, to help them manage the disease," said Rick Johnston, vice president of constituent relations for the ADA. "ClubPed, which complements our recently updated and enhanced exercise content on diabetes.org, reinforces the importance of physical activity and provides a fun tool and some cool rewards to keep it going. And walking is a natural — it's free, requires no special equipment, people of all ages can enjoy it all year long, and people do it everyday anyway."

For more information visit www.diabetes.org/clubped. ■