

First Incretin Mimetic Drug Wins FDA Approval

The Food and Drug Administration (FDA) has approved Byetta (exenatide, Eli Lilly and Company, Indianapolis, and Amylin Pharmaceuticals, Inc, San Diego) as an adjunctive therapy to improve blood sugar control.

The first drug in a new medicine class called incretin mimetics, exenatide is indicated for use in type 2 diabetic patients who have not achieved adequate blood sugar control with metformin and/or sulfonylurea. Exenatide lowered postmeal and fasting glucose levels during three 30-week controlled trials. It exhibited some of the same effects as glucagons-like peptide-1 (GLP-1).

"The availability of a treatment that lowers blood sugar and has the potential to restore the response of the body's insulin-producing cells is an exciting advance for patients with type 2 diabetes," said David Kendall, MD, medical director at the International Diabetes Center, Minneapolis,

and exenatide clinical investigator, in a news release.

The intensity of any adverse events was mild to moderate, with the most frequent event being dose-dependent nausea. As therapy continued, the frequency and severity of nausea subsided. When used in combination with sulfonylurea, patients may experience an increased risk of hypoglycemia and they should consider reducing its dosing.

The FDA also stated that exenatide is approvable as a monotherapy, and additional data supporting its use in this capacity will receive a 6-month review. The injection should not be used in patients with type 1 diabetes; end stage renal disease or severe renal impairment; severe gastrointestinal disease; or for the treatment of diabetic ketoacidosis. It should not be used as a substitute for insulin.

For more information, visit www.BYETTA.com.

SYMLIN Approved for Patients Who Use Insulin

When used in conjunction with insulin, Symlin (pramlintide acetate, Amylin Pharmaceuticals, Inc, San Diego) has been approved by the FDA to control blood sugar levels for adults with type 1 and 2 diabetes.

Symlin is not intended for all diabetic patients; it should be used by patients who have failed to achieve desired glucose control despite optimal insulin therapy. Taken as a self-administered injection before mealtime, Symlin helps patients achieve lower blood glucose levels after meals. Clinical studies enrolling over 5,300 patients showed that patients who used less mealtime insulin had a reduction in body weight versus those who took insulin alone.

"Symlin provides a new option for many patients who, despite their best efforts with insulin therapy, continue to struggle to achieve their glucose control targets. These patients often experience weight gain and continued high blood sugar after meals," said Robert E. Ratner, MD, investigator for Symlin clinical studies, in a news release. "The science behind Symlin has improved our understanding of the physiology of diabetes and has provided a welcomed new tool for insulin users." Dr. Ratner is the vice president for scientific affairs at the MedStar Research Institute and professor of medicine at Georgetown University Medical School.

Amylin is offering educational programs for physicians, diabetes care teams and patients to help ensure appropriate administration and patient selection. For more information, visit www.amylin.com or www.symmlin.com.

Glucose Monitor, Temperature Probe Now FDA Approved

The Advance Micro-draw blood glucose system (Hypoguard USA, Inc, Edina, Minn) and TempTouch (Xilas Medical, Inc, San Antonio) have received FDA approval.

The newly-cleared blood glucose monitoring system may now be used on the palm of diabetic patients instead of the fingertip, which may relieve pain associated from recurrent testings.

The TempTouch, a home infrared temperature probe, tests temperatures of the skin on the surface and may now be used both at home or in the clinic. Diabetic patients regardless of age can use the product to track foot temperature changes. The unit is portable and non-invasive.

During two trials sponsored by the National Institutes of Health, the TempTouch was tested and found to reduce the presence of foot ulcers by 10 times in those diabetic patients who used it. The device works by offering patients an indication when inflammation is present.

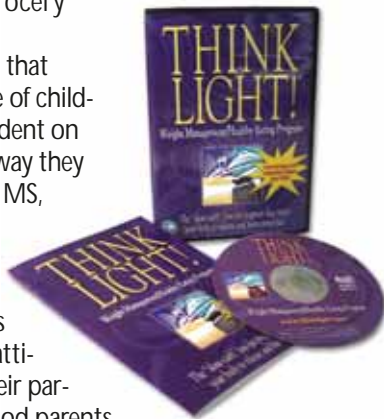
Family Friendly Program Targets Weight Management

Statistics from the American Obesity Association and the Centers for Disease Control suggest that over 15% of children and adolescents aged 6 to 19 years are obese.

The Think Light! Weight Management/Healthy Eating Program (www.thinklight.com) is based on the notion that healthy lifestyles start at home. The company has developed a family friendly approach to adopting healthy eating patterns. The 8-week eating plan includes healthy menus, recipes and weekly grocery lists.

"Most experts agree that reducing the incidence of childhood obesity is dependent on families changing the way they eat," said Greg Phillips, MS, creator of the Think Light! program, in a news release.

"Children's perceptions are influenced by the attitudes and habits of their parents and peers, and good parents lead by being good examples."



Optimizing DPN Care with Educational Program

A new educational and developmental program aimed at improving awareness and detection of diabetic peripheral neuropathy (DPN) is underway, thanks to the collaboration of NeuroMetrix, Inc (Waltham, Mass) and Eli Lilly and Company (Indianapolis).

The program will increase awareness and understanding of DPN diagnosis among endocrinologists, internal medicine physicians and other physicians who manage patients with diabetes. Through the agreement, a broad series of 84 educational and developmental programs, focusing on diabetic microvascular complications and the diagnosis of DPN, will be conducted over the next 16 months. Included in the series are nerve conduction studies, NC-stat System's application in DPN and the benefits of using the NC-stat System. The system allows physicians to diagnose neuropathies or diseases of the nerves.

For more information, call NeuroMetrix, Inc at 781-890-9989.

Management Program Beats Goals for HbA1c

WakeMed Health & Hospitals (Raleigh, NC), a 752-bed hospital system announced that its 2-year pediatric diabetes program reduced readmissions, lowered HbA1c levels and increased compliance through education and behavior modification.

- The program was successful in reducing ER visits and hospital admissions by >80% since its inception.
- An average HbA1c <8 is associated with improved long-term outcomes and fewer complications. The goal of lowering program participant's average HbA1c (3-month blood sugar average) level to <8 was achieved.
- For all children, a goal of 75% adherence to individualized blood glucose monitoring was surpassed by 20%, for a total of 95% compliance.

"The results from this program prove that with education and diligence, children can learn to play a large role in their personal disease management," said Debbe Langdon, WakeMed Pediatric Diabetes Program director, in a news release.

For more information, visit www.wakemed.org.

HHS Launches African-American Obesity Initiative

Department of Health and Human Services Secretary Mike Leavitt has awarded \$1.2 million to national African-American organizations for use in improving efforts to reduce obesity among blacks.

"The obesity epidemic is one of the major health challenges facing our nation, and African American communities are highly affected by this disease and its health consequences," Mr. Leavitt said in a news release. "The initiative we are announcing today will mobilize three of the nation's premier academic and civic organizations to join us in a new partnership."

The National Association for Equal Opportunity in Higher Education will work with the National Urban League and the National Council of Negro Women. Initiatives planned by these organizations include prevention, education, public awareness and outreach activities intended to bring about a greater understanding of the impact of obesity on other conditions.

An estimated 129.6 million Americans are overweight or obese. Between 1999 and 2002, adult black women had age-adjusted obesity rates of 48.8%, compared to 30.7% for adult white women, according to data from the Centers for Disease and Prevention (CDC). Black

children also had higher rates of overweight than white children in the same age groups.

The National Council of Negro Women will conduct a research-based public education campaign to educate young and mid-life women (aged 35 to 59 years) about healthy aging and improving their overall health. The National Urban League will pilot-test an Urban Health and Fitness Campaign focused on physical activity, nutrition and prevention of diseases such as diabetes. Working through selected local affiliates, the project aims to develop comprehensive community action plans, influence school-based curricula and health/fitness activities, and provide technical assistance to meet community needs.

Regular Testing, Healthy Lifestyle Encouraged

Staying on track with regular blood sugar testing and healthy lifestyle habits are two objectives from the Better Care Program, a free diabetes support community sponsored by AmMed Direct Diabetes Care.

The program was launched in 2003, and now it has over 150,000 members who utilize its services. Members receive a free consultation with a certified diabetes educator, a national prescription savings card (where members can save up to 30% off prescription medications), a glucose test log and a booklet called "Test and Feel Better," a guide to glucose self-testing.

"Everyone knows diabetes is reaching epidemic proportions worldwide," said Tom Milam, general manager of AmMed Direct, in a news release. "Active glucose testing is a crucial part of diabetes management to improve quality of life. Since glucose testing is our core business, we are dedicated to including as many people in the free program as possible. No other diabetes test supply company offers anything like this."

Members receive a free Better Care kit, with specialty product samples, coupons, healthy recipes and health management updates. They also receive a free 1-year subscription to "Diabetes Directions," and access to a licensed pharmacist to answer member questions.

Diabetes test supplies are generally covered by insurance, but those who are uninsured may still qualify for the Better Care Program. AmMed Direct Diabetes Care is Medicare-approved, and it accepts most Blue Cross/Blue Shield and other major insurance providers. The program is not available to those on HMOs.

For more information, visit www.ammeddirect.com or call 800-435-1458.

17-test Drum Allows for Easy, Fast Testing

Testing with the ACCU-CHEK (Roche Diagnostics, Chicago) Compact blood glucose meter provides fast results from one of six sites.

The ACCU-CHEK Compact system is less painful and patients can test on their forearm, palm, upper arm, thigh or calf instead of sensitive fingers. ACCU-CHEK products are preferred on most health care plan formularies helping to keep out-of-pocket costs to a minimum.

"Good diabetes management is within reach and may be done with less pain, which, as our research has shown, is one of the major barriers to regular testing," said Nancy Lonsinger, Vice President of Diabetes Care Marketing at Roche Diagnostics.

The system, which is known as "The one with the Drum," has a 17-test drum and displays results in 8 seconds. The memory has a 100-value, and it stores the time, date and averaging.

For more information, please visit <http://www.accu-chek.com>.

Machine Efficient for Long-Term Diabetes Care

For the 26% of nursing home residents that have diabetes, Assure 3 (Hypoguard, Edina, Minn) provides fast and accurate blood glucose monitoring with minimal pain.

The advancement in blood glucose monitoring requires a smaller blood sample (3uL) and takes 10 seconds to be read.

"At Hypoguard we strive to create products that ensure the quality of care in long-term care facilities," said David Conn, president of Hypoguard, in a news release. "When blood glucose test results are delivered in a fast and efficient manner, health care professionals can spend their time focusing on patients rather than waiting for test results."

A default energy saver automatically activates the monitor when a Guide-Me Curve test strip is inserted or removed. The test strips extend away from the meter, and there is no contamination on the meter when blood is applied to the strip. A code chip, which comes with each bottle of test strips, is inserted in to the Assure 3 to ensure lot-specific calibration.

For more information, visit www.hypoguard.com. ■

