

Ertrapenam Approved for Foot Infection

The Food and Drug Administration (FDA) has approved ertapenem (Invanz, Merck, Whitehouse Station, NJ), a once-daily injectable antibiotic, for the treatment of moderate-to-severe complicated foot infection due to indicated pathogens in diabetic patients without osteomyelitis. The approval of this additional indication was based on the results of the SIDESTEP study, the largest prospective, randomized and double-blind clinical trial ever conducted in diabetic patients

with moderate to severe complicated foot infection.

Invanz is indicated for the treatment of moderate to severe complicated skin and skin structure infections including diabetic foot infections without osteomyelitis due to *Staphylococcus aureus* (methicillin-susceptible isolates only), *Streptococcus agalactiae*, *Streptococcus pyogenes*, *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, *Bacteroides fragilis*, *Peptostreptococcus species*, *Porphyromonas asaccharolytica* or *Prevotella bivia*.

Certain Parenteral Products can Interfere With GDH-PQQ Glucose Monitoring Systems

The FDA warns that the use of parenteral products containing maltose or galactose, or oral xylose among patients who are subsequently tested using glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) based glucose monitoring system may yield falsely elevated glucose readings.

Although this is a known drug-device interaction, there have been reports of the inappropriate administration of insulin and consequent life-threatening/fatal hypoglycemia in response to erroneous test results obtained from patients receiving parenteral products containing maltose. Cases of true hypoglycemia can go untreated if the hypoglycemic state is masked by false elevation of glucose read-

ings. Since hypoglycemia may be life threatening, it is important that health care providers prescribing and/or administering products containing the sugars shown below be aware of possible interference leading to incorrect results. A preliminary listing of US products that may cause interference is presented in Table 1.

Exenatide Reduced HbA1c When Added to TZDs

Exenatide (Byetta), when used in conjunction with thiazolidinediones (TZD) in type 2 diabetes patients, helped lower HbA1c in patients not achieving acceptable control.

Amylin (San Diego) and Eli Lilly and Company (Indianapolis) announced that the positive results will form the basis of a supplemental New Drug Application submission to the FDA.

TABLE 1. PRELIMINARY LIST OF US PRODUCTS THAT MAY INTERFERE WITH GDH-PQQ BASED GLUCOSE MONITORING SYSTEMS

Manufacturer	Trade Name	Proper Name	Sugar	Sugar Concentration
Octapharma	Octagam 5%	Immune Globulin IV (Human)	Maltose	10%
Talecris	Gamimune N 5%	Immune Globulin IV (Human) 5% Solvent/Detergent Treated	Maltose	9-11%
Cangene	WinRho SDF Liquid	Rho(D) Immune Globulin IV (Human)	Maltose	10%
Cangene	Vaccinia Immune Globulin (Human)	Vaccinia Immune Globulin (Human)	Maltose	10%
NERL Diagnostics, others	D-Xylose USP	d-Xylose	d-Xylose	Usual dose 25g
Baxter	Extraneal	(icodextrin) Peritoneal Dialysis Solution	icodextrin	7.5 gm/100 mL

Accessed at www.fda.gov/cber/safety/maltose110405.htm.

HbA1c improved by about 0.9% at the end of the 16-week study for patients receiving twice-daily 10- μ m subcutaneous injections of exenatide in addition to their usual regimen of TZD or TZD plus metformin.

Type 1 Diabetes Trials

The National Institutes of Health (NIH) is encouraging patient participation in two clinical research trials for type 1 diabetes.

The Type 1 Diabetes TrialNet and the Type 1 Diabetes Genetic Consortium are both multicenter, international clinical studies that are supported by the NIH, American Diabetes Association (ADA), the Centers for Disease Control and the Juvenile Diabetes Research Foundation International.

For more information on these trials visit www.diabetes-trialnet.com or www.t1dgc.org. E-mail TrialNet at trialnet@biostat.bsc.gwu.edu or call 800-HALT-DM1. E-mail diabetes@benaroyaresearch.org or call 800-888-4187 for for genetics consortium inquiries.

Choose to Live Challenge

A new Web-based resource has been unveiled by the ADA and will be featured at www.diabetes.org/challenge.

The resource is part of the Choose to Live Challenge, a health challenge focusing on diabetes care. Topics include managing blood glucose, blood pressure and cholesterol, and learning about food portions and ways to increase physical activity. The challenge:

- addresses essential components of diabetes care (practicing healthy eating habits, engaging in physical activity and managing medicines);
- provides tips, suggestions and resources for improving overall health; and
- presents viewpoints and information from experts through monthly interactive Web chats.

Web site visitors may also order a free copy of "Choose to Live: Your Diabetes Survival Guide." This comprehensive resource provides patients with information on managing diabetes.

ASCRS Forms Retina Clinical Committee

The American Society of Cataract and Refractive Surgery (ASCRS) announced the formation of the ASCRS Retina Clinical Committee (CC).

"The purpose of our Retina CC is to provide the

members of ASCRS, who are predominantly anterior segment surgeons, with a resource to stay abreast of the latest advances in retinal treatment modalities as they relate to the anterior segment surgery," said ASCRS President Roger Steinert, MD, in a news release.

"Recognizing that cataract/anterior segment surgeons are occasionally faced with retinal disease ... ASCRS hopes to provide education and heighten awareness of the issues for its members as well as update them on advances in posterior segment surgery and treatment options surrounding macular degeneration and various forms of retinopathy. This is an exciting development that will enhance patient care."

Lee M. Jampol, MD, professor and chair, Northwestern University Feinberg School of Medicine and chief of ophthalmology, Northwestern Memorial Hospital will chair the new group. Other committee members include Neil M. Bressler, MD, department of ophthalmology, The Wilmer Eye Institute, Johns Hopkins University School of Medicine; James P. Gills, MD, professor of ophthalmology, The Wilmer Eye Institute, Johns Hopkins University School of Medicine; Julia A. Haller, MD, Katharine Graham professor of ophthalmology, The Wilmer Eye Institute, The Johns Hopkins University School of Medicine and director of Wilmer's Vitreoretinal Surgical Fellowship Training Program; Harry W. Flynn Jr, MD, professor, The J. Donald M. Gass Distinguished chair of ophthalmology, Bascom Palmer Eye Institute, University of Miami Miller School of Medicine; and H. Richard McDonald, MD, associate clinical professor of ophthalmology, University of California, San Francisco.

Johnson & Johnson to Acquire Animas Corporation

Johnson & Johnson (New Brunswick, NJ) and Animas Corporation (West Chester, Pa), an insulin delivery company, announced a definitive agreement whereby Animas will be acquired in a cash-for-stock merger transaction. Animas is expected to operate as a stand-alone entity reporting through LifeScan Inc, a Johnson & Johnson company offering blood glucose monitoring systems. The acquisition affords LifeScan immediate entry into the fast-growing insulin delivery pump market.

Under the terms of the agreement, Animas stockholders will receive \$24.50 for each outstanding Animas share. The net value of the transaction as of the anticipated closing date is estimated to be approximately \$518 million based upon Animas' 22 million fully diluted shares outstanding, net of estimated cash on hand at time of closing. ■