

# Education About Safely Losing Weight

At a time when an estimated 65% of US adults are overweight or obese, a coalition of consumer, nutrition and public health groups has joined forces with the US Surgeon General to disseminate how to safely lose weight.

Many overweight Americans may use diet books and infomercials as sources for correct diet habits. To diffuse this, the Partnership for Essential Nutrition has joined forces with Surgeon General Richard H. Carmona in a campaign that focuses on those principles associated with healthy and lasting weight loss.

They include making food choices that restrict calories and meet current guidelines for nutritional completeness; engaging in regular physical activity; and adopting a comprehensive weight-loss program that avoids extreme lifestyle changes.

The Partnership for Essential Nutrition comprises 12 organizations, including the Alliance for Aging Research, American Association of Diabetes Educators, American Institute for Cancer Research, National Consumers League, Shape Up America! and the Society for Women's Health Research.

## New Indication Sought for Ramipril

King Pharmaceuticals (Bristol, Tenn) has filed a supplemental new drug application seeking a new indication for ramipril (Altace). The company is seeking approval of an additional indication for the drug as initial therapy in a multidrug regimen to delay the progression of chronic kidney disease in hypertensive patients with nondiabetic kidney disease. According to a company news release, Charles L. Pamplin III, MD, vice president, medical affairs said: "Reducing the progression of chronic kidney disease will not only improve the quality of life for many patients suffering from chronic kidney disease and end-stage renal disease [ESRD], but will also reduce the significant healthcare burden associated with these ailments."

The expansion of the label indication is based on data from two, randomized clinical trials: the AASK (African American Study of Kidney Disease and Hypertension) trial and the REIN (Ramipril Efficacy In Nephropathy) trial. AASK evaluated the efficacy of ramipril and two other treatment regimens in 1,094 black patients with hypertension using clinical outcomes of changes in glomerular filtration rate (GFR), slowing the progression of ESRD and mortality.

## New Technology May Improve Vision for DME Patients

Alimera Sciences Inc (Atlanta), in collaboration with Control Delivery Systems Inc (Watertown, Mass) recently initiated a phase 3 clinical trial to study diabetic macular edema patients treated using Medidur (Control

Delivery Systems Inc) with fluocinolone acetonide.

The masked, randomized, multicenter study will follow 900 patients in the United States and Europe for 36 months. Patients will receive the Medidur implant, which is small enough to be injected through a needle during an in-office procedure and is expected to provide sustained delivery of fluocinolone acetonide to the back of the eye for up to 3 years.

## Potential New Treatment for Diabetic Neuropathy

Dainippon Pharmaceutical Co, Ltd (Osaka, Japan) and Eisai Co, Ltd (Tokyo) signed an exclusive licensing agreement for AS-3201 (ranirestat), an investigational drug for the treatment of diabetic neuropathy that was discovered and is being developed by Dainippon Pharmaceutical.

Under the agreement, Eisai will assume the exclusive rights to further develop, manufacture and market this compound worldwide (outside of Japan), while Dainippon Pharmaceutical will retain the rights to Japan and to co-promote the compound with Eisai in major countries.

AS-3201 is designed to improve the symptoms of diabetic neuropathy by suppressing the accumulation of sorbitol within cells through strongly inhibiting aldose reductase. It is estimated that 3.6 million in the United States, 2.6 million in the five major European countries and 1.7 million in Japan have diabetic neuropathy.

Dainippon Pharmaceutical has been developing AS-3201 on its own as a global strategic product, aiming at an early application for approval. The company is currently conducting phase 3 clinical trials in the United States and Canada. ■