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Cardiometabolic Health Congress Expert Faculty Examine Clinical Implications of a New Treatment Option for Patients with Severe Hypertriglyceridemia

Boston, August 1, 2012 – The Food and Drug Administration (FDA) approved on July 22, 2012, a new treatment option for clinical management of patients with severe hypertriglyceridemia. This FDA decision prompted the Cardiometabolic Health Congress (CMHC) expert faculty to examine the potential implications this newly approved treatment option may have on physician practice and patient care.

Christie Ballantyne, M.D., chief, Section of Cardiovascular Research and Cardiology at Baylor College of Medicine; and director of the Center for Cardiovascular Disease Prevention at Methodist DeBakey Heart and Vascular Center, commented that, "The approval of Vascepa[™] (icosapent ethyl) gives health care providers another option for treatment of the patient with very high triglycerides. These patients are often challenging to treat as they frequently have multiple comorbidities such as obesity and diabetes, so it is helpful to have a new option."

Harold Bays, M.D., medical director and president of Louisville Metabolic and Atherosclerosis Research Center, explained in more detail, "Vascepa is a triglyceride-lowering agent indicated for treatment of very high triglyceride levels; it does not significantly raise low-density lipoprotein cholesterol levels. In addition to triglyceride lowering, Vascepa also significantly lowers apo B, both of which may be clinically meaningful to lipidologists and their patients."

William Cromwell, M.D., adjunct associate professor, Hypertension and Vascular Disease Center at Wake Forest University School of Medicine, and chief of the Lipoprotein and Metabolic Disorders Institute, echoed similar feedback in his statement: "The FDA approval of Vascepa, a highly purified omega-3 fatty acid containing 96% EPA, extends the medication options available to clinicians treating patients with significant triglyceride elevations. Beyond significant triglyceride reduction, I am encouraged by recent data from the MARINE and ANCHOR trials showing that Vascepa may significantly lower apo B, a measure of total atherogenic lipoprotein particle number. Long-term outcome trials will be needed to assess the impact of Vascepa-induced changes in lipid and lipoprotein biomarkers on cardiovascular events." Hypertriglyceridemia affects one-third of U.S. adults, or approximately 74 million individuals.^{1,2} Causes of elevated levels of triglycerides include obesity, physical inactivity, cigarette smoking, excessive alcohol intake, and high-carbohydrate diets.³ Despite the evidence for the cardiovascular benefits of adequately managing hypertriglyceridemia, lipid-lowering therapy is considerably underused in everyday clinical practice. Only 4% of individuals with high triglycerides are receiving any form of triglyceride-lowering therapy.² And less than half of the individuals who qualify for any kind of lipid-lowering therapy are receiving it.¹

In response to the clear need to raise awareness and provide evidence-based solutions for the management of hypertriglyceridemia, as well as other forms of dyslipidemia, the CMHC is providing stateof-the-art, practical education within its program agenda to assist clinicians in optimizing care for patients with a variety of lipid disorders.

"As clinicians, we face many challenges in caring for the ever-increasing number of patients with cardiometabolic risk. The CMHC provides an invaluable opportunity to hear cutting-edge science, clinical perspectives, and the newest information on managing cardiovascular and metabolic risk," said JoAnne Foody, M.D., medical director of the Cardiovascular Wellness Program, Brigham and Women's Hospital, and associate professor at Harvard Medical School.

The 7th Annual CMHC, the premier multidisciplinary congress providing the best cardiometabolic science and clinical education, will convene October 10–13, 2012, in Boston, Massachusetts; and is co-chaired by George L. Bakris, M.D.; Christie M. Ballantyne, M.D.; Robert H. Eckel, M.D.; and Jay S. Skyler, M.D., M.A.C.P. The congress features 60 world-renowned experts in cardiovascular and metabolic health dedicated to providing the medical community with cutting-edge strategies for the prevention, diagnosis, and management of obesity; type 2 diabetes; atherosclerosis; hypertension; dyslipidemia; thrombosis; acute coronary syndrome; chronic kidney disease; and related comorbidities.

Christie Ballantyne, M.D., is a consultant to Amarin and the primary investigator of the ANCHOR study.

Harold Bays, M.D., served as an advisor, protocol consultant, and investigator for the Vascepa development program. He was the principal investigator and first author for the MARINE trial, which was the pivotal study reflective of Vascepa's approved indication.

William Cromwell, M.D., is a consultant to Amarin.

For more information, contact Dina Kouveliotes at <u>info@cardiometabolichealth.org</u> or 877.571.4700, or visit <u>www.cardiometabolichealth.org</u>.

- 1. American Heart Association. *Heart disease and stroke statistics 2012 update.* Available at http://www.americanheart.org. Accessed January 31, 2012.
- 2. Ford ES et al. Hypertriglyceridemia and its pharmacologic treatment among US adults. *Arch Intern Med.* 2009;169:572–578.
- 3. Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. Executive summary of the third report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). *JAMA*. 2001;285:2486–2497.

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