



# American Association of Clinical Endocrinologists

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## **For Immediate Release**

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## **Leading U.S. Medical Association's Assembly of Domestic and International Diabetes Experts Concludes Use of SGLT2 Inhibitors for Treatment of Diabetes Should Continue With No Changes in Current Recommendations**

**Jacksonville, FL – (October 27, 2015)** – The American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE) organized a gathering of U.S. and international diabetes physicians, scientists, and other experts to conduct a rigorous examination of potential issues surrounding SGLT2i (sodium-glucose cotransporter-2 inhibitors), a class of prescription medicines used to lower blood sugar in adults with diabetes, and its possible relationship to diabetic ketoacidosis (DKA).

The distinguished group of experts met in Dallas, Texas October 24 - 25, to conduct an intensive review of the available scientific and clinical data during the **“AACE/ACE Scientific and Clinical Review: Association of SGLT2 Inhibitors and DKA.”**

Upon review of the available material, together with a thorough discussion of the impact of SGLT2i on human metabolism, the experts concluded that the prevalence of DKA is infrequent and the risk-benefit ratio overwhelmingly favors continued use of SGLT2i with no changes in current recommendations.

The conference was convened in response to published reports of DKA occurring in type 1 and type 2 diabetes patients being treated with SGLT2i, prompting the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) to issue a warning advising caution when prescribing this agent until evidence is gathered and examined. DKA is an acute, potentially life-threatening complication of diabetes. A full media toolkit is available [here](#).

The prominent U.S. and international medical dignitaries included: Henning Beck-Nielsen, MD, DMSc, head of the Danish Diabetes Academy and chairman of the Board of the Danish Centre for Strategic Research in Type 2 Diabetes – DD2; Ele Ferrannini, MD, Associate of the Metabolism Unit at Italy's National Research Council Institute of Clinical Physiology; John Nolan, FRCPI, FRCP (ED), CEO, Director of the Steno Diabetes Center in Denmark; Ralph DeFronzo, MD, BMS, MS, BS, Deputy Director, Texas Diabetes Institute; Sam Dagogo-Jack, MD, MBBS, FRCP, FACE, President, Medicine and Science, American Diabetes Association; and Arthur Vinik, MD, PhD, Professor of Medicine, Pathology and Anatomy, Eastern Virginia Medical School.

AACE and ACE call upon pharmaceutical companies to continue to investigate the mechanisms behind the metabolic effect of SGLT2i, and make note that the diagnosis of DKA is often missed or delayed due to atypical presentation involving lower-than-anticipated glucose levels or other misleading laboratory values. In addition, AACE and ACE encourages all associated stakeholders including medical societies, insurance companies, the pharmaceutical industry, hospitals, patient associations, and other interested parties to initiate educational activities to teach physicians and other related healthcare professionals who manage diabetes, on the proper ways to identify and treat DKA.

“With the input of the noteworthy expertise assembled during the conference, we achieved our objective of performing a thorough, objective and balanced evaluation of the data in order to issue recommendations for this important issue,” said Yehuda Handelsman, MD, FACP, FACE, FNLA, Committee Program Chair and Medical Director of the Metabolic Institute of America in California.

“The wealth of scientific and clinical data presented at this symposium has been ideal to enhance our understanding of the relationship between SGLT2 inhibitors and DKA,” said Robert Henry, MD, FACE, Program Chair and Chief, Section of Diabetes, Endocrinology & Metabolism and the Center for Metabolic Research at the San Diego VA Medical Center. “I am confident this data will enable AACE to provide recommendations to minimize the occurrence of this complication in patients with diabetes.”

“This successful conference was yet another example of what AACE does best to enhance the ability of its members to deliver optimal care to their patients,” said AACE President George Grunberger, MD, FACP, FACE. “When important clinical issues arise to which we do not have definite answers, we assemble the best minds nationally and globally to examine the available evidence and provide practical guidance to health care professionals and patients as well as to the scientific community to guide future research. We have done this recently for prediabetes, diabetes and cancer, obesity, glucose monitoring and now for the question of the relationship of use of SGLT2 inhibitors and DKA.”

A summary of the conference conclusions can be found [here](#). A complete white paper with clinical recommendations will be published in a future issue of the AACE scientific journal, *Endocrine Practice*.

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#### **About the American Association of Clinical Endocrinologists (AACE)**

*The American Association of Clinical Endocrinologists (AACE) represents more than 6,000 endocrinologists in the United States and abroad. AACE is the largest association of clinical endocrinologists in the world. The majority of AACE members are certified in Diabetes, Endocrinology and Metabolism and concentrate on the treatment of patients with endocrine and metabolic disorders including diabetes, thyroid disorders, osteoporosis, growth hormone deficiency, cholesterol disorders, hypertension and obesity. Visit our website at [www.aace.com](http://www.aace.com).*

#### **About the American College of Endocrinology (ACE)**

*The American College of Endocrinology (ACE) is the charitable, educational and scientific arm of the American Association of Clinical Endocrinologists (AACE). ACE is the leader in advancing the care and prevention of endocrine and metabolic disorders by: providing professional education and reliable public health information; recognizing excellence in education, research and service; promoting clinical research and defining the future of Clinical Endocrinology. For more information, please visit <http://www.aace.com/college/>.*