American Diabetes Association.

83RD SCIENTIFIC SESSIONS
SAN DIEGO, CA / HYBRID | JUNE 23–26, 2023

News Release

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Cholesterol Lowering Drug Shown to Cut Major Heart-Related Events and Risk of Death from Heart Disease by One-Third for Statin-Intolerant Patients

First-of-its-Kind Data Underscore Importance of Early Use of Drug Therapy as a Primary Prevention, Especially for Those Living with Diabetes

SAN DIEGO, Ca. (June 24, 2023) – Today, a new trial revealed data on the effects of bempedoic acid – a non-statin cholesterol-lowering drug – on cardiovascular outcomes, demonstrating that patients with risk factors for coronary artery disease (CAD) and high cholesterol, particularly those with diabetes, should be treated with a cholesterol-lowering drug. The results were presented as a late-breaking poster at the 83rd Scientific Sessions of the American Diabetes Association® (ADA) in San Diego, CA and simultaneously published in *The Journal of the American Medical Association*.

Statins are a common type of cholesterol-lowering medicine that can help reduce the amount of low-density lipoprotein, otherwise known as LDL-C or "bad cholesterol" in the blood. However, about 1 in every 10-12 patients have statin-intolerance (SI), and there is also a 30% increase in SI associated with diabetics, females, obesity, and other health and ethnicity-related factors. Some studies have found that the use of statins increases blood sugar due to the medicine stopping insulin from processing blood sugar properly. As a result, this can put people at higher risk of developing type 2 diabetes. The study aimed to determine the effects of bempedoic acid on cardiovascular outcomes in statin-intolerant patients.

The CLEAR Outcomes trial was a masked, randomized, trial that enrolled 13,970 statin-intolerant patients. This study included 4,206 patients with risk factors for heart disease but without a prior heart-related event (primary prevention). The mean age for these participants was 68 years, 67% had diabetes and 59% were female. The primary efficacy endpoint was a composite of cardiovascular death, nonfatal myocardial infarction (MI), nonfatal stroke, or coronary revascularization.
The study showed a 22% reduction in LDL-C with the drug bempedoic acid. Treatment for 40 months was associated with a significant risk reduction for the primary endpoint, 111 (5.3%) versus 161 events (7.6%), adjusted hazard ratio (HR) 0.70, 95% CI 0.55-0.89, P=0.002. This represents a 30% reduction in major heart-related events. A 39% reduction in the risk of death from heart disease was also observed.
“We know early prevention measures are critical to slowing the progression of heart disease, especially for people with comorbidities like diabetes,” said the study’s lead author Steven E. Nissen MD, Chief Academic Officer, Heart Vascular & Thoracic Institute at Cleveland Clinic. “Unfortunately, less than half of patients in the US similar to the study patient population are being treated with cholesterol-lowering drugs – leaving them at risk. The results presented today are a wake-up call for

the clinical community that patients with risk factors for coronary disease and high cholesterol, particularly those with diabetes, should be treated with a cholesterol-lowering drug."

Bempedoic acid is a novel, nonstatin drug currently approved for 2 groups of patients by the FDA, including those with heterozygous familial hypercholesterolemia and those with atherosclerotic cardiovascular disease. The drug is also the first adenosine triphosphate-citrate lyase (ACL) inhibitor for use as an LDL-C lowering therapy and works by inhibiting cholesterol biosynthesis in the same pathway as statins.

The authors of this study note that further analysis is needed on the role bempedoic acid has on cholesterol-lowering versus anti-inflammatory effects.

Research presentation details:

Dr. Nissen will present the findings at the following sessions:

- Late Breaking Poster:
  LDL Cholesterol Reduction and Cardiovascular Outcomes in High-Risk Primary Prevention Patients
- Presented on Saturday, June 24, 2023 at 11:30 AM –12:30 PM PST (General Poster Session) and 5:40 – 5:50 PM PST (ePoster Theater)

About the ADA's Scientific Sessions

The ADA's 83rd Scientific Sessions, the world's largest scientific meeting focused on diabetes research, prevention, and care, will be held in San Diego, CA on June 23–26. More than 12,000 leading physicians, scientists, and health care professionals from around the world are expected to convene both in person and virtually to unveil cutting-edge research, treatment recommendations, and advances toward a cure for diabetes. Attendees will receive exclusive access to thousands of original research presentations and take part in provocative and engaging exchanges with leading diabetes experts. Join the Scientific Sessions conversation on social media using #ADA2023.

About the American Diabetes Association

The American Diabetes Association (ADA) is the nation's leading voluntary health organization fighting to bend the curve on the diabetes epidemic and help people living with diabetes thrive. For 82 years, the ADA has driven discovery and research to treat, manage, and prevent diabetes while working relentlessly for a cure. Through advocacy, program development, and education we aim to improve the quality of life for the over 133 million Americans living with diabetes or prediabetes. Diabetes has brought us together. What we do next will make us Connected for Life. To learn more or to get involved, visit us at diabetes.org or call 1-800-DIABETES (1-800-342-2383). Join the fight with us on Facebook (American Diabetes Association), Spanish Facebook (Asociación Americana de la Diabetes), LinkedIn (American Diabetes Association), Twitter (@AmDiabetesAssn), and Instagram (@AmDiabetesAssn).

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