

EMBARGOED UNTIL JUNE 28, 2021 at 4:15 p.m. ET

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WEEKLY INJECTION OF GLUCOSE-REDUCING DRUG OFFERS SAFE AND EFFECTIVE WAY TO SIGNIFICANTLY REDUCE CARDIORENAL EVENTS FOR PEOPLE WITH TYPE 2 DIABETES

The New England Journal of Medicine: AMPLITUDE O trial reveals regular use of efpeglenatide has potential to improve outcomes for high-risk diabetes patients with heart or kidney disease

WASHINGTON, DC (June 28, 2021) – Data released today from a large-scale, international clinical trial show significant reduction in the first occurrence of a heart attack, stroke, or death, and a reduction in progression of kidney disease in patients with type 2 diabetes with weekly use of efpeglenatide, an injectable drug with glucose- and weight-lowering effects. The findings were presented at the virtual 81st Scientific Sessions of the American Diabetes Association® (ADA) and simultaneously published in *The New England Journal of Medicine*.

The majority (98%) of adults with type 2 diabetes have at least one comorbid chronic condition, including cardiorenal conditions impacting the heart and kidney. In fact, 24% of people living with diabetes have kidney disease, 22% have cardiovascular disease, and 82% of people with diabetes have hypertension—a leading cause of heart disease.¹

Efpeglenatide is a glucagon-like peptide-1 receptor agonist drug (GLP-1 RA), a class of drug used to treat diabetes that reduces glucose levels, weight, and blood pressure. Earlier trials have shown that GLP-1 RA drugs based on human GLP-1 reduce cardiovascular and kidney outcomes. This study assessed the effects of a GLP-1 RA based on exendin-4 (animal GLP-1) either with or without an SGLT2 inhibitor drug in patients with cardiovascular and/or kidney disease.

The AMPLITUDE O trial was conducted in 28 countries and included more than 4,000 participants with type 2 diabetes. Over two years, patients assigned to weekly injections of efpeglenatide versus placebo had a 27% lower risk of a heart attack, stroke, or cardiovascular death; a 32% lower risk of kidney disease progression; and a 27% lower

¹ Kristy Iglay, Hakima Hannachi, Patrick Joseph Howie, Jinfei Xu, Xueying Li, Samuel S. Engel, Lori M. Moore & Swapnil Rajpathak (2016) Prevalence and co-prevalence of comorbidities among patients with type 2 diabetes mellitus, *Current Medical Research and Opinion*, 32:7, 1243-1252, DOI: 10.1185/03007995.2016.1168291

risk of a heart attack, stroke, or death from any cause. Similar effects were observed in the presence and absence of an SGLT2 inhibitor drug. There were no serious side effects.

“The AMPLITUDE O trial establishes efpeglenatide, an exendin-4 based GLP-1 RA, as an effective cardioprotective drug for type 2 diabetes patients with cardiovascular and/or kidney disease,” said **Hertzel C. Gerstein, MD, MSc, Professor, McMaster University and Hamilton Health Sciences, and Deputy Director Population Health Research Institute in Ontario, Canada.** “We are encouraged that this once-a-week injection, safely and effectively reduced cardiovascular and progression of kidney disease in patients with long-standing diabetes who had a high prevalence of cardiovascular and kidney disease.”

Research presentation details:

- Dr. Gerstein and other study investigators will present the findings of the AMPLITUDE O trial during a symposium listed below (Dr. Gerstein will speak at 3:00 p.m. ET)
 - [Symposium - First Results of the Effect of Efpeglenatide on Cardiovascular Outcomes \(AMPLITUDE-O\) Trial](#)
 - **Date:** Monday, June 28, 2:15–4:15 p.m. ET (all sessions will be recorded and accessible for 90 days)
- Dr. Gerstein will be providing an overview of the study findings and will be available for virtual media interviews on Tuesday, June 29 from 9:00–10:00 a.m. ET
 - If interested in speaking with Dr. Gerstein [register here](#).

For more information or to request an interview with Dr. Gerstein, please contact the ADA Scientific Sessions media team at SciSessionsPress@diabetes.org.

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About the ADA’s Scientific Sessions

The ADA’s 81st Scientific Sessions, the world’s largest scientific meeting focused on diabetes research, prevention, and care, will be held virtually June 25–29. Leading physicians, scientists, and health care professionals from around the world will unveil cutting-edge research, treatment recommendations, and advances toward a cure for diabetes. Though the conference will be remote this year, attendees will receive exclusive access to nearly 2,000 original research presentations and take part in provocative and engaging exchanges with leading diabetes experts. Learn more and register at scientificsessions.diabetes.org and join the Scientific Sessions conversation on social media using #ADA2021.



**81ST SCIENTIFIC
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About the American Diabetes Association

Every day, more than 4,000 people are newly diagnosed with diabetes in America. More than 122 million Americans have diabetes or prediabetes and are striving to manage their lives while living with the condition. The 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 80 years, the ADA has been driving discovery and research to treat, manage, and prevent diabetes while working relentlessly for a cure. We help people with diabetes thrive by fighting for their rights and developing programs, advocacy, and education designed to improve their quality of life. 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](https://www.facebook.com/AmericanDiabetesAssociation)), Twitter ([@AmDiabetesAssn](https://twitter.com/AmDiabetesAssn)), and Instagram ([@AmDiabetesAssn](https://www.instagram.com/AmDiabetesAssn)).