



Boehringer Ingelheim and Lilly Partner with Duke Clinical Research Institute to Advance Multidisciplinary Care for People with Type 2 Diabetes and Cardiovascular Disease

December 13, 2018

RIDGEFIELD, Conn. and INDIANAPOLIS, Dec. 13, 2018 /PRNewswire/ -- The Duke Clinical Research Institute (DCRI) is leading a new clinical study to optimize care for people with type 2 diabetes and cardiovascular disease through evaluation of a multidisciplinary approach at cardiology clinics across the U.S. The research program, COORDINATE-Diabetes (COOrdinating CaRDiology CliNics RANdomized Trial of Interventions to Improve OutcomEs), will be funded by Boehringer Ingelheim and Eli Lilly and Company (NYSE: LLY).

"The public health impact of type 2 diabetes and cardiovascular disease in the U.S. is immense," said Christopher Granger, M.D., professor of medicine in the Division of Cardiology at Duke University and lead researcher for COORDINATE-Diabetes. "While highly effective evidence-based treatments have been developed, these treatments are not consistently used, and thus preventable death and disability are occurring. Our goal with COORDINATE-Diabetes is to better understand the effectiveness of specific interventions at cardiology clinics to achieve best practices for improving patient health."

People with diabetes are up to four times more likely to develop cardiovascular disease than those without diabetes, and cardiovascular disease ranks as their leading cause of death and disability despite available treatments. To help improve these striking statistics, COORDINATE-Diabetes will examine the impact of multifaceted interventions involving guideline-based therapies among cardiologists, endocrinologists, primary care providers and patients, including the recommendations outlined in the American Diabetes Association (ADA) 2018 Standards of Medical Care in Diabetes and the American College of Cardiology (ACC) Expert Consensus Decision Pathway on novel therapies for cardiovascular risk reduction in adults with type 2 diabetes and atherosclerotic cardiovascular disease.

The trial will include 46 cardiology clinics in the U.S. and aims to enroll 30 patients at each site. The clinics will be randomized to a basic education arm (in which patients will be treated by clinicians who receive only basic information about guideline-based therapy) or an intensive intervention arm (that focuses on coordinating care between cardiologists and endocrinologists to develop and implement an integrated, multidisciplinary care pathway). The care teams at the intervention sites will be encouraged to communicate with patients' primary care physicians to facilitate a well-rounded, multidisciplinary approach to patient care. The trial will measure the impact of the intervention on the sites' use of guideline-recommended therapies after 12 months.

"We are pleased to support evidence-based research to understand how to best manage risks and optimize care for patients with type 2 diabetes and cardiovascular disease in a real-world, clinical setting," said Thomas Seck, M.D., senior vice president, Medicine and Regulatory Affairs, Boehringer Ingelheim Pharmaceuticals, Inc. "Although there are treatments with proven cardiovascular benefits recommended by the ADA and other organizations, many healthcare providers are not prescribing them to all their patients who may benefit. We look forward to learning more about how healthcare providers can work together to improve adherence to these treatment guidelines in the quest to reduce patients' cardiovascular risk."

The trial will also leverage the power of electronic health record data from a consortium of health systems across the U.S. that have curated their data to support research and improve outcomes. Researchers will begin enrolling clinics and patients for the study in 2019 with the goal of sharing the main results by 2021.

"Few rigorous studies have tested the effectiveness of a multidisciplinary approach to improving care among this vulnerable patient population," noted Sherry Martin, M.D., vice president, Medical Affairs, Lilly. "Given the serious cardiovascular complications associated with type 2 diabetes, it is important for cardiologists and endocrinologists to work collaboratively to help improve care for people with type 2 diabetes and cardiovascular disease."

About Diabetes and Cardiovascular Disease

Approximately 30 million Americans and an estimated 425 million people worldwide have diabetes, and nearly 24 percent of Americans with diabetes—or more than 7 million people—are undiagnosed. In the U.S., approximately 12 percent of those aged 18 and older have diabetes. Type 2 diabetes is the most common type, accounting for an estimated 90 to 95 percent of all diagnosed adult diabetes cases in the U.S. Diabetes is a chronic condition that occurs when the body does not properly produce or use the hormone insulin.

Due to the complications associated with diabetes, such as high blood sugar, high blood pressure and obesity, cardiovascular disease is a major complication and the leading cause of death associated with diabetes. People with diabetes are up to four times more likely to develop cardiovascular disease than people without diabetes. Approximately 50 percent of deaths in people with type 2 diabetes worldwide and approximately two-thirds of deaths in people with type 2 diabetes in the U.S. are caused by cardiovascular disease. In the U.S., healthcare costs for managing cardiovascular conditions in patients with diabetes totaled more than \$23 billion in 2012.

Having a history of diabetes at age 60 can shorten a person's lifespan by as much as six years compared with someone without diabetes. And having both diabetes and a history of heart attack or stroke at age 60 can shorten a person's lifespan by as much as 12 years compared with someone without these conditions.

Boehringer Ingelheim and Eli Lilly and Company

In January 2011, Boehringer Ingelheim and Eli Lilly and Company announced an alliance in diabetes that centers on compounds representing several of the largest diabetes treatment classes. This alliance leverages the strengths of two of the world's leading pharmaceutical companies. By joining forces, the companies demonstrate commitment in the care of patients with diabetes and stand together to focus on patient needs. Find out more about the alliance at www.boehringer-ingelheim.com or www.lilly.com.

About Boehringer Ingelheim

Boehringer Ingelheim Pharmaceuticals, Inc., based in Ridgefield, Conn., is the largest U.S. subsidiary of Boehringer Ingelheim Corporation.

Boehringer Ingelheim is one of the world's top 20 pharmaceutical companies. Headquartered in Ingelheim, Germany, the company operates globally with approximately 50,000 employees. Since its founding in 1885, the company has remained family-owned and today creates value through innovation for three business areas including human pharmaceuticals, animal health and biopharmaceutical contract manufacturing.

Boehringer Ingelheim is committed to improving lives and providing valuable services and support to patients and their families. Our employees create and engage in programs that strengthen our communities. Please visit www.boehringer-ingelheim.us/csr to learn more about how we make more health through our Corporate Social Responsibility initiatives.

In 2017, Boehringer Ingelheim achieved net sales of about \$20.4 billion (18.1 billion euros). R&D expenditure corresponds to approximately \$3.4 billion (three billion euros), or 17.0 percent of its net sales.

For more information please visit www.boehringer-ingelheim.us, or follow us on Twitter @BoehringerUS.

About Lilly Diabetes

Lilly has been a global leader in diabetes care since 1923, when we introduced the world's first commercial insulin. Today we are building upon this heritage by working to meet the diverse needs of people with diabetes and those who care for them. Through research and collaboration, a wide range of therapies and a continued determination to provide real solutions—from medicines to support programs and more—we strive to make life better for all those affected by diabetes around the world. For more information, visit www.lillydiabetes.com.

About Eli Lilly and Company

Lilly is a global healthcare leader that unites caring with discovery to make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at www.lilly.com and newsroom.lilly.com/social-channels.

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MPR-US-100698


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