Boehringer Ingelheim and Lilly modernise alliance to focus full expertise on Jardiance®

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- Alliance to focus combined expertise and investment to maximise Jardiance® for people with type 2 diabetes, heart failure, and chronic kidney disease

- Alliance to continue to include three product families – empagliflozin, linagliptin and insulin glargine

INGELHEIM, Germany, and INDIANAPOLIS, Nov. 4, 2019 /PRNewswire/ -- In a move to better serve people living with and without diabetes, Boehringer Ingelheim and Eli Lilly and Company (NYSE: LLY) will modernise their current alliance as of 1 January 2020 and focus its combined expertise and investment on the continued development and commercialisation of Jardiance® (empagliflozin) in type 2 diabetes, heart failure, and chronic kidney disease. Trajenta® (linagliptin) and Basaglar® (insulin glargine) continue to be part of the Alliance, with primary responsibility for development and commercialisation led by the innovator company. Boehringer Ingelheim will continue as strategic lead for Trajenta®, and Lilly for Basaglar®.

Under the amended and restated agreement, there will be a revised margin sharing structure for ongoing payments starting 1 January 2020. There are no changes to Lilly's 2019 financial guidance or 2020 financial goals as a result of this amendment. The specific impact on the upcoming year will be incorporated into Lilly's 2020 guidance, currently scheduled to be issued on 17 December 2019. The net result of the revised margin sharing structure is not expected to be financially material over the duration of the agreement.

"The Alliance has experienced significant success since its formation in 2011, with Jardiance®, Trajenta® and Basaglar® becoming strong brands and continuing to grow in their respective classes globally," said Carine Brouillon, Head of Global Therapeutic Areas, Boehringer Ingelheim. "As the versatility of the SGLT2 inhibitor class continues to be realised, focusing our combined expertise and investment to support this important treatment will not only result in greater value for both companies but better enable us to help more people with and without type 2 diabetes."

Jardiance® is the most prescribed SGLT2 inhibitor in many markets worldwide, including the US. It is also the first type 2 diabetes medicine approved by regulatory authorities to significantly reduce the risk of cardiovascular death in adults with type 2 diabetes and established cardiovascular disease, or to include data on the reduction of the risk of cardiovascular death in the label. Furthermore, the cardiovascular benefits of empagliflozin in type 2 diabetes and established cardiovascular disease have been endorsed in more than 60 guidelines worldwide. The American College of Cardiology (ACC) Expert Consensus Decision Pathway recommends empagliflozin as the preferred SGLT2 inhibitor for its proven benefit in reducing the risk of cardiovascular death in adults with type 2 diabetes and established cardiovascular disease.[1]

"Building on EMPA-REG OUTCOME®, a number of important clinical trials are ongoing to evaluate the safety and efficacy of Jardiance® in people with heart failure or chronic kidney disease, including in people with and without type 2 diabetes. The results from these trials will help us understand how to further improve quality of life for these populations. Jardiance® has a bright future, and the Alliance is absolutely committed to its success," said Mike Mason, senior vice president, Lilly Connected Care and Insulins. Mason will become president of Lilly Diabetes starting 1 January 2020.

About Diabetes and Cardiovascular Disease

More than 425 million people worldwide have diabetes, of which over 212 million are estimated to be undiagnosed.[2] By 2045, the number of people with diabetes is expected to rise to 629 million people worldwide.[2] Type 2 diabetes is the most common form of diabetes, responsible for around 90 percent of diabetes cases in high-income countries. Diabetes is a chronic condition that occurs when the body either does not properly produce, or use, the hormone insulin.[3]

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.[3,4] People with diabetes are two to four times more likely to develop cardiovascular disease than people without diabetes.[5,6] In 2017, diabetes caused four million deaths worldwide, with cardiovascular disease as the leading cause.[2] Approximately 50 percent of deaths in people with type 2 diabetes worldwide are caused by cardiovascular disease.[7,8]

Having a history of diabetes at age 60 can shorten a person's life span by as much as six years compared with someone without diabetes. And having both diabetes and a history of heart attack or stroke by age 60 can shorten a person's life span by as much as 12 years compared with someone without these conditions.[9]

Worldwide, more than 60 guidelines have been updated to endorse type 2 diabetes agents with proven cardiovascular benefits since 2016, including a Consensus Report initiated by the American Diabetes Association® and European Association for the Study of Diabetes, recommending that, in patients with type 2 diabetes and established atherosclerotic cardiovascular disease, SGLT2 inhibitors (such as empagliflozin) or GLP1 receptor agonists with proven cardiovascular benefits are recommended as part of glycaemic management.[10]

About Empagliflozin

Empagliflozin (marketed as Jardiance®) is an oral, once daily, highly selective sodium glucose cotransporter 2 (SGLT2) inhibitor and the first type 2 diabetes medicine to include cardiovascular death risk reduction data in the label in several countries.[11,12,13]

Inhibition of SGLT2 with empagliflozin in people with type 2 diabetes and high blood sugar levels leads to excretion of excess sugar in the urine. In addition, initiation of empagliflozin increases excretion of salt from the body and reduces the fluid load of the body's blood vessel system (i.e. intravascular volume). Empagliflozin induces changes to the sugar, salt and water metabolism in the body that may contribute to the reductions in

cardiovascular death observed in the EMPA-REG OUTCOME® trial.

About Boehringer Ingelheim and Eli Lilly and Company
In January 2011, Boehringer Ingelheim and Eli Lilly and Company announced an alliance that centers on compounds representing several of the largest diabetes treatment classes. Depending on geographies, the companies either co-promote or separately promote the respective molecules each contributing to the alliance. The alliance leverages the strengths of two of the world's leading pharmaceutical companies to focus on patient needs. By joining forces, the companies demonstrate their commitment, not only to the care of people with diabetes, but also to investigating the potential to address areas of unmet medical need to help those living with heart failure or chronic kidney disease.

Currently, no Boehringer Ingelheim and Lilly products are approved for the treatment of heart failure or chronic kidney disease.

Boehringer Ingelheim
Improving the health of humans and animals is the goal of the research-driven pharmaceutical company Boehringer Ingelheim. The focus in doing so is on diseases for which no satisfactory treatment option exists to date. The company therefore concentrates on developing innovative therapies that can extend patients' lives. In animal health, Boehringer Ingelheim stands for advanced prevention.

Family-owned since it was established in 1885, Boehringer Ingelheim is one of the pharmaceutical industry's top 20 companies. Some 50,000 employees create value through innovation daily for the three business areas human pharmaceuticals, animal health and biopharmaceuticals. In 2018, Boehringer Ingelheim achieved net sales of around 17.5 billion euros. R&D expenditure of almost 3.2 billion euros, corresponded to 18.1 percent of net sales.

As a family-owned company, Boehringer Ingelheim plans in generations and focuses on long-term success. The company therefore aims at organic growth from its own resources with simultaneous openness to partnerships and strategic alliances in research. In everything it does, Boehringer Ingelheim naturally adopts responsibility towards mankind and the environment.

More information about Boehringer Ingelheim can be found on www.boehringer-ingelheim.com or in our annual report: http://annualreport.boehringer-ingelheim.com.

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 programmes 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 health care leader that unites caring with discovery to create medicines that 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 lilly.com and lilly.com/newsroom. P-LLY

Intended audiences
Please be aware that information relating to the approval status and labels of approved products may vary from country to country, and a country-specific press release on this topic may have been issued in the countries where Boehringer Ingelheim and Eli Lilly and Company do business.

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about clinical trials to evaluate empagliflozin as a treatment for adults with chronic kidney disease and reflects Lilly's current belief. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialisation. Among other things, there can be no guarantee that future study results will be consistent with the results to date or that empagliflozin will receive additional regulatory approvals. For further discussion of these and other risks and uncertainties, see Lilly's most recent Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.

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[4] World Heart Federation. Diabetes as a Risk Factor for Cardiovascular Disease. Available at: www.world-heart-federation.org/cardiovascular-health/cardiovascular-disease-risk-factors/diabetes. Accessed: September 2019.

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[6] Di Angelantonio E, Kaptoge S ,Wormser D, et al. The Emerging Risk Factors Collaboration: Association of Cardiometabolic Multimorbidity With Mortality. JAMA. 2015;314:52-60

[7] Morrish NJ, Wang SL, Stevens LK, *et al.* Mortality and Causes of Death in the WHO Multinational Study of Vascular Disease in Diabetes. *Diabetologia.* 2001;44(2):S14-21.

[8] Einarson TR, Acs A, Ludwig C, *et al*. Prevalence of cardiovascular disease in type 2 diabetes: a systematic literature review of scientific evidence from across the world in 2007–2017. *Cardiovasc Diabetol.* 2018;17:83.

[9] The Emerging Risk Factors Collaboration. Association of Cardiometabolic Multimorbidity With Mortality. *JAMA.* 2015;314(1):52-60.

[10] Davies MJ, D'Alessio DA, Fradkin J, et al. Management of Hyperglycemia in Type 2 Diabetes, 2018. A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). Diabetes Care. 2018;41(12):2669-2701.

[11] Jardiance® (empagliflozin) tablets. U.S. Prescribing Information, approved October 2018.

[12] Jardiance® (empagliflozin) tablets. European Summary of Product Characteristics, approved February 2019.

[13] Jardianz® (empagliflozin) tablets. Mexican Full Prescribing Information, approved August 2017.

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