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Boehringer Ingelheim's Diabetes Pipeline Continues to Advance as the Company Announces Conclusion of Robust Phase III Pivotal Trials Programme for linagliptin

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Following the release of linagliptin Phase II data earlier this year, Boehringer Ingelheim has now announced the conclusion of the linagliptin pivotal Phase III clinical trials. The company confirmed that first results from the Phase III clinical trials programme consistently support the favourable efficacy and safety profile already observed in earlier linagliptin investigational studies, such as the Phase II data which had shown significant results in haemoglobin A1c (HbA1c)-lowering (-0,73 percent, 5 mg dose) and a safety profile comparable to placebo.

Linagliptin belongs to the class of DPP-4 inhibitors and is being developed as an oral once-daily tablet for patients with Type 2 diabetes. The five pivotal Phase III clinical trials included more than 4,000 patients in over 40 countries worldwide. The primary objective of these studies was to evaluate the efficacy and safety profile of linagliptin alone and in combination with commonly used diabetes treatments including metformin, sulfonyleureas and thiazolidinediones (TZDs). The overall linagliptin clinical trials programme includes longer term studies and also studies to assess the safe and efficacious use of linagliptin in Type 2 diabetes patients with renal impairment. Full results from the Phase III trials will be presented at international scientific congresses in 2010 and beyond.

Professor Anthony Barnett, Professor of Medicine and Clinical Director of the Department of Diabetes and Endocrinology, Heart of England NHS Foundation Trust, Birmingham, UK commented, "Every ten seconds a person dies from diabetes-related causes. It can't be emphasised enough that research needs to focus on treating the condition effectively, avoiding the complications inherent to the condition, and delaying disease progression. Medication needs to be easy to take, with good tolerability, low risk of drug-drug interactions and a low risk of side effects, including weight gain and hypoglycaemia. The DPP-4 inhibitors belong to a newer class of pharmacological treatments which appear to have many advantages over traditional therapies."

"For Type 2 diabetes treatments it is important that these not only help patients to achieve optimal blood glucose levels, but also ensure that the reduction is maintained stable and long-term. Therapies to date have not been able to achieve constant long-term glucose control and, in addition, the traditional combinations have shown an increased risk for side effects, such as hypoglycaemia. Furthermore, it is essential that treatments not only prevent the long-term complications often found in advanced stages of the disease, but also prove to be a therapeutic option in those patients who have developed complications, such as renal impairment," said Professor Klaus Dugi, Head of Corporate Medical Affairs, Boehringer Ingelheim. "First data from the Phase III clinical trials programme so far suggest that linagliptin is likely to achieve these goals. The ongoing analyses of the complete set of data obtained from these trials will help to assess the full potential of linagliptin for the treatment of Type 2 diabetes," he added.

Despite significant advances in treatments, the prevalence of Type 2 diabetes continues to rise across the globe. There are approximately 250 million people worldwide with diabetes, with Type 2 diabetes being the most common form, accounting for up to 95 percent of all diabetes cases in the developed world. Each year, more than 3.8 million people worldwide die from diabetes and its complications.

Traditional therapies have frequently failed to meet the demands of today's Type 2 diabetes landscape and new, effective and tolerable treatments are required. At Boehringer Ingelheim's largest Research & Development site and the centre of excellence for metabolic diseases in Biberach, Germany, the research teams have been focusing on the discovery and development of oral anti-diabetic treatments targeting new principles, such as the inhibition of DPP (dipeptidyl peptidase)-4 and inhibition of SGLT (sodium-dependent glucose transporter)-2. These compounds reflect the Company's dedication to harnessing the most advanced science to efficiently control Type 2 diabetes and its often fatal consequences.

For full version please visit

http://www.boehringer-ingelheim.com/corporate/news/press_releases/detail.asp?ID=6935

(Due to the length of this URL, it may be necessary to copy and paste this hyperlink into your Internet browser's URL address field. Remove the space if one exists.)

For more information about Type 2 diabetes, please also visit

<http://www.youtube.com/user/diabetesmatters> and

<http://www.boehringer-ingenelheim-webcast.com/diabetes>

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