Merck’s Investigational Insulin Glargine, MK-1293, Met Primary Endpoint in Two Phase 3 Studies, Showing Non-Inferiority to Lantus®

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Data in Patients with Type 1 and Type 2 Diabetes Presented for the First Time at the 76th Scientific Sessions of the American Diabetes Association

KENILWORTH, N.J.--(BUSINESS WIRE)--Merck (NYSE: MRK), known as MSD outside of the United States and Canada, today announced results from two Phase 3 studies evaluating MK-1293, Merck’s investigational, follow-on biologic* insulin glargine candidate for the treatment of people with type 1 and type 2 diabetes. In both studies, MK-1293 achieved its primary endpoint by demonstrating non-inferiority in change from baseline A1C (a measure of average blood glucose) and similar safety to Lantus® (insulin glargine)** after 24 weeks in patients with type 1 and type 2 diabetes. Furthermore, in both studies, MK-1293 met its pre-specified secondary efficacy endpoints of statistical A1C equivalence to Lantus, a measure used to show that an investigational treatment is similar, within an acceptable range, to a current therapy.

“It is encouraging to see that the investigational agent MK-1293 met its primary and secondary endpoints,” said Philip Home, D.M., D.Phil, professor of diabetes medicine, Newcastle University, United Kingdom. “These data, together with other clinical studies of its time-action profile, suggest that Merck’s insulin glargine, if approved, could help provide glycemic control in appropriate patients with type 1 and type 2 diabetes.”

MK-1293 has the same amino acid sequence as Lantus, the originator insulin glargine. The development of MK-1293 builds on an agreement between Merck and Samsung Bioepis established in February 2013 to develop and commercialize multiple biosimilar candidates across different therapeutic areas. Under the terms of a subsequent 2014 agreement, Merck is responsible for the clinical development, manufacturing and, if approved, commercialization of MK-1293. Samsung Bioepis is partially funding its development.

“The investigational agent MK-1293 represents Merck’s entry into insulin therapeutics and into treatments that may be useful for patients with type 1 diabetes, and we are pleased with these Phase 3 results,” said Peter Stein, M.D., vice president, late stage development, diabetes and endocrinology, Merck. “As a follow-on biologic, MK-1293 has the potential to offer a treatment option for pediatric and adult patients with type 1 diabetes and for adults with type 2 diabetes who use basal insulin to help control their glucose levels.”

MK-1293 in Patients with Type 1 Diabetes (296-OR)

The Phase 3, randomized, active-controlled, open-label trial assessed the efficacy and safety of MK-1293 (n= 245) compared with Lantus (n=263) in patients with type 1 diabetes. The primary efficacy endpoint was non-inferiority of change from baseline A1C at week 24. At baseline, patients had an A1C level equal to or less than 11.0 percent and were taking basal and prandial insulin.

The primary endpoint of the study was met, demonstrating the non-inferiority of MK-1293 to Lantus in
patients with type 1 diabetes. The least-squares mean difference in A1C (MK-1293 minus Lantus) was 0.04 percent (95% CI: -0.11, 0.19), meeting A1C non-inferiority (upper bound of the confidence interval <0.4%) and equivalence (confidence interval within -0.4% and 0.4%) criteria. Basal insulin doses were similar between groups (MK-1293 minus Lantus; difference of -0.7 U/day; 95% CI -2.5, 1.0 U/day).

The primary safety objective was anti-insulin antibody (AIA) development. Similar AIA, including incidence and titers, and similar neutralizing antibody responses were seen between treatment groups. The study found that 74 percent of patients receiving Lantus and 70 percent receiving MK-1293, irrespective of AIA status at baseline, had an AIA positive result at or before week 24. Additionally, 36 percent of patients receiving Lantus and 33 percent of patients receiving MK-1293 who were negative for AIA at baseline had an AIA positive result at or before week 24.

No clinically meaningful difference in safety endpoints of interest were seen between treatment groups. In this study, 76.4 percent of patients receiving Lantus and 71.0 percent of patients receiving MK-1293 experienced symptomatic hypoglycemia. In addition, 0.4 percent of patients receiving Lantus and 0.8 percent of patients receiving MK-1293 experienced an injection site reaction; 0.4 percent of patients receiving MK-1293 and none taking Lantus experienced a systemic allergic reaction; 1.9 percent of patients receiving Lantus and 0.4 percent of patients receiving MK-1293 experienced angioedema or a severe cutaneous adverse reaction. There were no reports of anaphylactic response in either treatment group.

**MK-1293 in Patients with Type 2 Diabetes (926-P)**

The Phase 3, randomized, active-controlled, open-label trial assessed the efficacy and safety of MK-1293 (n=265) compared to Lantus (n=266) in patients with type 2 diabetes inadequately controlled on diet and exercise alone. The primary efficacy endpoint was non-inferiority of change from baseline A1C at week 24. At baseline, patients had an A1C level equal to or less than 11.0 percent and were eligible for or were taking basal insulin greater than or equal to 10 U/day.

MK-1293 met the study's primary endpoint, demonstrating non-inferiority to Lantus with a least-squares mean difference in A1C (MK-1293 minus Lantus) of 0.03 percent (95% CI: -0.12, 0.18), meeting A1C non-inferiority (upper bound of the confidence interval <0.4%) and equivalence (confidence interval within -0.4% and 0.4%) criteria. Basal insulin doses were similar between groups (MK-1293 minus Lantus; difference of 1.4 U/day; 95% CI -2.2, 4.9 U/day).

The primary safety objective was anti-insulin antibody (AIA) development. Similar AIA, including incidence and titers, and similar neutralizing antibody responses were seen between treatment groups. In the study, 29.0 percent of patients receiving Lantus and 34.7 percent being treated with MK-1293, irrespective of AIA status at baseline, had an AIA positive at or before week 24. Additionally, 14.9 percent of patients receiving Lantus and 19.3 percent of patients receiving MK-1293 who were negative of AIA at baseline had an AIA positive at or before week 24.

No clinically meaningful between-group differences were found for pre-defined safety endpoints of interest. Symptomatic hypoglycemia was observed in 52.1 percent of patients receiving Lantus and 53.2 percent of patients receiving MK-1293. In the study, 0.4 percent of patients receiving Lantus and 1.9 percent of patients receiving MK-1293 experienced an injection site reaction; 0.4 percent of patients receiving MK-1293 and none taking Lantus experienced a systemic allergic reaction; 0.4 percent of patients receiving MK-1293 and none taking Lantus experienced an anaphylactic response; and 1.1 percent of patients receiving Lantus and 0.4 percent of patients receiving MK-1293 experienced angioedema or severe cutaneous adverse reaction.

**About Merck**

For 125 years, Merck has been a global health care leader working to help the world be well. Merck is known as MSD outside the United States and Canada. Through our prescription medicines, vaccines, biologic therapies, and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to health care through far-reaching policies, programs and partnerships. For more information, visit www.merck.com and connect with us on Twitter, Facebook, YouTube and LinkedIn.

**Forward-Looking Statement of Merck & Co., Inc., Kenilworth, N.J., USA**

This news release of Merck & Co., Inc., Kenilworth, N.J., USA (the “company”) includes “forward-looking statements” within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company’s management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.
Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's 2015 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

*A follow-on biologic is a similar, but not identical, version of an approved reference product. In the U.S., MK-1293 is referred to as a follow-on biologic because of its regulatory pathway. In other countries, it is considered to be a biosimilar.

**LANTUS is a registered trademark of Sanofi-Aventis, which is not affiliated with the maker of MK-1293 and does not endorse MK-1293.

Language: English
Contact:
Merck
Media:
Doris Li, 908-246-5701
Kristen Drake, 908-334-4688
or
Investor:
Justin Holko, 908-740-1879

Ticker Slug:
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