



NEWS RELEASE

## Jan7Merck Submits New Drug Application to the Japanese Pharmaceuticals and Medical Devices Agency for Omarigliptin, an Investigational Once-Weekly DPP-4 Inhibitor for Type 2 Diabetes

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Merck (NYSE:MRK), known as MSD outside the United States and Canada, today announced that the company has submitted a new drug application for omarigliptin, its investigational once-weekly DPP-4 inhibitor for the treatment of type 2 diabetes, to the Japanese Pharmaceuticals and Medical Devices Agency (PMDA).

“Merck is committed to helping patients with type 2 diabetes and we are excited about the submission of the new drug application for omarigliptin in Japan,” said Peter Stein, M.D., vice president, clinical research, diabetes and endocrinology, Merck Research Laboratories. “More than six million adults in Japan have type 2 diabetes<sup>1</sup>. If approved in Japan, omarigliptin could provide an important new treatment option to help these patients attain their blood sugar goals.”

The new drug application for omarigliptin is based on a comprehensive clinical development program in Japan. The results from the first Phase 3 study of omarigliptin, conducted in Japan, were presented recently at the 50th European Association for the Study of Diabetes (EASD) Annual Meeting<sup>2</sup>.

Japan is the first country with a regulatory filing for omarigliptin. Worldwide, Merck is supporting omarigliptin with a clinical development program that includes nine Phase 3 clinical trials involving approximately 7,500 patients with type 2 diabetes in support of planned regulatory filings.

## Merck's Commitment to Diabetes

Through our research initiatives, on our own and in collaboration with others, Merck is committed to strengthening its leadership in diabetes to deliver a broad portfolio of products to help patients with type 2 diabetes.

## About Merck

Today's Merck is a global healthcare 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 healthcare through far-reaching policies, programs and partnerships. For more information, visit [www.merck.com](http://www.merck.com) and connect with us on **Twitter**, **Facebook** and **YouTube**.

## Merck Forward-Looking Statement

This news release includes "forward-looking statements" within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of Merck'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; Merck'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 Merck's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

Merck 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 Merck's 2013 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](http://www.sec.gov)).

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1 IDF Diabetes Atlas. 6th Edition. Available at

[http://www.idf.org/sites/default/files/DA6\\_Regional\\_factsheets\\_0.pdf](http://www.idf.org/sites/default/files/DA6_Regional_factsheets_0.pdf)

2 Gantz, I et al. Effect of a novel once weekly DPP-4 inhibitor, omarigliptin in patients with type 2 diabetes: a double-blind, placebo- and sitagliptin-controlled, non-inferiority trial. Presentation 115, presented at 50th EASD Annual Meeting on September 17 2014. Available at

<http://www.easd.org/images/easdwebfiles/annualmeeting/50thmeeting/Prog-at-Glance.html>. Last accessed September 2014.

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