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Merck & Co., Inc. and Pfizer Enter Worldwide Collaboration Agreement to Develop and Commercialize Ertugliflozin, an Investigational Medicine for Type 2 Diabetes

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"We believe ertugliflozin has the potential to complement our strong portfolio of investigational and marketed products, and we look forward to collaborating with Pfizer on its development."

Merck & Co., Inc. (NYSE: MRK), known as MSD outside the United States and Canada (“Merck”), and Pfizer Inc. (NYSE:PFE) today announced that they have entered into a worldwide (except Japan) collaboration agreement for the development and commercialization of Pfizer’s ertugliflozin (PF-04971729), an investigational oral sodium glucose cotransporter (SGLT2) inhibitor being evaluated for the treatment of type 2 diabetes. Ertugliflozin is Phase III ready, with trials expected to begin later in 2013.

“We are pleased to join forces with Merck in the battle against type 2 diabetes and the burden that it poses on global health,” said John Young, president and general manager, Pfizer Primary Care. “Through this collaboration, we believe we can build on Merck’s leadership position in diabetes care with the introduction of ertugliflozin, an innovative SGLT2 inhibitor discovered by Pfizer scientists.”

Under the terms of the agreement, Merck, through a subsidiary, and Pfizer will collaborate on the clinical development and commercialization of ertugliflozin and ertugliflozin-containing fixed-dose combinations with metformin and JANUVIA® (sitagliptin) tablets. Merck will continue to retain the rights to its existing portfolio of sitagliptin-containing products. Pfizer has received an upfront payment and milestones of $60 million and will be eligible for additional payments associated with the achievement of pre-specified future clinical, regulatory and commercial milestones. Merck and Pfizer will share potential revenues and certain costs on a 60/40 percent basis.

“Merck continues to build upon our leadership position in the oral treatment of type 2 diabetes through our own research and business development,” said Nancy Thornberry, senior vice president and Diabetes and Endocrinology franchise head, Merck Research Laboratories. “We believe ertugliflozin has the potential to complement our strong portfolio of investigational and marketed products, and we look forward to collaborating with Pfizer on its development.”

About JANUVIA® (sitagliptin) tablets

JANUVIA is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

JANUVIA should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

JANUVIA has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk of developing pancreatitis while taking JANUVIA.

Selected Important Risk Information About JANUVIA

JANUVIA is contraindicated in patients with a history of a serious hypersensitivity reaction to sitagliptin, such as anaphylaxis or angioedema.

There have been postmarketing reports of acute pancreatitis, including fatal and nonfatal hemorrhagic or necrotizing pancreatitis, in patients taking JANUVIA. After initiating JANUVIA, observe patients carefully for signs and symptoms of pancreatitis. If pancreatitis is suspected, promptly discontinue JANUVIA and initiate appropriate management. It is unknown whether patients with a history of pancreatitis are at increased risk of developing pancreatitis while taking JANUVIA.

Assessment of renal function is recommended prior to initiating JANUVIA and periodically thereafter. A dosage adjustment is recommended in patients with moderate or severe renal insufficiency and in patients with end-stage renal disease requiring hemodialysis or peritoneal dialysis. Caution should be used to ensure that the correct dose of JANUVIA is prescribed.

There have been postmarketing reports of worsening renal function, including acute renal failure, sometimes requiring dialysis. A subset of these reports involved patients with renal insufficiency, some of whom were prescribed inappropriate doses of sitagliptin.

When JANUVIA was used in combination with a sulfonylurea or insulin, medications known to cause hypoglycemia, the incidence of hypoglycemia was increased over that of placebo. Therefore, a lower dose of sulfonylurea or insulin may be required to reduce the risk of hypoglycemia.

The incidence (and rate) of hypoglycemia based on all reports of symptomatic hypoglycemia were: 12.2 percent (0.59 episodes per patient-year) for JANUVIA® (sitagliptin) 100 mg in combination with glimepiride (with or without metformin), 1.8 percent (0.24 episodes per patient-year) for placebo in combination with glimepiride (with or without metformin), 15.5 percent (1.06 episodes per patient-year) for JANUVIA 100 mg in combination with insulin (with or without metformin), and 7.8 percent (0.51 episodes per patient-year) for placebo in combination with insulin (with or without metformin).

There have been postmarketing reports of serious hypersensitivity reactions in patients treated with JANUVIA, such as anaphylaxis, angioedema, and exfoliative skin conditions including Stevens-Johnson syndrome. Onset of these reactions occurred within the first 3 months after initiation of treatment with JANUVIA, with some reports occurring after the first dose. If a hypersensitivity reaction is suspected, discontinue JANUVIA, assess for other potential causes for the event, and institute alternative treatment for diabetes.

Angioedema has also been reported with other dipeptidyl peptidase-4 (DPP-4) inhibitors. Use caution in a patient with a history of angioedema with another DPP-4 inhibitor because it is unknown whether such patients will be predisposed to angioedema with JANUVIA.

There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with JANUVIA or with any other antidiabetic drug.

In clinical studies, the adverse reactions reported, regardless of investigator assessment of causality, in greater than or equal to 5 percent of patients treated with JANUVIA as monotherapy and in combination therapy and more commonly than in patients treated with placebo, were upper respiratory tract infection, nasopharyngitis, and headache.

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 Statesand Canada. Through our prescription medicines, vaccines, biologic therapies, and consumer care 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 and connect with us on Twitter,Facebook and YouTube.

Pfizer Inc.: Working together for a healthier world™

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more, please visit us at www.pfizer.com.

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 2012 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).

Pfizer Disclosure Notice

The information contained in this release is as of April 29, 2013. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about ertugliflozin, an investigational oral SGLT2 inhibitor being evaluated for the treatment of type 2 diabetes, and a collaboration agreement between Pfizer and Merck for the development and commercialization of ertugliflozin, including their potential benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things:

- the uncertainties inherent in research and development, including the ability to meet anticipated clinical trial commencement and completion dates, regulatory submission and approval dates, and launch dates, as well as the possibility of unfavorable clinical trial results, including unfavorable new clinical data or additional analyses of existing clinical data;
- decisions by regulatory authorities regarding whether and when to approve any drug applications that may be filed for any potential indication for ertugliflozin as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of any such potential indication and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2012 and in its reports on Form 10-Q and Form 8-K.

Prescribing Information and Medication Guide for JANUVIA® (sitagliptin) are available at http://www.merck.com/product/usa/pi_circulars/j/januvia/januvia_pi.pdf and http://www.merck.com/product/usa/pi_circulars/j/januvia/januvia_mg.pdf.

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