NEWS RELEASE

Merck and Pfizer Announce Investigational Ertugliflozin Met Primary Endpoint of A1C Reduction When Added to Sitagliptin and Metformin in People with Type 2 Diabetes

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New Phase 3 Data Presented at the European Association for the Study of Diabetes Annual Meeting – Study Achieved Primary and All Key Secondary Endpoints

KENILWORTH, N.J., and NEW YORK, N.Y. -- Merck (NYSE: MRK), known as MSD outside the United States and Canada, in partnership with Pfizer Inc. (NYSE: PFE) today announced that a Phase 3 study (VERTIS SITA2) of ertugliflozin, an investigational oral SGLT2 inhibitor for the treatment of patients with type 2 diabetes, met its primary endpoint. Both 5 mg and 15 mg daily doses of ertugliflozin showed significantly greater reductions in A1C* of 0.69 percent and 0.76 percent, respectively, compared with placebo ($p<0.001$, for both comparisons), when added to patients on a background of sitagliptin (100 mg/day) and stable metformin (≥1500 mg/day). These study results were presented for the first time during an oral session today at the 52nd Annual Meeting of the European Association for the Study of Diabetes (EASD) in Munich, Germany.

Merck and Pfizer plan to submit New Drug Applications to the U.S. Food and Drug Administration for ertugliflozin and two fixed-dose combinations (ertugliflozin plus JANUVIA® (sitagliptin) and ertugliflozin plus metformin) by the end of 2016, with additional regulatory submissions outside of the U.S. to follow in 2017.

“It is encouraging to see further data from the VERTIS clinical development program in support of combining ertugliflozin, an SGLT2 inhibitor, with the DPP-4 inhibitor sitagliptin, which was first approved 10 years ago,” said Peter Stein, M.D., vice president, late stage development, diabetes and endocrinology, Merck.

In this double-blind, randomized, placebo-controlled study, 463 patients with type 2 diabetes and a baseline A1C of 7.0 – 10.5 percent were randomized to receive ertugliflozin 5 mg, ertugliflozin 15 mg, or placebo in a 1:1:1 ratio. In addition to meeting the primary endpoint of reducing A1C at 26 weeks, ertugliflozin also met the following key secondary endpoints in the study:

- A greater proportion of patients taking ertugliflozin 5 mg and 15 mg achieved the A1C treatment goal of less than 7.0 percent (32.1 percent and 39.9 percent, respectively) compared with the placebo group (17.0 percent) ($p<0.001$, for both comparisons based on adjusted odds ratios);

- Placebo-adjusted mean reduction in body weight of 4.4 lbs (2.0 kg) for the 5 mg dose and 3.7 lbs (1.7 kg) for the 15 mg dose ($p<0.001$, for both comparisons);

- Placebo-adjusted mean reductions in fasting plasma glucose (FPG) of 25.1 mg/dl (1.4 mmol/L) for the 5 mg dose and 31.3 mg/dl (1.7 mmol/L) for the 15 mg dose ($p<0.001$, for both comparisons);

- Placebo-adjusted mean reductions in systolic blood pressure of 2.9 mmHg (5 mg, $p=0.019$) and 3.9 mmHg (15 mg, $p=0.002$).

“We are pleased to share these new data on investigational ertugliflozin with the scientific community, following the first presentations of Phase 3 data for ertugliflozin at the American Diabetes Association’s 76th Scientific Sessions in June,” said James Rusnak, M.D., Ph.D., chief development officer, cardiovascular & metabolics, Pfizer. “Type 2 diabetes is a progressive disease and these study results help support the clinical profile of ertugliflozin as an add-on therapy for patients who may require multiple treatment combinations to help reach their blood sugar goals.”

Overall adverse event (AE) rates were generally similar between ertugliflozin 5 mg (41.7 percent), ertugliflozin 15 mg (43.8 percent) and placebo (48.4 percent), with a similar rate of one or more serious AEs across all groups (4.5 percent for ertugliflozin 5 mg; 2.0 percent for ertugliflozin 15 mg; 3.3 percent for placebo). The rates of discontinuations due to AEs were low across all groups (3.2 percent for ertugliflozin 5 mg; 0.7 percent for ertugliflozin 15 mg; 0.7 percent for placebo). In the study, a higher incidence of genital mycotic infections was observed in patients taking ertugliflozin 5 mg and ertugliflozin 15 mg (males: 4.9 percent and 3.7 percent, respectively, vs. no events for placebo; females: 8.0 percent and 12.7 percent, respectively, vs. 1.9 percent for placebo). Urinary tract infection rates were low across the ertugliflozin 5 mg, ertugliflozin 15 mg and placebo groups (2.6 percent, 4.6 percent and 2.0 percent, respectively). Across groups, there were similar rates for symptomatic hypoglycemia (3.8 percent for ertugliflozin 5 mg; 0.7 percent for ertugliflozin 15 mg; 2.6 percent for placebo) and for hypovolemia adverse events (0.6 percent for ertugliflozin 5 mg; no events for ertugliflozin 15 mg; 0.7 percent for placebo).

About the VERTIS Clinical Development Program for Ertugliflozin

In addition to the **VERTIS MONO and VERTIS FACTORIAL studies**, which were presented at the 76th Scientific Sessions of the American Diabetes Association, VERTIS SITA2 is a part of the VERTIS clinical development program comprised of a total of nine Phase 3 trials in approximately 12,600 adults with type 2 diabetes. Results from the other six VERTIS trials will be submitted for publication and/or presentation at future scientific congresses.

Important Information about JANUVIA® (sitagliptin) 25 mg, 50 mg and 100 mg 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% (0.59 episodes/patient-year) for JANUVIA 100 mg in combination with glimepiride (with or without metformin), 1.8% (0.24 episodes/patient-year) for placebo in combination with glimepiride (with or without metformin), 15.5% (1.06 episodes/patient-year) for JANUVIA 100 mg in combination with insulin (with or without metformin), and 7.8% (0.51 episodes/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 postmarketing reports of severe and disabling arthralgia in patients taking DPP-4 inhibitors. The time to onset of symptoms following initiation of drug therapy varied from 1 day to years. Patients experienced relief of symptoms upon discontinuation of the medication. A subset of patients experienced a recurrence of symptoms when restarting the same drug or a different DPP-4 inhibitor. Consider DPP-4 inhibitors as a possible cause for severe joint pain and discontinue drug if appropriate.

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 ≥5% 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

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**.

About Pfizer Inc.

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 healthcare 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. For more information, please visit us at **www.pfizer.com**. In addition, to learn more, follow us on Twitter **@Pfizer** and **@Pfizer_News**, **LinkedIn** , **YouTube** and like us on Facebook at **Facebook.com/Pfizer.**

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**).

Pfizer Disclosure Notice

The information contained in this release is as of September 15, 2016. 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 a product candidate, ertugliflozin, including its potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated trial commencement and completion dates and regulatory submission dates, as well as the possibility of unfavorable clinical trial results, including unfavorable new clinical data and additional analyses of existing clinical data; whether and when any applications for ertugliflozin may be filed with regulatory authorities in any jurisdictions; whether and when regulatory authorities in any jurisdictions may approve such applications, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of ertugliflozin; and competitive developments. The competitive landscape for type 2 diabetes therapies, including SGLT 2-inhibitors, continues to evolve. The success of our ertugliflozin program is dependent on developments in that space.

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, 2015 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at **www.sec.gov(link is external)** and **www.pfizer.com**.

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

http://www.merck.com/product/usa/pi_circulars/j/januvia/januvia_mg.pdf.

*A1C is an average measure of blood glucose over the past two to three months

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