



NEWS RELEASE

Late-Breaking Data to be Presented from the Comparative Trials with Sitagliptin (CompoSIT) Program on the Continuation of JANUVIA® (sitagliptin) Treatment Among Patients Initiating Insulin Therapy

6/18/2018

Merck to present new Phase 3 data on JANUVIA, STEGLATRO™ (ertugliflozin), and real-world evidence research at the 78th Scientific Sessions of the American Diabetes Association

KENILWORTH, N.J., June 18, 2018 – Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced that 31 studies from Merck’s diabetes portfolio – including new data for JANUVIA® (sitagliptin), STEGLATRO™ (ertugliflozin) and real-world research – will be presented at the 78th Scientific Sessions of the American Diabetes Association (ADA) in Orlando, June 22 - 26, 2018. Presentations include efficacy and safety data for JANUVIA in various settings across the treatment paradigm. Data on the long-term efficacy and safety of STEGLATRO, which was developed in collaboration with Pfizer, will also be presented.

“We look forward to sharing new clinical data across our diabetes portfolio, which spans different and complementary mechanisms that may help address gaps in glycemic goal attainment,” said Dr. Sam Engel, associate vice president, diabetes, endocrinology and women’s health, Merck Research Laboratories.

“At Merck, we’re committed to demonstrating the clinical and economic value of our medicines using real-world, observational data,” said Dr. Swapnil Rajpathak, executive director, Center for Observational and Real World Evidence (CORE), Merck. “Real-world data provide valuable insights on the challenges of managing diabetes in



everyday settings and help to identify barriers to patients attaining treatment goals.”

Select data to be presented include:

JANUVIA® (sitagliptin)

- Safety and Efficacy of Continuing Sitagliptin When Initiating Insulin Therapy in Subjects with Type 2 Diabetes Mellitus (Abstract #112-LB, Monday, June 25, 12:00 - 1:00 p.m.)
- Safety and Efficacy of Sitagliptin Compared with Dapagliflozin in Subjects with Type 2 Diabetes, Mild Renal Impairment and Inadequate Glycemic Control on Metformin ± a Sulfonylurea (Abstract #1142-P, Sunday, June 24, 12:00 - 1:00 p.m.)
- Efficacy and Safety of Sitagliptin-based Dual and Triple Combination Therapy in Older Chinese People with T2D (Abstract #1144-P, Sunday, June 24, 12:00 - 1:00 p.m.)

STEGLATRO™ (ertugliflozin)

- Long-term Efficacy and Safety of Ertugliflozin in Patients with Type 2 Diabetes Mellitus Inadequately Controlled with Metformin Monotherapy: 104-week VERTIS MET Trial (Abstract #1129-P, Sunday, June 24, 12:00 - 1:00 p.m.)
- Evaluation of Fractures, Bone Mineral Density and Bone Biomarkers in Patients with Type 2 Diabetes Mellitus Receiving Ertugliflozin (Abstract # 1145-P, Sunday, June 24, 12:00 - 1:00 p.m.)
- A Pooled Analysis of the Efficacy and Safety of Ertugliflozin as Add-on Therapy to Metformin (Abstract #1140-P, Sunday, June 24, 12:00 - 1:00 p.m.)
- Assessment of Adverse Renal Effects in Patients with Type 2 Diabetes Mellitus Receiving Ertugliflozin (Abstract #1168-P, Sunday, June 24, 12:00 - 1:00 p.m.)

Real-World Data – Type 2 Diabetes

- Impact of Switching from Sulfonylureas to Dipeptidyl Peptidase-4 Inhibitors on Hypoglycemia Burden in the U.S.: A Predictive Modeling Approach (Abstract #385-P, Saturday, June 23, 11:30 a.m. – 12:30 p.m.)
- Distance from Glycemic Target at the Time of Add-on Initiation in Patients with Type 2 Diabetes Failing Metformin Monotherapy in the U.S. (Abstract #1628-P, Sunday, June 24, 12:00 - 1:00 p.m.)
- Relationship between Glycemic Control and Treatment Intensity in Patients with Type 2 Diabetes (Abstract #1632-P, Sunday, June 24, 12:00 - 1:00 p.m.)
- Impact of Early Intensification with Sitagliptin on Glycemic Goal Attainment Among Patients with Metformin Monotherapy Failure (Abstract #1641-P, Sunday, June 24, 12:00 - 1:00 p.m.)

Discovery

- Restoration of Insulin-Receptor Expression in Adulthood Reverses Diabetic Phenotype in Type 2 Diabetic Models (Abstract #239-LB, Monday, June 25, 12:00 - 1:00 p.m.)

For more information, including a complete list of abstract titles at the meeting, please visit: https://plan.core-apps.com/tristar_ada18.

Our Commitment to Diabetes

At Merck, we're committed to scientific innovation, and we believe it's our responsibility to help address the global diabetes epidemic, one community and one patient at a time.^[i]

Our legacy in diabetes is rooted in research, which led to the first FDA approval in 2006 of a DPP-4 inhibitor in the U.S., JANUVIA (sitagliptin), but our work didn't stop there.^[ii] We continue to invest our resources and capabilities and collaborate with others to develop and deliver a range of treatments and educational tools for patients and healthcare providers to help address this public health challenge.ⁱ

For more information about our commitment to diabetes, visit www.merck.com/about/our-work/diabetes.html.

Indications and Usage for 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 (sitagliptin)

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 (sitagliptin) and initiate appropriate management. It is unknown whether patients with a history of pancreatitis are at increased risk of developing pancreatitis while taking JANUVIA.

An association between dipeptidyl peptidase-4 (DPP-4) inhibitor treatment and heart failure has been observed in cardiovascular outcomes trials for two other members of the DPP-4 inhibitor class. These trials evaluated patients

with type 2 diabetes mellitus and atherosclerotic cardiovascular disease. Consider the risks and benefits of JANUVIA prior to initiating treatment in patients at risk for heart failure, such as those with a prior history of heart failure and a history of renal impairment, and observe these patients for signs and symptoms of heart failure during therapy. Advise patients of the characteristic symptoms of heart failure and to immediately report such symptoms. If heart failure develops, evaluate and manage according to current standards of care and consider discontinuation of 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 impairment 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 impairment, 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 (sitagliptin), assess for other potential causes for the event, and institute alternative treatment for diabetes.

Angioedema has also been reported with other 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.

Postmarketing cases of bullous pemphigoid requiring hospitalization have been reported with DPP-4 inhibitor use. In reported cases, patients typically recovered with topical or systemic immunosuppressive treatment and discontinuation of the DPP-4 inhibitor. Tell patients to report development of blisters or erosions while receiving JANUVIA. If bullous pemphigoid is suspected, JANUVIA should be discontinued and referral to a dermatologist should be considered for diagnosis and appropriate treatment.

There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with JANUVIA.

In clinical studies, the adverse reactions reported, regardless of investigator assessment of causality, in $\geq 5\%$ 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.

Indications and Usage for STEGLATRO (ertugliflozin) 5 mg and 15 mg tablets

STEGLATRO is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. STEGLATRO is not recommended in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.

Selected Important Risk Information about STEGLATRO (ertugliflozin)

STEGLATRO is contraindicated in patients with severe renal impairment, end-stage renal disease or on dialysis, or with a history of a serious hypersensitivity reaction to ertugliflozin.

STEGLATRO causes intravascular volume contraction. Symptomatic hypotension may occur after initiating STEGLATRO, particularly in patients with impaired renal function (estimated glomerular filtration rate [eGFR] less than 60 mL/min/1.73 m²), elderly patients (≥ 65 years), patients with low systolic blood pressure or patients on diuretics. Before initiating STEGLATRO (ertugliflozin), volume status should be assessed and corrected if indicated. Monitor for signs and symptoms after initiating therapy.

Ketoacidosis, a serious life-threatening condition requiring urgent hospitalization, has been reported in patients with type 1 and type 2 diabetes receiving SGLT2 inhibitors including STEGLATRO. Some cases were fatal. Assess patients with signs and symptoms of metabolic acidosis for ketoacidosis, regardless of blood glucose level. If

ketoacidosis is suspected, STEGLATRO should be discontinued, patient should be evaluated, and prompt treatment should be instituted. Before initiating STEGLATRO, consider risk factors for ketoacidosis, including pancreatic insulin deficiency from any cause, caloric restriction, and alcohol abuse. In patients treated with STEGLATRO, consider monitoring for ketoacidosis and temporarily discontinuing STEGLATRO in clinical situations known to predispose to ketoacidosis (e.g., prolonged fasting due to acute illness or surgery).

STEGLATRO causes intravascular volume contraction and can cause renal impairment. There have been postmarketing reports of acute kidney injury, some requiring hospitalization and dialysis, in patients receiving SGLT2 inhibitors. Before initiating STEGLATRO, consider factors that may predispose patients to acute kidney injury. Consider temporarily discontinuing STEGLATRO in any setting of reduced oral intake or fluid losses; monitor patients for signs and symptoms of acute kidney injury. If acute kidney injury occurs, discontinue STEGLATRO promptly and institute treatment.

STEGLATRO increases serum creatinine and decreases eGFR. Patients with moderate renal impairment (eGFR 30 to less than 60 mL/min/1.73 m²) may be more susceptible to these changes. Renal function abnormalities can occur after initiating STEGLATRO. Renal function should be evaluated prior to initiating STEGLATRO and periodically thereafter. Use of STEGLATRO (ertugliflozin) is not recommended when eGFR is persistently between 30 and less than 60 mL/min/1.73 m² and is contraindicated in patients with an eGFR less than 30 mL/min/1.73 m².

There have been postmarketing reports of serious urinary tract infections, including urosepsis and pyelonephritis, requiring hospitalization in patients receiving SGLT2 inhibitors. Cases of pyelonephritis also have been reported in patients treated with STEGLATRO in clinical trials. Treatment with SGLT2 inhibitors increases the risk for urinary tract infections. Evaluate patients for signs and symptoms of urinary tract infections and treat promptly, if indicated.

An increased risk for lower limb amputation has been observed in clinical studies with another SGLT2 inhibitor. Across seven Phase 3 clinical trials with STEGLATRO, non-traumatic lower limb amputations were reported in 1 (0.1%) patient in the comparator group, 3 (0.2%) patients in the STEGLATRO (ertugliflozin) 5 mg group, and 8 (0.5%) patients in the STEGLATRO 15 mg group. A causal association between STEGLATRO and lower limb amputation has not been definitively established. Before initiating STEGLATRO, consider factors that may predispose patients to the need for amputations. Counsel patients about the importance of routine preventative foot care. Monitor patients and discontinue STEGLATRO if complications occur.

Insulin and insulin secretagogues (e.g., sulfonylurea) are known to cause hypoglycemia. STEGLATRO may increase the risk of hypoglycemia when used in combination with insulin and/or an insulin secretagogue. Therefore, a lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with STEGLATRO (ertugliflozin).

STEGLATRO increases the risk of genital mycotic infections. Patients who have a history of genital mycotic infections or who are uncircumcised are more likely to develop genital mycotic infections. Monitor and treat appropriately.

Dose-related increases in low-density lipoprotein cholesterol (LDL-C) can occur with STEGLATRO. Monitor and treat as appropriate.

There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with STEGLATRO.

The most common adverse reactions associated with STEGLATRO (incidence $\geq 5\%$) were female genital mycotic infections.

About Merck

For more than a century, Merck, a leading global biopharmaceutical company known as MSD outside of the United States and Canada, has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases. 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. Today, Merck continues to be at the forefront of research to advance the prevention and treatment of diseases that threaten people and communities around the world - including cancer, cardio-metabolic diseases, emerging animal diseases, Alzheimer's disease and infectious diseases including HIV and Ebola. For more information, visit www.merck.com and connect with us on [Twitter](#), [Facebook](#), [Instagram](#), [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 2017 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).

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

Please see Prescribing Information for STEGLATRO™ (ertugliflozin) at http://www.merck.com/product/usa/pi_circulars/s/steglatro/steglatro_pi.pdf and Medication Guide for STEGLATRO at http://www.merck.com/product/usa/pi_circulars/s/steglatro/steglatro_mg.pdf

[i] International Diabetes Federation. Diabetes Atlas. 8th ed. Brussels, Belgium. International Diabetes Federation. 2018.1-150.

[ii] Sitagliptin U.S. PI. Pages 1-23. Accessed: April 2018.

Merck

Media:

Pamela Eisele, 267-305-3558

or

Megan Wilkinson, 267-305-6463

or

Investors:

Michael DeCarbo, 908-740-1807