# ACROSS THE US, MANY PEOPLE 65 AND OLDER ARE LIVING WITH TYPE 2 DIABETES<sup>1</sup>...

# 15.9 million\*

people 65 and older have diagnosed or undiagnosed diabetes<sup>1†</sup>

The ADA recommends older adults who are otherwise healthy should have **lower glycemic goals** (A1C <7.0–7.5%), while those with certain health issues should have **less stringent glycemic goals** (A1C <8.0%)<sup>2‡</sup>



Older patients with **type 2 diabetes** may benefit from

achieving individualized glycemic goals<sup>2‡</sup>

\*Refer to the 2023 ADA Standards of Care in Diabetes for full recommendations.
\*Estimated based on 2017-March 2020 National Health and Nutrition Examination Survey.
\*Type 2 diabetes accounts for 90% to 95% of all diabetes cases.<sup>1</sup>



ADA=American Diabetes Association; CV=cardiovascular.

# ...AND MAY NEED GLUCOSE CONTROL<sup>1,3</sup>

-17% of people with diabetes\* 65 and older have A1C ≥8%<sup>1†</sup>



# Over a one year period, **~5 million people**

65 and older were treated with generic antidiabetic pills only<sup>3</sup> and may have needed additional glucose control

Based on regimen for latest paid claim per patient in the last 12 months ending September 2022.

Consider hypoglycemia when selecting medications for older patients with type 2 diabetes, as they have an **increased risk of** hypoglycemia<sup>2‡</sup>



The ADA recommends taking **cost of care** and **insurance coverage** into consideration when treating patients 65 and older<sup>2‡</sup>

<sup>+</sup>Refer to the 2023 ADA Standards of Care in Diabetes for full recommendations.

\*Type 2 diabetes accounts for 90% to 95% of all diabetes cases."

\*Estimate is a crude percentage based on 2017-March 2020 National Health and Nutrition Examination Survey.

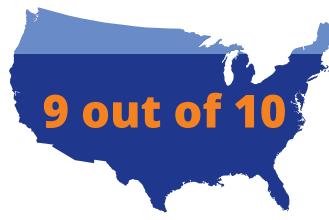


**References: 1.** Centers for Disease Control and Prevention. National Diabetes Statistics Report website. https://www.cdc.gov/diabetes/data/ statistics-report/index.html. Accessed March 9, 2023. **2.** ElSayed NA, Aleppo G, Aroda VR, et al; on behalf of the American Diabetes Association. Standards of Care in Diabetes—2023. *Diabetes Care*. 2023;46(suppl 1):S216. **3.** IQVIA LAAD. September 2022.

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# DO YOUR PATIENTS 65 AND OLDER LIVING WITH TYPE 2 DIABETES NEED MORE A1C CONTROL?<sup>1</sup>

# **MANY OF THEM MAY BE RYBELSUS® READY**



patients 65 and older on Medicare Part D are covered for RYBELSUS<sup>®2,a</sup>

Actor portrayal of hypothetical patient.

1 in 2 patients with type 2 diabetes on Medicare may qualify for full Extra Help (LIS), and pay no more than **[\$10.35**\*] for RYBELSUS® per month.<sup>3</sup>

\*Centers for Medicare and Medicaid Services, Department of Health & Human Services. Medicare & You 2023: The official U.S. government Medicare handbook. https://www.medicare.gov/publications/10050-Medicare-and-You.pdf. Accessed January 3, 2023.

<sup>a</sup>Novo Nordisk defines access as covered when brand is available on formulary with or without restrictions. Coverage status and tier vary by plan and are subject to change. Please check directly with health plan to confirm coverage for individual patients.

# **Indication and Usage**

RYBELSUS<sup>®</sup> (semaglutide) tablets 7 mg or 14 mg is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes.

## Limitations of Use

- RYBELSUS® has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis
- RYBELSUS® is not indicated for use in patients with type 1 diabetes

# **Important Safety Information**

### WARNING: RISK OF THYROID C-CELL TUMORS

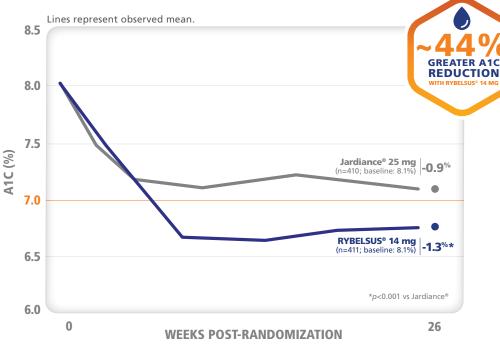
- In rodents, semaglutide causes dose-dependent and treatment-duration dependent thyroid C-cell tumors at clinically relevant exposures. It is unknown whether RYBELSUS® causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of semaglutide-induced rodent thyroid C-cell tumors has not been determined
- RYBELSUS<sup>®</sup> is contraindicated in patients with a personal or family history of MTC and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk for MTC with the use of RYBELSUS<sup>®</sup> and inform them of symptoms of thyroid tumors (e.g. a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with RYBELSUS<sup>®</sup>





# **RYBELSUS® demonstrated superior A1C reduction** vs Jardiance<sup>®</sup>, with comparable weight loss<sup>1,4</sup>

## SUPERIOR A1C REDUCTION VS JARDIANCE<sup>®1,4</sup> PIONEER 2 PRIMARY ENDPOINT



#### **COMPARABLE WEIGHT LOSS VS JARDIANCE®1,4**

**RYBELSUS®** is not indicated for weight loss. Mean change in body weight from baseline at Week 26 was a confirmatory secondary endpoint.



ADDED TO METFORMIN CI=confidence interval; ETD=estimated treatment difference.

**6%** of patients were

In the PIONEER 2 trial,

65 and older<sup>6</sup>

PIONEER 2 study design<sup>1,4</sup>

In an open-label trial with a primary endpoint of mean change in A1C from baseline to 26 weeks, 822 adult patients with type 2 diabetes on metformin were randomized to RYBELSUS® 14 mg (n=411) or Jardiance® 25 mg (n=410), both once daily.

• Confirmatory secondary endpoint: Mean change in body weight from baseline at 26 weeks

# No overall differences in safety or effectiveness for RYBELSUS® have been observed between patients 65 years of age and older and younger adult patients.<sup>1</sup>

# **Important Safety Information**

### Contraindications

• RYBELSUS<sup>®</sup> is contraindicated in patients with a personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2), and in patients with a prior serious hypersensitivity reaction to semaglutide or to any of the excipients in RYBELSUS<sup>®</sup>. Serious hypersensitivity reactions including anaphylaxis and angioedema have been reported with RYBELSUS<sup>®</sup>

### **Warnings and Precautions**

- Risk of Thyroid C-Cell Tumors: Patients should be further evaluated if serum calcitonin is measured and found to be elevated or thyroid nodules are noted on physical examination or neck imaging
- **Pancreatitis:** Has been reported in clinical trials. Observe patients carefully for signs and symptoms of pancreatitis (including persistent severe abdominal pain, sometimes radiating to the back and which may or may not be accompanied by vomiting). If pancreatitis is suspected, discontinue RYBELSUS<sup>®</sup> and initiate appropriate management; if confirmed, do not restart RYBELSUS<sup>®</sup>

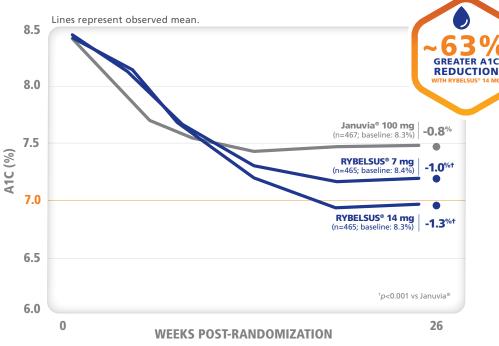




Please see additional Important Safety Information throughout. Please click here for Prescribing Information, including Boxed Warning.

# **RYBELSUS<sup>®</sup> demonstrated superior A1C reduction and weight loss** vs Januvia<sup>®1,5</sup>

## SUPERIOR A1C REDUCTION VS JANUVIA<sup>®1,5</sup> PIONEER 3 PRIMARY ENDPOINT



#### PIONEER 3 study design<sup>1,5</sup>

In a double-blind, double-dummy trial with a primary endpoint of mean change in A1C from baseline to 26 weeks, 1864 adult patients with type 2 diabetes on metformin alone or metformin with a sulfonylurea were randomized to RYBELSUS® 3 mg (n=466), RYBELSUS® 7 mg (n=465), RYBELSUS® 14 mg (n=465), or Januvia® 100 mg (n=467), all once daily.

• Confirmatory secondary endpoint: Mean change in body weight from baseline at 26 weeks

## SUPERIOR WEIGHT LOSS VS JANUVIA®1,5

**RYBELSUS®** is not indicated for weight loss. Mean change in body weight from baseline at Week 26 was a confirmatory secondary endpoint.



# Superior vs Januvia<sup>®</sup> 100 mg

ADDED TO METFORMIN WITH OR WITHOUT SULFONYLUREA CI=confidence interval; ETD=estimated treatment difference.

In the PIONEER 3 trial, ~27% of patients were 65 and older<sup>6</sup>

# No overall differences in safety or effectiveness for RYBELSUS<sup>®</sup> have been observed between patients 65 years of age and older and younger adult patients.<sup>1</sup>

# **Important Safety Information**

### **Warnings and Precautions**

• Diabetic Retinopathy Complications: In a pooled analysis of glycemic control trials with RYBELSUS<sup>®</sup>, patients reported diabetic retinopathy related adverse reactions during the trial (4.2% with RYBELSUS<sup>®</sup> and 3.8% with comparator). In a 2-year trial with semaglutide injection involving patients with type 2 diabetes and high cardiovascular risk, more events of diabetic retinopathy complications occurred in patients treated with semaglutide injection (3.0%) compared to placebo (1.8%). The absolute risk increase for diabetic retinopathy complications was larger among patients with a history of diabetic retinopathy at baseline than among patients without a known history of diabetic retinopathy.

Rapid improvement in glucose control has been associated with a temporary worsening of diabetic retinopathy. Patients with a history of diabetic retinopathy should be monitored for progression of diabetic retinopathy

• Hypoglycemia: Patients receiving RYBELSUS<sup>®</sup> in combination with an insulin secretagogue (e.g., sulfonylurea) or insulin may have an increased risk of hypoglycemia, including severe hypoglycemia. Inform patients using these concomitant medications of the risk of hypoglycemia and educate them on the signs and symptoms of hypoglycemia





# Your patients 65 and older, like Steve, may be RYBELSUS<sup>®</sup> ready

# Steve is looking for a treatment that can help lower A1C, and has demonstrated CV safety and weight loss in clinical trials.<sup>1</sup>

RYBELSUS<sup>®</sup> is not indicated for weight loss.

A1C: 8.1%

BMI: 31

Steve, 67



 $\odot$ 

Living with type 2 diabetes for 6 years

To treat type 2 diabetes, Steve takes metformin (2000 mg/day), along with diet and exercise, but his doctor discussed the need for additional glycemic control

# There is no dosage adjustment recommended for patients 65 and older for RYBELSUS<sup>®1</sup>

No overall differences in safety or effectiveness for RYBELSUS<sup>®</sup> have been observed between patients 65 years of age and older and younger adult patients.<sup>1</sup>

BMI=body mass index; CV=cardiovascular.

Actor portrayal of hypothetical patient.

# **Important Safety Information**

## **Warnings and Precautions**

- Acute Kidney Injury: There have been postmarketing reports of acute kidney injury and worsening of chronic renal failure, which may sometimes require hemodialysis, in patients treated with GLP-1 receptor agonists, including semaglutide. Some of these events have been reported in patients without known underlying renal disease. A majority of the reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. Monitor renal function when initiating or escalating doses of RYBELSUS<sup>®</sup> in patients reporting severe adverse gastrointestinal reactions
- Hypersensitivity: Serious hypersensitivity reactions (e.g., anaphylaxis, angioedema) have been reported in patients treated with RYBELSUS<sup>®</sup>. If hypersensitivity reactions occur, discontinue use of RYBELSUS<sup>®</sup>, treat promptly per standard of care, and monitor until signs and symptoms resolve. Use caution in a patient with a history of angioedema or anaphylaxis with another GLP-1 receptor agonist
- Acute Gallbladder Disease: Acute events of gallbladder disease such as cholelithiasis or cholecystitis have been reported in GLP-1 receptor agonist trials and postmarketing. In placebo-controlled trials, cholelithiasis was reported in 1% of patients treated with RYBELSUS<sup>®</sup> 7 mg. Cholelithiasis was not reported in RYBELSUS<sup>®</sup> 14 mg or placebo-treated patients. If cholelithiasis is suspected, gallbladder studies and appropriate clinical follow-up are indicated

### **Adverse Reactions**

• Most common adverse reactions (incidence >5%) are nausea, abdominal pain, diarrhea, decreased appetite, vomiting and constipation





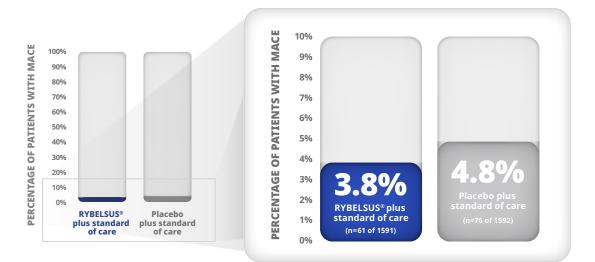


In a CVOT comparing RYBELSUS<sup>®</sup> plus standard of care vs placebo plus standard of care (16 months median observation time)

# **RYBELSUS<sup>®</sup> - Demonstrated CV safety with no increased risk of MACE<sup>1</sup>**

## Noninferiority of RYBELSUS® vs placebo, both in addition to standard of care, was confirmed<sup>1,a</sup>

#### PERCENTAGE OF PATIENTS WITH MACE



#### PIONEER 6: Cardiovascular Safety<sup>1,7</sup>

In a double-blind trial, 3183 adult patients with inadequately controlled type 2 diabetes at high CV risk ( $\geq$ 50 years of age with CVD or CKD or  $\geq$ 60 years of age with CV risk factors) were randomized to RYBELSUS® 14 mg (n=1591) once daily or placebo (n=1592), both in addition to standard of care, for a median observation time of 16 months. Background antidiabetic therapy included OADs and/or insulin. Patients could also be treatment-naïve. Most patients were also on antihypertensive therapies, lipid-lowering therapies, and antiplatelet or antithrombotic therapy.

• Primary endpoint: Time to first occurrence of MACE, which included CV death, nonfatal myocardial infarction, and nonfatal stroke

CKD=chronic kidney disease; CV=cardiovascular; CVD=cardiovascular disease; CVOT=cardiovascular outcomes trial; MACE=major adverse cardiovascular event; NS=not significant; OADs=oral antidiabetic drugs.

<sup>a</sup>Treatment arms included patients taking either RYBELSUS® or placebo who were either treatment-naïve or taking OADs and/or insulin.<sup>6</sup>

## **Important Safety Information**

#### **Drug Interactions**

- RYBELSUS<sup>®</sup> stimulates insulin release in the presence of elevated blood glucose concentrations. When initiating RYBELSUS<sup>®</sup>, consider reducing the dose of concomitantly administered insulin secretagogue (such as sulfonylureas) or insulin to reduce the risk of hypoglycemia
- RYBELSUS<sup>®</sup> delays gastric emptying and has the potential to impact the absorption of other oral medications. Closely follow RYBELSUS<sup>®</sup> administration instructions when coadministering with other oral medications and consider increased monitoring for medications with a narrow therapeutic index, such as levothyroxine

#### **Use in Specific Populations**

• **Pregnancy:** Available data with RYBELSUS<sup>®</sup> are not sufficient to determine a drug-associated risk for major birth defects, miscarriage, or other adverse maternal or fetal outcomes. Based on animal reproduction studies, there may be risks to the fetus from exposure to RYBELSUS<sup>®</sup>. Use only if the potential benefit justifies the potential risk to the fetus





There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with RYBELSUS®

21% fewer MACE events with RYBELSUS<sup>®</sup> vs placebo, both in addition to standard of care, which helped establish no increased risk of MACE (*p*=0.17, NS)<sup>7</sup>

Patients were at high CV risk and followed up for a relatively short duration<sup>1</sup>

In the PIONEER 6 trial, **58%** of patients were **65 and older**. The mean age at baseline in this trial was 66 years of age.<sup>1,6</sup>

No overall differences in safety or effectiveness for RYBELSUS<sup>®</sup> have been observed between patients 65 years of age and older and younger adult patients.<sup>1</sup>



# FOR YOUR APPROPRIATE PATIENTS 65 AND OLDER **START RYBELSUS® TODAY** LOWER A1C. DEMONSTRATED CV SAFETY AND WEIGHT LOSS.<sup>1</sup>

**RYBELSUS®** is not indicated for weight loss.



See the Variety of Benefits Medicare Part D Has to Offer at www.medicare.gov/plan-compare

### FOR PERSONALIZED SUPPORT AND HELPFUL INFORMATION, ANY PATIENT CAN SIGN UP FOR RYBELSUS® CONNECT AT [RYBELSUS.COM]

<sup>†</sup>Centers for Medicare and Medicaid Services, Department of Health & Human Services. Medicare & You 2023: The official U.S. government Medicare handbook. https://www.medicare.gov/publications/10050-Medicare-and-You.pdf. Accessed January 3, 2023. CV=cardiovascular.

# **Important Safety Information**

### **Use in Specific Populations**

- Lactation: There are no data on the presence of semaglutide in human milk, the effects on the breastfed infant, or the effects on milk production. Because of the unknown potential for serious adverse reactions in the breastfed infant due to the possible accumulation of salcaprozate sodium (SNAC), an absorption enhancer in RYBELSUS<sup>®</sup>, from breastfeeding and because there are alternative formulations of semaglutide that can be used during lactation, advise patients that breastfeeding is not recommended during treatment with RYBELSUS<sup>®</sup>
- Discontinue RYBELSUS® in women at least 2 months before a planned pregnancy due to the long washout period for semaglutide
- Pediatric Use: Safety and effectiveness of RYBELSUS® have not been established in pediatric patients

#### Please see additional Important Safety Information throughout. Please click here for Prescribing Information, including Boxed Warning.

References: 1. RYBELSUS<sup>®</sup> [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; January 2023. 2. Data from MMIT Formulary bridge through January: 2023 Nomenclature, and Xponent PlanTrak using week-ending 1/20/2023; only considers bridged volume; excludes cash and mail order data. 3. IQVIA LAAD 2022, Medicare patients. 4. Rodbard HW, Rosenstock J, Canani LH, et al; for the PIONEER 2 Investigators. Oral semaglutide versus empagliflozin in patients with type 2 diabetes uncontrolled on metformin: the PIONEER 2 trial. *Diabetes Care*. 2019;42(12):2272-2281. 5. Rosenstock J, Allison D, Birkenfeld AL, et al; for the PIONEER 3 Investigators. Effect of additional oral semaglutide vs sitagliptin on glycated hemoglobin in adults with type 2 diabetes uncontrolled with metformin alone or with sulfonylurea: the PIONEER 3 randomized clinical trial. *JAMA*. 2019;321(15):1466-1480. 6. Data on file, Novo Nordisk Inc. 7. Husain M, Birkenfeld AL, Donsmark M, et al; for the PIONEER 6 Investigators. Oral semaglutide and cardiovascular outcomes in patients with type 2 diabetes. *N Engl J Med*. 2019;381(9):841-851.



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