



## **TheracosBio and SmithRx Collaborate to Offer Newly Approved Diabetes Drug Brenzavvy™ (bexagliflozin) to Members with Type 2 Diabetes**

**Marlborough, MA and San Francisco** – August 17, 2023 – [TheracosBio](#) and SmithRx, a next-generation pharmacy benefits management (PBM) company, today announced that SmithRx will offer access to BRENZAVVY™ (bexagliflozin), TheracosBio’s FDA-approved oral medication for adults with type 2 diabetes, through its partnership with Mark Cuban Cost Plus Drug Company (Cost Plus Drugs). Working with TheracosBio and Cost Plus Drugs, SmithRx now provides BRENZAVVY as an option following its launch in July 2023.

BRENZAVVY is available through the Cost Plus Drugs online mail-order pharmacy for \$47.85 plus shipping and handling for a 30-day supply. BRENZAVVY is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes, including those with chronic kidney disease that has progressed to stage 3. BRENZAVVY is not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus.

“TheracosBio’s commercial strategy for BRENZAVVY is focused on transparent pricing and expanding the population of patients who could benefit from SGLT2 inhibitors without cost-related concerns,” said Brian Connelly, President and CEO of TheracosBio. “SmithRx has partnered with Cost Plus Drugs because they share our commitment to delivering effective, lower-cost drugs to patients who need them. We are pleased that this partnership will further expand patient access to BRENZAVVY.”

“Unlike traditional PBMs, SmithRx prioritizes transparency and up-front cost savings. Diabetes medications are most employers’ top category of drug expense, so we’re looking for ways to make care more affordable for employers and patients,” said Jake Frenz, CEO and founder of SmithRx. “We’re excited to work with TheracosBio and Cost Plus Drugs to bring BRENZAVVY to our members.”

About 37 million Americans (~11% of the population) have diabetes and current estimates show that 1 in 3 Americans will develop the chronic disease sometime in their lifetime. Diabetes is the most expensive chronic condition in the U.S. and accounts for 1 of every 4 dollars spent on healthcare. Diabetes treatment and care costs employers billions per year in direct and indirect costs.

“We started SmithRx because the PBM model was broken,” added Frenz. “Our technology platform combined with our innovative sourcing channels allow us to find the lowest prices and pass through the savings to plan sponsors and patients. As the diabetes treatment landscape has evolved this year it has created a number of opportunities to lower overall drug costs and increase access to patients.”

SmithRx works with more than 300 broker offices and serves more than 3,500 employers coast to coast. Employers that work with SmithRx save significantly on their pharmacy benefit costs - often 30% or more - providing critical relief to the bottom line of main street businesses throughout the country.

To learn more about BRENZAVVY and for full prescribing information visit <https://www.brenzavvy.com>. To report suspected adverse reactions, contact TheracosBio at 1-855-BRENZAVVY (1-855-273-6928) or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

### **Important Safety Information about BRENZAVVY**

#### Diabetic Ketoacidosis in Patients with Type 1 Diabetes Mellitus and Other Ketoacidosis

In patients with type 1 diabetes mellitus, BRENZAVVY significantly increases the risk of diabetic ketoacidosis, a life-threatening event, beyond background rate. In placebo-controlled trials of patients with type 1 diabetes mellitus, the risk of ketoacidosis was markedly increased in patients who received sodium glucose transporter 2 (SGLT2) inhibitors compared to patients who received placebo. BRENZAVVY is not indicated for glycemic control in patients with type 1 diabetes mellitus.

Type 2 diabetes mellitus and pancreatic disorders (e.g., history of pancreatitis or pancreatic surgery) are also risk factors for ketoacidosis. There have been postmarketing reports of fatal events of ketoacidosis in patients with type 2 diabetes mellitus using SGLT2 inhibitors, including BRENZAVVY.

Precipitating conditions for diabetic ketoacidosis or other ketoacidosis include acute febrile illness, reduced caloric intake, ketogenic diet, surgery, insulin dose reduction, volume depletion, and alcohol abuse.

Signs and symptoms are consistent with dehydration and severe metabolic acidosis and include nausea, vomiting, abdominal pain, generalized malaise, and shortness of breath. Blood glucose levels at presentation may be below those typically expected for diabetic ketoacidosis (e.g., less than 250 mg/dL). Ketoacidosis and glucosuria may persist longer than typically expected. Urinary glucose excretion persists for 3 days after discontinuing BRENZAVVY; however, there have been postmarketing reports of ketoacidosis and glucosuria lasting greater than 6 days and some up to 2 weeks after discontinuation of SGLT2 inhibitors.

Consider ketone monitoring in patients at risk for ketoacidosis if indicated by the clinical situation. Assess for ketoacidosis regardless of presenting blood glucose levels in patients who present with signs and symptoms consistent with severe metabolic acidosis. If ketoacidosis is suspected, discontinue BRENZAVVY, promptly evaluate, and treat ketoacidosis, if confirmed. Monitor patients for resolution of ketoacidosis before restarting BRENZAVVY.

Withhold BRENZAVVY, if possible, in temporary clinical situations that could predispose patients to ketoacidosis. Resume BRENZAVVY when the patient is clinically stable and has resumed oral intake.

Educate all patients on the signs and symptoms of ketoacidosis and instruct patients to discontinue BRENZAVVY and seek medical attention immediately if signs and symptoms occur.

### Lower Limb Amputation

An increased incidence of lower limb amputations occurred in BRENZAVVY-treated patients compared to placebo-treated patients (8.3 versus 5.1 events per 1,000 patient-years) in a randomized, placebo-controlled trial evaluating patients with type 2 diabetes who had either established cardiovascular disease (CVD) or were at risk for CVD.

Of the 23 BRENZAVVY-treated patients who had amputations, 15 were amputations of the toe and midfoot and 8 were amputations above and below the knee. Some patients had multiple amputations.

Lower limb infections, gangrene, ischemia, and osteomyelitis were the most common precipitating medical events leading to the need for an amputation. The risk of amputation was highest in patients with a baseline history of prior amputation, peripheral vascular disease, and neuropathy.

Before initiating BRENZAVVY, consider factors in the patient history that may predispose to the need for amputations, such as a history of prior amputation, peripheral vascular disease, neuropathy and diabetic foot ulcers. Counsel patients about the importance of routine preventative foot care. Monitor patients receiving BRENZAVVY for signs and symptoms of infection (including osteomyelitis), new pain or tenderness, sores or ulcers involving the lower limbs, and discontinue BRENZAVVY if these complications occur.

### Volume Depletion

BRENZAVVY can cause intravascular volume contraction which may sometimes manifest as symptomatic hypotension or acute transient changes in creatinine. There have been postmarketing reports of acute kidney injury, some requiring hospitalization and dialysis, in patients with type 2 diabetes mellitus receiving SGLT2 inhibitors. Patients with impaired renal function (eGFR less than 60 mL/min/1.73 m<sup>2</sup>), elderly patients, patients with low systolic blood pressure, or patients on loop diuretics may be at increased risk for volume depletion or hypotension. Before initiating BRENZAVVY in patients with one or more of these characteristics, assess volume status and renal function. In patients with volume depletion, correct this condition before initiating BRENZAVVY. Monitor for signs and symptoms of volume depletion, and renal function after initiating therapy.

### Urosepsis and Pyelonephritis

There have been reports of serious urinary tract infections, including urosepsis and pyelonephritis, requiring hospitalization in patients receiving SGLT2 inhibitors, including BRENZAVVY. Treatment with SGLT2 inhibitors, including BRENZAVVY, increases the risk for urinary tract infections. Evaluate patients for signs and symptoms of urinary tract infections and treat promptly, if indicated.

### Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues

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

### Necrotizing Fasciitis of the Perineum (Fournier's Gangrene)

Reports of necrotizing fasciitis of the perineum (Fournier’s Gangrene), a rare but serious and life-threatening necrotizing infection requiring urgent surgical intervention, have been identified in postmarketing surveillance in patients with diabetes mellitus receiving SGLT2 inhibitors. Cases have been reported in both females and males. Serious outcomes have included hospitalization, multiple surgeries, and death.

Patients treated with BRENZAVVY presenting with pain or tenderness, erythema, or swelling in the genital or perineal areas, along with fever or malaise, should be assessed for necrotizing fasciitis. If suspected, start treatment immediately with broad-spectrum antibiotics and, if necessary, surgical debridement. Discontinue BRENZAVVY, closely monitor blood glucose levels, and provide appropriate alternative therapy for glycemic control.

### Genital Mycotic Infections

BRENZAVVY 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.

The most common adverse reactions (incidence > 5%) were female genital mycotic infections, urinary tract infection and increased urination.

### **About SmithRx**

Pharmacy costs have been rising rapidly over the past decade, putting strain on patients and employers throughout the country. SmithRx, a privately-held technology company was founded in 2016 with the goal of reducing these costs by operating with a 100 percent transparent, pass-through PBM business model. With this approach, SmithRx is forging new pathways to affordable drugs while giving clients full access to their data. SmithRx’s simple per member per month (PMPM) revenue model contrasts with legacy PBMs’ use of spread pricing and is fully aligned with its clients’ affordability goals. Learn more at <https://smithrx.com/>.

### **About TheracosBio**

TheracosBio develops novel therapeutics for diseases with significant societal impact. The mission of TheracosBio is to expand access to new medications for patients with common diseases.

### **About Mark Cuban Cost Plus Drug Company**

The Mark Cuban Cost Plus Drug Company, PBC (Cost Plus Drugs) aims to fundamentally change the way the pharmaceutical industry operates. As a public-benefit corporation, its social mission of improving public health is just as important as the bottom line. Cost Plus Drugs transparently charges a standard markup on every drug it sells. The [costplusdrugs.com](https://costplusdrugs.com) online pharmacy launched in January 2022 now carries over 1,000 prescription products, delivered by mail to thousands of happy customers every day. Cost Plus Drugs is working with health plans, managed-care organizations, pharmacy benefits managers (PBMs) and self-insured employers to bring these same savings to employer-sponsored benefit plans nationwide.

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