TheracosBio and BAMCO Africa Partner to Bring Affordably Priced Diabetes Medication to Sub-Saharan Africa

Marlborough, MA & Kigali, Rwanda – October 17, 2024 – TheracosBio and BAMCO Africa, Inc. today announced they have partnered to bring BRENZAVVY® (bexagliflozin), an FDA-approved oral sodium-glucose cotransporter 2 (SGLT2) inhibitor for the treatment of type 2 diabetes, to patients in Sub-Saharan Africa. BAMCO is a pioneering healthcare company committed to providing access to innovative therapies for patients in Sub-Saharan Africa. BAMCO was carefully selected by TheracosBio due to the two companies' shared mission and BAMCO's strong leadership team and depth of experience in the region.

"The mission of TheracosBio is to bring effective treatments to patients in need at affordable prices and BAMCO is working to do the same for patients in Sub-Saharan Africa" said Brian Connelly, CEO of TheracosBio. "We are excited to work with BAMCO to provide doctors and their patients in the region with access to BRENZAVVY, a cost-effective therapy to manage type 2 diabetes," Mr. Connelly added.

"BAMCO's mission is that all patients in Sub-Saharan Africa deserve better and need to have equitable and timely access to the latest innovative treatments that save and improve their lives." said Markus Gemuend, CEO of BAMCO Africa. He added: "We are thrilled to partner with TheracosBio to provide access to BRENZAVVY for patients with type 2 diabetes, a fast growing health burden, and engage with medical communities to launch this innovative treatment in Sub-Saharan Africa".

BRENZAVVY is available as 20 mg oral tablets to be taken once daily, in the morning with or without food. BRENZAVVY treatment can be initiated in adults with type 2 diabetes with an estimated glomerular filtration rate (eGFR) greater than or equal to 30 mL/min/1.73 m^2. Patients with eGFR between 30 and 59 mL/min/1.73 m^2 are said to be in stage 3 chronic kidney disease. Phase 3 clinical studies have shown BRENZAVVY significantly reduces hemoglobin A1c and fasting blood sugar after 24 weeks, either as a monotherapy, in combination with metformin, or as an add-on to standard-of-care treatment consisting of a variety of regimens, including metformin, sulfonylureas, insulin, DPP4 inhibitors or combinations of these agents. Although BRENZAVVY is not approved for weight loss or blood pressure reduction, modest decreases in both weight and blood pressure have been observed in the clinical program.

To learn more about BRENZAVVY, please visit https://www.brenzavvy.com.

To learn more about TheracosBio, please visit https://theracosbio.com.

To learn more about BAMCO, please visit https://bamcoafrica.com

INDICATION AND SAFETY SUMMARY WITH WARNINGS

BRENZAVVY is not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus.

BRENZAVVY is contraindicated in patients who are hypersensitive to bexagliflozin or any other ingredient in the BRENZAVVY tablet. The most common side effects of taking BRENZAVVY include female genital mycotic infections, urinary tract infections, and changes in urination, but more serious side effects are possible (see below).

For BRENZAVVY 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.

Important Safety Information about BRENZAVVY

Limitation of Use: BRENZAVVY (bexagliflozin) is not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients.

Contraindications

BRENZAVVY is contraindicated in patients with hypersensitivity to bexagliflozin or any excipient in BRENZAVVY. Anaphylaxis and angioedema have been reported with sodium-glucose cotransporter 2 (SGLT2) inhibitors.

Warnings and Precautions

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

BRENZAVVY increases the risk of life-threatening ketoacidosis in patients with type 1 diabetes. Type 2 diabetes and pancreatic disorders are also risk factors for ketoacidosis and fatal events of ketoacidosis have been reported in patients with type 2 diabetes using SGLT2 inhibitors. Precipitating conditions for diabetic ketoacidosis or other ketoacidosis include under-insulinization due to insulin dose reduction or missed insulin doses, acute febrile illness, reduced caloric intake, ketogenic diet, surgery, volume depletion, and alcohol abuse. Signs and symptoms of diabetic ketoacidosis are consistent with dehydration and severe metabolic acidosis and include nausea, vomiting, abdominal pain, generalized malaise, and shortness of breath. Assess patients who present with signs and symptoms of metabolic ketoacidosis, regardless of blood glucose levels. If suspected, discontinue BRENZAVVY, treat promptly and monitor for resolution before restarting. Consider ketone monitoring in patients with type 1 diabetes mellitus as well as in others at risk for ketoacidosis. Withhold BRENZAVVY in clinical situations known to predispose to ketoacidosis and resume when clinically stable. 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

Lower limb amputations have been observed in patients treated with BRENZAVVY in a study of 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's 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 receiving BRENZAVVY about the importance of routine preventative foot care and monitor for signs and symptoms of diabetic foot infection (including osteomyelitis), new pain or tenderness, sores or ulcers involving the lower limbs, and institute appropriate treatment.

Volume Depletion
BRENZAVVY can cause intravascular volume contraction which may sometimes manifest as symptomatic hypotension or acute transient changes in creatinine. Acute kidney injury requiring hospitalization and dialysis has been reported in patients with type 2 diabetes receiving SGLT2 inhibitors. Before initiating, assess volume status and renal function in patients with impaired renal function (eGFR less than 60 mL/min/1.73 m^2), elderly patients, patients with low systolic blood pressure, or patients on loop diuretics. In patients with volume depletion, correct this condition. After initiating, monitor for signs and symptoms of volume depletion and renal function.

Urosepsis and Pyelonephritis
Serious urinary tract infections including urosepsis and pyelonephritis requiring hospitalization have been identified in patients receiving SGLT2 inhibitors, including BRENZAVVY. Treatment with BRENZAVVY increases the risk for urinary tract infections. Evaluate patients for signs and symptoms of urinary tract infections and treat them promptly.

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)
Serious, life-threatening cases requiring urgent surgical intervention have been identified in postmarketing surveillance in both males and females with diabetes mellitus receiving SGLT2 inhibitors. Serious outcomes have included hospitalization, multiple surgeries, and death. Assess patients presenting with pain or tenderness, erythema, or swelling in the genital or perineal areas, along with fever or malaise. If suspected, start treatment, and discontinue BRENZAVVY.

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.

MOST COMMON ADVERSE REACTIONS (>5%): Female genital mycotic infections, urinary tract infection and increased urination.

USE IN SPECIFIC POPULATIONS

- Pregnancy: BRENZAVVY is not recommended during the second and third trimesters.
- Lactation: BRENZAVVY is not recommended when breastfeeding.

- Geriatric patients: There is a higher incidence of adverse reactions related to volume depletion.
- Renal Impairment: There is a higher incidence of adverse reactions related to reduced renal function.
- Hepatic Impairment: BRENZAVVY is not recommended for patients with severe hepatic impairment.

DRUG INTERACTIONS:

Inducers of UGT1A9 could result in more rapid clearance of BRENZAVVY by metabolism. Doses of insulin and sulfonylureas may need to be reduced to offset the action of BRENZAVVY. The safety of BRENZAVVY is compromised when it is coupled with insulin or an insulin secretagogue (sulfonylureas and meglitinides – the latter rarely used in the US). Lithium carbonate is used as a mood stabilizer in bipolar disorder. Lithium ions might be preferentially (compared to sodium ions) taken up with glucose in the kidney. Empirical evidence has shown that lithium levels can be lower when SGLT2 inhibitors are administered. SGLT2 inhibitors produce pronounced glucosuria, which makes urine testing for glucose diagnostically useless. Measurements of 1,5-anhydroglucitol are also compromised.

For additional important safety information about BRENZAVVY, please see the full Prescribing Information.

About TheracosBio

TheracosBio was founded in 2000 and develops affordably priced 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 BAMCO

Since our founding in 2023, BAMCO Africa has prioritized oncology and cardio-metabolic diseases, working closely with governments and other partners across select Sub-Saharan African countries. We collaborate to address unique healthcare challenges, co-create sustainable solutions, and implement them for long-term societal and patient benefit. The mission of BAMCO Africa is to make standard of care medicines affordable and available in Sub Saharan Africa through partnerships, medical education, and clinical research.

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