NEW DRUGS

BEXAGLIFLOZIN
(Brenzavvy—TheracosBio)

Drug class: Brenzavvy is a sodium-glucose cotransporter-2 (SGLT-2) inhibitor.

Indication: Brenzavvy is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Recommended dosage and administration: The recommended dose is 20 mg once daily, taken in the morning, with or without food. The tablet should not be crushed or chewed. Renal function should be assessed prior to initiation of Brenzavvy and as clinically indicated. Correct volume depletion before initiation occurs.

Common adverse effects: The most common adverse reactions in patients taking Brenzavvy are female genital mycotic infections, urinary tract infection, and increased urination.

Warnings and precautions: Brenzavvy is not recommended in patients with type 1 diabetes mellitus as it may increase the risk of diabetic ketoacidosis in these patients. Use of Brenzavvy is also not recommended in patients with an eGFR <30 mL/min/1.73 m^2. Brenzavvy is contraindicated in patients with a hypersensitivity to bexagliflozin or any excipient in Brenzavvy and patients on dialysis. Patients of reproductive potential should be advised of the potential risk to a fetus especially during the second and third trimesters of pregnancy. Brenzavvy is not recommended during the second and third trimesters of pregnancy or while breastfeeding. In geriatric patients, there is a higher incidence of adverse reactions related to volume depletion. In patients with renal impairment, there is a higher incidence of adverse reactions related to reduced renal function. Brenzavvy is not recommended for use in patients with hepatic impairment.

Assess patients who present with signs and symptoms of metabolic acidosis for ketoacidosis, regardless of blood glucose level. If suspected, discontinue, evaluate, and treat promptly. Before initiating treatment with Brenzavvy, consider risk factors for ketoacidosis. Patients may require monitoring and temporary discontinuation of therapy in clinical situations known to predispose to ketoacidosis. Consider factors that may increase the risk for amputations before initiating Brenzavvy. Monitor patients for signs and symptoms of infection or ulcers of the lower limbs and discontinue if these occur. Before initiating Brenzavvy, assess and correct volume status in patients with impaired renal function or low systolic blood pressure, older patients, or those on diuretics.

Evaluate patients for signs and symptoms of urinary tract infections and treat promptly, if indicated. Consider a lower dose of insulin or insulin secretagogue to reduce the risk of hypoglycemia when used in combination with Brenzavvy. Serious, life-threatening cases of necrotizing fasciitis of the perineum have occurred in both females and males treated with SGLT-2 inhibitors.

Assess patients presenting with pain, tenderness, erythema, or swelling in the genital or perineal area, along with fever or malaise. Monitor and treat genital mycotic infections as appropriate.

PIRTOBRUTINIB
(Jaypirca—Loxo Oncology)

Drug class: Jaypirca is a kinase inhibitor.

Indication: Jaypirca is indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after at least 2 lines of systemic therapy, including a BTK inhibitor.

Recommended dosage and administration: The recommended dosage is 200 mg orally once daily, swallowed whole with water, with or without food. Reduce dose in patients with severe renal impairment.

Common adverse effects: The most common adverse reactions in patients with MCL are fatigue, musculoskeletal pain, diarrhea, edema, dyspnea, pneumonia, bruising, decreased neutrophil count, decreased lymphocyte count, and decreased platelet count.

Warnings and precautions: Avoid concomitant use with strong CYP3A inhibitors. If concomitant use is unavoidable, reduce the Jaypirca dose. Avoid concomitant use with strong or moderate CYP3A inducers. If concomitant use is unavoidable, increase the Jaypirca dose. For substrates where minimal concentration changes may increase the risk of adverse reactions, follow recommendations for coadministration with CYP2C8, CYP2C19, CYP3A, P-gp, or BRCP inhibitors provided in their approved product labeling. Monitor for signs and symptoms of infection, evaluate promptly, and treat. Monitor for bleeding as hemorrhage may occur. Monitor complete blood counts during treatment. Monitor for symptoms of arrhythmias such as atrial fibrillation and atrial flutter. Other malignancies have developed, including skin cancers and other carcinomas. Monitor and advise patients to use sun protection. Jaypirca can cause fetal harm. Advise patients of reproductive potential of possible risk to a fetus and to use effective contraception. Jaypirca should not be used while breastfeeding.

ELACESTRANT
(Orserdu—Stemline Therapeutics)

Drug class: Orserdu is an estrogen receptor antagonist.

Indication: Orserdu is indicated for treatment of postmenopausal women or adult men, with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy.

Recommended dosage and administration: The recommended dosage of Orserdu is one 345 mg tablet taken orally, once daily, with food.

Dose interruption, reduction, or permanent discontinuation may be required due to adverse reactions.

Common adverse effects: The most common adverse reactions in patients taking Orserdu were musculoskeletal pain, nausea, increased cholesterol, increased AST, increased triglycerides, fatigue, decreased hemoglobin, vomiting, increased ALT, decreased sodium, increased creatinine, decreased appetite, diarrhea, headache, constipation, abdominal pain, hot flashes, and dyspepsia.

Warnings and precautions: Orserdu can cause fetal harm. Patients should be advised of the potential risk to a fetus and to use effective contraception. Patients should be advised not to breastfeed while taking Orserdu. Avoid use in patients with severe hepatic impairment. Reduce the dosage for patients with moderate hepatic impairment. Avoid concomitant use with strong or moderate CYP3A4 inducers and inhibitors. Orserdu may cause hypercholesterolemia and hypertriglyceridemia. Monitor lipid profile prior to starting treatment and periodically thereafter.

NEW DOSAGE FORMS

RISPERIDONE
(Rykindo—Luye Pharma)

Drug class: Risperidone is an atypical antipsychotic.

Indication: Rykindo is indicated for the treatment of schizophrenia in adults and as monotherapy or as adjunctive therapy to lithium or valproate for the maintenance treatment of bipolar I disorder in adults.

Recommended dosage and administration: Prior to initiating treatment with Rykindo, patients must show tolerability with oral risperidone. Rykindo should be administered by I.M. injection in the gluteal muscle by a health care provider. The recommended dosage of Rykindo is 25 mg I.M. every 2 weeks. Patients not responding to 25 mg may benefit from 37.5 mg or 50 mg. Dosage should not be titrated more frequently than every 4 weeks. The maximum recommended dosage is 50 mg every 2 weeks. The first dose of Rykindo should be administered along with 7 days of oral risperidone. In patients with renal or hepatic impairment, titrate with oral risperidone up to at least 2 mg prior to initiating treatment with Rykindo. A starting dose of 12.5 mg may be appropriate for some patients.

Common adverse effects: The most common adverse reactions in patients with schizophrenia were headache, parkinsonism, dizziness, akathisia, fatigue, constipation, dyspepsia, sedation, weight increase, pain in extremity, and dry mouth. The most common adverse reactions in patients with bipolar disorder were increased weight, tremor, and parkinsonism.

Boxed warning: Older patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Rykindo is not approved for use in patients with dementia-related psychosis.

Other warnings and precautions: Rykindo is contraindicated in patients with a known hypersensitivity to risperidone, paliperidone, or to any components in Rykindo. When taken with strong CYP2D6 inhibitors, there may be an increased risperidone plasma concentration. When taken with strong CYP3A4 inducers, there may be a decreased plasma concentration of risperidone. Rykindo may cause extrapyramidal and withdrawal symptoms in neonates with third trimester exposure. There is an increased risk of cerebrovascular adverse reactions in older patients with dementia-related psychosis. If neuroleptic malignant syndrome occurs, manage with immediate discontinuation and close monitoring. Tardive dyskinesia may occur. Monitor for hyperglycemia, dyslipidemia, and weight gain. Prolactin elevations may occur and persist during chronic administration of Rykindo. Hyperprolactinemia, when associated with hypogonadism, can lead to decreased bone density in males and females. Monitor heart rate and blood pressure and warn patients with known cardiovascular disease or cerebrovascular disease, and risk of dehydration or syncope. Perform complete blood cell counts in patients with a history of clinically significant low white blood cell count or history of leukopenia or neutropenia. Consider discontinuing Rykindo if a clinically significant decline in white blood cell count occurs in the absence of other causative factors. There is potential for cognitive and motor impairment so patients should use caution when operating machinery. Use cautiously in patients with a history of seizures or with conditions that potentially lower the seizure threshold. Priapism has been reported during postmarketing use of other risperidone products. Severe priapism may require surgical intervention. ■

Also in this issue

Airsupra: The first and only rescue inhaler approved to treat symptoms of asthma (page 16)