NEW DRUGS

ZAVEGEPANT
(Zavzpret—Pfizer)

Drug class: Zavzpret is a calcitonin gene-related peptide receptor antagonist.

Indication: Zavzpret is indicated for the acute treatment of migraine with or without aura in adults. It is not indicated for the preventative treatment of migraine.

Recommended dosage and administration: The recommended dose is 10 mg given as a single spray in one nostril, as needed. The maximum dose in a 24-hour period is 10 mg or 1 spray. The safety of treating more than 8 migraines in a 30-day period has not been established.

Common adverse effects: The most common adverse reactions in patients being treated with Zavzpret were taste disorders, nausea, nasal discomfort, and vomiting.

Warnings and precautions: Zavzpret is contraindicated in patients with a history of hypersensitivity reaction to zavegepant or to any components of Zavzpret. If a serious hypersensitivity reaction occurs, discontinue Zavzpret and initiate appropriate therapy. Hypersensitivity reactions including facial swelling and urticaria have occurred. Avoid use in patients with severe hepatic impairment or a creatinine clearance of <30 mL/min. Avoid use of Zavzpret with drugs that inhibit or induce OATP1B3 or NTCP transporters. Avoid use of intranasal decongestants. If unavoidable, administer intranasal decongestants at least 1 hour after Zavzpret administration.

TROFINETIDE
(Daybue—Acadia Pharmaceuticals)

Drug class: The mechanism by which trofinetide exerts therapeutic effects in patients with Rett syndrome is unknown.

Indication: Daybue is indicated for the treatment of Rett syndrome in adults and pediatric patients 2 years and older.

Recommended dosage and administration: Recommended dosage is twice daily (morning and evening), according to patient weight. Daybue can be administered orally or via gastrostomy tube, with or without food. Doses administered via gastrojejunal (GJ) tubes must be administered through the G-port. Depending on the weight of the patient, doses can range from 5,000 mg (25 mL) twice daily to 12,000 mg (60 mL) twice daily.

Common adverse effects: The most common adverse reactions were diarrhea and vomiting.

Warnings and precautions: Most patients experience diarrhea during treatment with Daybue. Advise patients to stop taking laxatives before starting treatment. If diarrhea occurs, patients should start antidiarrheal treatment, increase oral fluids, and notify their health care provider. Interrupt, reduce dose, or discontinue Daybue if severe diarrhea occurs or if dehydration is suspected. Weight loss may occur in patients treated with Daybue. Monitor weight and interrupt, reduce dose, or discontinue Daybue if significant weight loss occurs. Daybue is not recommended in patients with moderate to severe renal impairment. Closely monitor for adverse reactions if Daybue is used concomitantly with orally administered CYP3A4 sensitive substrates for which a small change in substrate plasma concentration may lead to serious toxicities. Avoid concomitant use with OATP1B1 and OATP1B3 substrates for which a small change in substrate plasma concentration may lead to serious toxicities.

LENIOLISIB
(Joenja—Pharming)

Drug class: Joenja is a kinase inhibitor.

Indication: Joenja is indicated for the treatment of activated phosphoinositide 3-kinase delta syndrome (APDS) in adult and pediatric patients 12 years and older.

Recommended dosage and administration: The recommended dosage is 70 mg administered orally twice daily approximately 12 hours apart, with or without food, in adult and pediatric patients 12 years and older and weighing greater than or equal to 45 kg. Verify pregnancy status in patients of reproductive potential prior to initiating treatment.

Common adverse effects: The most common adverse reactions were headache, sinusitis, and atopic dermatitis.

Warnings and precautions: Joenja may cause fetal harm. Advise patients of the potential risk to a fetus and to use effective contraception. Live, attenuated vaccinations may be less effective if administered during Joenja treatment. Advise patients not to breastfeed during treatment. Use in patients with moderate to severe hepatic impairment is not recommended. Avoid concomitant use with strong CYP3A4 inhibitors, strong or moderate CYP3A4 inducers, CYP1A2 metabolized drugs with a narrow therapeutic index, and BCRP, OATP1B1, and OATP1B3 substrates.

SPARSENTAN
(Filspari—Travere Therapeutics)

Drug class: Filspari is an endothelin and angiotensin II receptor antagonist.

Indication: Filspari is indicated to reduce proteinuria in adults with

primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatine ratio greater than or equal to 1.5 g/g.

Recommended dosage and administration: Prior to initiating treatment with Filspari, discontinue use of renin-angiotension-aldosterone system inhibitors, endothelin receptor antagonists (ERAs), or aliskiren. Initiate treatment with Filspari at 200 mg orally once daily. After 14 days, increase to the recommended dose of 400 mg once daily, as tolerated. When resuming treatment with Filspari after an interruption, consider titration of Filspari, starting at 20 mg once daily. After 14 days, increase to the recommended dose of 400 mg once daily. Instruct patients to swallow tablets whole with water prior to the morning or evening meal.

Common adverse effects: The most common adverse reactions are peripheral edema, hypotension, dizziness, hyperkalemia, and anemia.

Warnings and precautions: Filspari is contraindicated in pregnancy and patients should be advised not to breastfeed during treatment. Do not administer Filspari with angiotensin receptor blockers, ERAs, or aliskiren. Hepatotoxicity, hypotension, acute kidney injury, hyperkalemia, and fluid retention may occur. It has not been established whether Filspari slows kidney function decline in patients with IgAN. Avoid concomitant use with strong CYP3A inhibitors and inducers. Increased sparsentan exposure may lead to adverse reactions if Filspari is used with moderate CYP3A inhibitors. Avoid use of antacids within 2 hours before or after use of sparsentan. Avoid concomitant use with acid reducing agents. Monitor for signs of worsening renal function if used with NSAIDs. If Filspari is used concomitantly with CYP2B6, 2C9, and 2C19 substrates, monitor for efficacy of the concurrently administered substrates as decreased exposure of these substrates may occur. Avoid concomitant use with sensitive P-gp and BCRP substrates. Monitor serum potassium frequently if Filspari is used with agents that increase serum potassium.

NEW INDICATIONS

ABEMACICLIB
(Verzenio—Eli Lilly and Company)

Drug class: Verzenio is a kinase inhibitor.

Indication: Verzenio is indicated in combination with endocrine therapy for the adjuvant treatment of adult patients with HR-positive, HER2-negative, node-positive, early breast cancer at high risk of recurrence, in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer, in combination with fulvestrant for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy, and as monotherapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.

Recommended dosage and administration: Verzenio tablets are taken orally with or without food. The recommended starting dose in combination with fulvestrant, tamoxifen, or an aromatase inhibitor is 150 mg twice daily. The recommended starting dose as monotherapy is 200 mg twice daily. Dosing interruption or dose reductions may be required based on individual safety and tolerability.

Common adverse effects: The most common adverse reactions were diarrhea, neutropenia, nausea, abdominal pain, infections, fatigue, anemia, leukopenia, decreased appetite, vomiting, headache, alopecia, and thrombocytopenia.

Warnings and precautions: Advise patients not to breastfeed during therapy with Verzenio. Avoid concomitant use of ketoconazole. Reduce the Verzenio dose with concomitant use of other strong or moderate CYP3A inhibitors. Avoid concomitant use with strong or moderate CYP3A inducers. Verzenio can cause severe cases of diarrhea, associated with dehydration and infections. Instruct patients at first sign of loose stools to initiate antidiarrheal therapy, increase oral fluids, and notify their health care provider. Monitor complete blood counts prior to the start of Verzenio therapy, every 2 weeks for the first 2 months, monthly for the next 2 months, and as clinically indicated. Severe and fatal cases of interstitial lung disease (ILD) and pneumonitis have been reported. Monitor for clinical symptoms or radiological changes indicative of ILD/pneumonitis. Permanently discontinue Verzenio in all patients with Grade 3 or 4 ILD or pneumonitis. Increases in serum transaminase levels have been observed. Perform liver function tests (LFTs) before initiating treatment with Verzenio. Monitor LFTs every 2 weeks for the first 2 months, monthly for the next 2 months, and as clinically indicated. Monitor patients for signs and symptoms of thrombosis and pulmonary embolism and treat as medically appropriate. Verzenio can cause fetal harm. Advise patients of potential risk to a fetus and to use effective contraception. ■

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Brenzavvy approved by FDA to improve glycemic control in patients with type 2 diabetes (page 21)