NEW DRUGS

FUTIBATINIB
(Lytgobi—Taiho Oncology)

Drug class: Futibatinib is a kinase inhibitor.

Indication: Lytgobi is indicated for the treatment of adult patients with previously treated, unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements.

Recommended dosage and administration: The recommended dose is 20 mg orally (five 4-mg tablets) once daily until disease progression or unacceptable toxicity occurs. The tablets should be swallowed whole, with or without food.

Common adverse effects: The most common adverse effects are nail toxicity, musculoskeletal pain, constipation, diarrhea, fatigue, dry mouth, alopecia, stomatitis, abdominal pain, dry skin, arthralgia, dysgeusia, dry eye, nausea, decreased appetite, urinary tract infection, palmar-plantar erythrodysesthesia syndrome, and vomiting.

Warnings and precautions: Avoid coadministration with dual P-glycoprotein and strong CYP3A inhibitors and dual P-glycoprotein and strong CYP31 inducers. Lytgobi should not be used in patients who are breastfeeding.

Lytgobi can cause retinal pigment epithelial detachment. A comprehensive ophthalmological examination including optical coherence tomography should be performed prior to initiation of therapy, every 2 months for the first 6 months, every 3 months thereafter, and urgently at any time for visual symptoms. Increases in phosphate levels can cause hyperphosphatemia leading to soft tissue mineralization, calcinosis, nonuremic calciphylaxis, and vascular calcification.

Patients should be monitored for hyperphosphatemia and the dose of Lytgobi should be withheld, reduced, or permanently discontinued based on the duration and severity. Lytgobi can cause fetal harm. Patients of reproductive potential should be advised on this potential risk and to use effective contraception.

NEW DOSAGE FORM

FUROSEMIDE
(Furoscix—scPharmaceuticals Inc.)

Drug class: Furosemide is a loop diuretic.

Indication: Furoscix is indicated for the treatment of congestion due to fluid overload in adults with New York Heart Association (NYHA) Class II/III chronic heart failure.

Recommended dosage and administration: The single use, on-body infusor is preprogrammed to deliver 30 mg of Furoscix over the first hour then 12.5 mg per hour for the subsequent 4 hours.

Common adverse effects: The most common adverse effects are administration side and skin reactions, erythema, bruising, edema, and infusion site pain.

Warnings and precautions: Furoscix is contraindicated in patients with anuria, hypersensitivity to furosemide or medical adhesives, hepatic cirrhosis, or ascites.

Furoscix is not indicated for emergency situations or in patients with acute pulmonary edema. It is not for chronic use and should be replaced with oral diuretics as soon as practical.

Serum electrolytes, CO_2, BUN, creatinine, glucose, and uric acid should be monitored regularly. Avoid use with aminoglycoside antibiotics as the combination increases the potential of ototoxicity.

Avoid combination with ethacrynic acid due to risk of ototoxicity. When used with salicylates, there is risk of salicylate toxicity. When combined with cisplatin and nephrotoxic drugs, there is a risk of ototoxicity and nephrotoxicity. Use of Furoscix with lithium increases risk of lithium toxicity.

In patients taking adrenergic blocking drugs, there is risk of potentiation. There is risk of toxicity potentiation when Furoscix is used in combination with drugs that undergo renal tubular secretion.

NEW INDICATION

COBIMETINIB FUMARATE
(Cotellic—Genentech Inc.)

Drug class: Cobimetinib fumarate is a kinase inhibitor.

Amoxicillin supply constraints

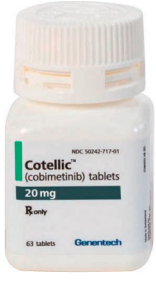
On October 28, 2022, FDA listed a shortage for the oral powder dosage form of amoxicillin. Amoxicillin is one of the most commonly prescribed antibiotics, especially for pediatric patients, and is used to treat bacterial infections such as pneumonia and bronchitis. The reason for the supply interruption is thought to be due to a significant demand for the medication in the United States, Canada, and Europe. On top of the increased demand, the pandemic has put manufacturing constraints on some of the key manufacturers of the drug. Manufacturers of amoxicillin have acknowledged the shortage and are taking steps to meet demand, such as increasing worker shifts.

Amoxicillin is available in a variety of dosage forms and strengths. While patients may struggle to find the exact strength that they were prescribed, if a pharmacy has a different strength available then the pharmacist and provider can have a discussion to determine an appropriate regimen for the patient. Additionally, alternative antibiotics can be used if necessary. ■

Indication: Cotellic is indicated for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation in combination with vemurafenib or as a single agent for the treatment of adult patients with histiocytic neoplasms.

Recommended dosage and administration: The recommended dose is 60 mg orally once daily for the first 21 days of each 28-day cycle until disease progression or unacceptable toxicity.

Common adverse effects: The most common adverse effects are diarrhea, photosensitivity reactions, nausea, pyrexia, acneiform dermatitis, infection, fatigue, edema, maculopapular rash, dry skin, pruritis, dyspepsia, dyspnea, vomiting, increased gamma-glutamyl transferase (GGT), increased creatine phosphokinase (CPK), hypophosphatemia, hyponatremia, hypokalemia, hypocalcemia, leukopenia, increased alanine transaminase (ALT), lymphopenia, increased aspartate aminotransferase (AST), and anemia.



Warnings and precautions: Do not breastfeed while taking Cotellic. Avoid concomitant administration with strong or moderate CYP3A inducers or inhibitors.

Patients taking Cotellic should be monitored for new malignancies prior to initiation of therapy, while on therapy, and for up to 6 months following the last dose. Major hemorrhagic events can occur so patients should be monitored for signs and symptoms of bleeding.

Evaluate left ventricular ejection fraction (LVEF) before treatment, after 1 month of treatment, then every 3 months thereafter during treatment with Cotellic as there is a risk for cardiomyopathy. Cotellic doses may need to be reduced, interrupted, or discontinued if severe dermatologic reactions occur. Ophthalmological evaluations should be performed at regular intervals and for any visual disturbances. Permanently discontinue Cotellic if retinal vein occlusion occurs.

Monitor liver laboratory tests during treatment and as clinically indicated. Monitor creatine phosphokinase periodically and as clinically indicated for signs and symptoms of rhabdomyolysis. Advise patients to avoid sun exposure. Advise patients of reproductive potential of the possible risk to a fetus and to use effective contraception.

RETEVMO

(Selpercatinib—Loxo Oncology Eli Lilly)

Drug class: Selpercatinib is a kinase inhibitor.

Indication: Retevmo is indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer with a RET gene fusion; adult and pediatric patients 12 years and older with advanced or metastatic medullary thyroid cancer with a RET mutation who require systemic therapy; adult and pediatric patients 12 years and older with advanced or metastatic medullary thyroid cancer with a RET mutation who require systemic therapy and are radioactive iodine–refractory; and adult patients with locally advanced or metastatic solid tumors with a RET gene fusion that have progressed on or following prior systemic treatment who have no satisfactory alternative treatment options.

Recommended dosage and administration: The recommended dosage in adults and pediatric patients 12 years or older is based on weight. If weight is < 50 kg, the recommended dosage is 120 mg orally twice daily. If weight is ≥ 50 kg, recommended dosage is 160 mg orally twice daily.

Common adverse effects: The most common adverse effects are edema, diarrhea, fatigue, dry mouth, hypertension, abdominal pain, constipation, rash, nausea, headache, decreased lymphocytes, increased ALT, increased AST, decreased sodium, and decreased calcium.

Warnings and precautions: Retevmo should not be used in patients who are breastfeeding. Monitor open growth plates in adolescent patients and consider interrupting or discontinuing treatment if abnormalities occur. Reduce the dose of Retevmo in patients with severe hepatic impairment. ALT and AST should be monitored prior to initiating Retevmo, every 2 weeks during the first 3 months, then monthly thereafter and as clinically indicated. Doses of Retevmo may need to be reduced, withheld, or discontinued based on severity of hepatotoxicity. Monitor for new or worsening pulmonary symptoms.

Do not initiate Retevmo in patients with uncontrolled hypertension. Optimize blood pressure prior to initiating Retevmo. Monitor blood pressure after 1 week of treatment and at least monthly thereafter and as clinically indicated. Monitor patients who are at significant risk of developing QTc prolongation. Permanently discontinue Retevmo in patients with severe or life-threatening hemorrhage. If a hypersensitivity reaction occurs, withhold Retevmo and initiate corticosteroids. Closely monitor patients at risk of tumor lysis syndrome and treat as clinically indicated. Withhold Retevmo for at least 7 days prior to elective surgery. Do not administer for at least 2 weeks following major surgery and until adequate wound healing. Monitor thyroid function before treatment with Retevmo and periodically during treatment. Retevmo may cause fetal harm and patients of reproductive potential should be advised of the possible risk to a fetus and to use effective contraception. ■

Also in this issue
Relyvrio: a new oral treatment approved for ALS (page 24).