Approvals & Updates

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PharMerica®

New Drug Approvals

Jemperli (dostarlimab-gxly)

Indication: Endometrial carcinoma

Mechanism of Action: Programmed death receptor-1 (PD-1)–blocking antibody

Dosage Form(s): Intravenous (IV) injection

Comments: Jemperli is FDA-approved for treating adults with mismatch repair deficient (dMMR) recurrent or advanced endometrial cancer, as diagnosed by an FDA-approved test, that has progressed on or after previous treatment with a platinum-containing regimen. Doses 1 through 4 of Jemperli should be administered as 500mg IV every 3 weeks, with all subsequent doses starting 3 weeks after dose 4 (dose 5 and all doses thereafter) increased to 1000mg every 6 weeks. Jemperli should be infused over 30 minutes without co-administration of other drugs in the same infusion line and administered until progression of disease or unacceptable toxicity occurs. Jemperli carries labeled warnings for immune-mediated adverse reactions, infusion-related reactions, complications of allogeneic HSCT after PD-1/L-1–blocking antibody, and embryo-fetal toxicity. While Jemperli has no outlined drug interactions, signs and symptoms of immune-mediated and infusion-related adverse reactions should be monitored throughout therapy. The most common adverse reactions (≥20%) reported with Jemperli were fatigue/asthenia, nausea, diarrhea, anemia, and constipation.

Nextstellis (drospirenone and estetrol)

Indication: Contraception

Mechanism of Action: Progestin and estrogen combination

Dosage Form(s): Tablets

Comments: Nextstellis is FDA-approved for preventing pregnancy in females with reproductive potential. It should be taken as one tablet by mouth once daily, according to the order on the blister pack, at about the same time every day without regard to food. Nextstellis carries a Boxed Warning for cigarette smoking and serious cardiovascular events and is contraindicated in females >35 years old who smoke. Nextstellis carries labeled warnings for thromboembolic disorders and other vascular problems, hyperkalemia, hypertension, migraine, hormonally-sensitive malignancy, liver disease, glucose tolerance and hypertriglyceridemia, gallbladder disease and cholestasis, and bleeding irregularities and amenorrhea. Blood pressure, glucose in patients with prediabetes or diabetes, serum potassium in patients at increased risk for hyperkalemia, and depression in patients with a history of depression should all be monitored while on Nextstellis therapy. Concomitant administration of Nextstellis with CYP3A inducers should be avoided, but if unavoidable, a backup or alternative contraceptive method should be considered during co-administration and for up to 28 days following discontinuation of the CYP3A inducer. The most common adverse reactions (≥2%) reported with Nextstellis were bleeding irregularities, mood disturbance, headache, breast symptoms, dysmenorrhea, acne, increased weight, and decreased libido.

Zynlonta (loncastuximab tesirine-lpyl)

Indication: Large B-cell lymphoma

Mechanism of Action: CD19-directed antibody

Dosage Form(s): IV injection

Comments: Zynlonta is FDA-approved for treating adults with relapsed or refractory large B-cell lymphoma following ≥2 lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from low grade lymphoma, and high-grade B-cell lymphoma. Patients should be premedicated for 3 days with dexamethasone 4mg by mouth or IV twice daily starting the day before initiation of Zynlonta. Zynlonta should then be administered IV over 30 minutes on the first day of each cycle as 0.15mg/kg every 3 weeks for 2 cycles followed by 0.075mg/kg every 3 weeks for all subsequent cycles. The infusion site should be monitored for subcutaneous infiltration during administration. Zynlonta carries labeled warnings for effusion and edema, myelosuppression, infections, cutaneous reactions, and embryo-fetal toxicity. Blood cell counts and signs and symptoms of infection, new or worsening edema or effusions, or new or worsening cutaneous reactions should be monitored throughout therapy. Zynlonta has no specific drug interactions outlined. The most common adverse reactions (≥20%) reported with Zynlonta were thrombocytopenia, increased gamma-glutamyltransferase, neutropenia, anemia, hyperglycemia, transaminase elevation, fatigue, hypoalbuminemia, rash, edema, nausea, and musculoskeletal pain.