| Brand Name | Generic Name | Indications | Route of Administration | Action |
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| LARTRUVO | olaratumab | Soft tissue Sarcoma | IV infusion | The FDA released a statement recommending that patients who are currently receiving Lartruvo (olaratumab) should consult with their healthcare provider **about whether to remain on treatment**. In addition, the FDA recommends that Lartruvo should not be initiated in new patients outside of an investigational study. Lartruvo was approved under the FDA's accelerated approval program in October 2016. As a condition of approval, Eli Lilly conducted a larger study, designed to confirm the clinical benefit of Lartruvo in these patients.<br>• The recently completed larger study (ANNOUNCE) did not confirm the clinical benefit of Lartruvo**. Specifically, the study did not meet the primary endpoint of improvement in overall survival for Lartruvo and doxorubicin as compared to placebo and doxorubicin.**<br>• The FDA is currently reviewing the data and working with the company to determine appropriate next steps. |
| ULORIC | febuxostat | *REVISED* Indication: chronic management of hyperuricemia in adult patients with gout who have an inadequate response to a maximally titrated dose of allopurinol, who are intolerant to allopurinol, or for whom treatment with allopurinol is not advisable | Oral | The FDA announced that there is an **increased risk of death** with Uloric (febuxostat) use compared to allopurinol. This conclusion was based on an in-depth review of results from a safety clinical trial that found an **increased risk of heart-related death and death from all causes with Uloric. Health care professionals should reserve Uloric for use only in patients who have failed or do not tolerate allopurinol.** Patients taking Uloric should be monitored for CV signs and symptoms. In addition, patients should be counseled about the CV risk with Uloric and they should be advised to seek medical attention immediately if they experience syptoms such as chest pain, shortness of breath, rapid/irregular heartbeat, etc. |

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| XELJANZ | tofacitinib | Rheumatoid Arthritis, active psoriatic arthritis, ulcerative colitis | Oral | The FDA announced that a safety study (A3921133) found an **increased risk of pulmonary embolism and death when Pfizer's Xeljanz (tofacitinib) 10 mg twice daily was used in patients with rheumatoid arthritis (RA).** Patients treated with Xeljanz 10 mg twice daily had a statistically and clinically important difference in the occurrence of pulmonary embolism vs. patients treated with a tumor necrosis factor inhibitor (TNFi). **An increase in overall mortality was also observed with the Xeljanz 10 mg twice daily group vs. the Xeljanz 5 mg twice daily and TNFi treatment arms.**<br>— Pfizer has taken steps to transition these study patients who are on Xeljanz 10 mg twice daily to Xeljanz 5 mg twice daily.<br>— Pfizer plans to continue and complete the study by the end of 2019. |