PULSE

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Pharmacy Benefit Dimensions®

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Clinical Update

FDA Approves Rubraca® (rucaparib) for Specific Subset of Prostate Cancer Patients

On May 15, 2020, the U.S. Food and Drug Administration (FDA) published a press release announcing the approval of Rubraca® (rucaparib) oral tablets to treat prostate cancer in adult patients with a specific genetic mutation (BRCA) whose disease progression has not responded to other medicines. The approval was granted under the FDA's Breakthrough Therapy designation, which is granted for drugs that may result in a substantial improvement in treatment of a serious condition when compared to currently available therapies. Rubraca® was initially approved under accelerate approval in 2016 for treatment of a specific type of ovarian cancer. Clinical trials evaluating the medication showed that 44% of patients treated with Rubraca® demonstrated a response to therapy (measured as objective response rate) and the majority of those patients had a duration of response of six months or longer. These results led to the Accelerated Approval of Rubraca® and continued approval may be contingent upon confirmation of clinical benefit in further trials.

Safety First

Amneal Pharmaceuticals Recalls Popular Diabetes Medication

On May 29, 2020, Amneal Pharmaceuticals, LLC. released a company announcement, published by the FDA, informing consumers of a voluntary nationwide recall of all lots of 500mg and 750mg metformin extended-release tablets. Metformin is commonly used to improve blood sugar control in the treatment of type 2 diabetes. The recall was initiated due to the detection of low levels of an impurity, known as N-Nitrosodimethylamine (NDMA), which is classified as a probable cancer-causing substance by the International Agency for Research on Cancer (IARC). Although Amneal has not received any reports of adverse events, they have arranged for the return of all recalled products. The FDA has also published recalls of metformin manufactured by other companies including Time-Cap Labs, Inc., Teva Pharmaceuticals, Marksans, and Apotex Corp. Patients have been advised to contact the manufacturer or their health care provider for further information.

From the Industry

Filgotinib Shows Promising Results in Treatment of Ulcerative Colitis

On May 20, 2020, Gilead Sciences published a press release announcing positive results associated with a clinical trial evaluating the safety and efficacy of filgotinib therapy for ulcerative colitis (UC). UC is a bowel condition that results in inflammation of the digestive tract and often involves mixed periods of active disease and inactive disease (remission). The trial evaluated once-daily filgotinib (100mg or 200mg) in patients with moderate to severe active UC. The trial showed statistically significant treatment results in achieving remission at Week 10 in patients receiving 200mg of filgotinib compared to placebo. However, statistically significant results were not achieved in the group of patients receiving 100mg of filgotinib. In evaluating maintenance of remission at Week 58, statistically significant results were achieved in both groups of patients receiving either 100mg or 200mg of filgotinib. The results of the trial suggest that filgotinib may play a role in helping more patients achieve and maintain remission of their condition using an oral therapy.

FDA Approvals

Recent FDA Approvals

Novel Drug Approval: Cerianna™ (fluoroestradiol F-18)
Intravenous injection used as an additive diagnostic agent in combination with biopsy for patients with recurrent or metastatic breast cancer [5/20/2020 – ZIONEXA]

Novel Drug Approval: Artesunate
Intravenous injection for the initial treatment of severe malaria in adult and pediatric patients [5/26/2020 – Orphan Drug; Priority Review – AMIVAS]

Novel Drug Approval: Tauvid™ (flortaucipir F-18)
Intravenous injection used as a diagnostic agent in adult patients with cognitive impairment who are being evaluated for Alzheimer's Disease [5/29/2020 – Priority Review – AVID RADIOPHARMS INC]

New Generics

New Generics Entering the Marketplace

Samsca® (tolvaptan)
Indication: Hyponatremia (low sodium blood levels)
Dosage Form/Strength: 30MG Oral Tablet
Average Wholesale Price (AWP): Generic = $5,859 | Brand = $6,167

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