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Clinical Update

FDA Approves Treatment for Acute Myeloid Leukemia

On September 1, 2020, the U.S. Food and Drug Administration (FDA) approved Onureg® (azacitidine) oral tablets for continued treatment of acute myeloid leukemia (AML). Onureg® is the only FDA-approved drug indicated for adult patients who achieved complete remission (CR) or complete remission with blood cell counts that have not yet returned to normal levels following intensive induction chemotherapy, but are unable to complete intensive curative therapy. AML is a type of cancer that typically originates in early forms of white blood cells in the bone marrow and can quickly spread to the blood. Onureg® works by altering the DNA and promoting death of the cancerous white blood cells, while preserving the function and growth of normal cells. The safety and efficacy of the medication were evaluated in the QUAZAR trial which included 472 patients and spanned over 6 years. Results have shown that patients receiving Onureg® had a significantly higher median overall survival (OS) compared to patients receiving placebo (24.7 months vs. 14.8 months, respectively). This benefit was shown in patients that yielded both CR and CRi. Onureg® was awarded Orphan Drug and Priority Review designations. Onureg® provides an additional treatment option for more than 64,000 Americans estimated to be living with AML.

Safety First

RLC Labs Inc. Issues Voluntary Nationwide Recall of Thyroid Medications

On September 3, 2020, RLC Labs Inc. announced a voluntary recall at the consumer level of 483 lots of Nature-Throid® and WP Thyroid® in all strengths and all counts of product within current expiry. The recall occurred after the FDA discovered samples from six lots of medication with a lower potency than indicated on the label, containing as low as 87% of labeled active ingredients. These medications are used to treat underactive thyroid, a common condition often known as hypothyroidism. Patients receiving sub-potent therapy with recalled lots may experience symptoms of hypothyroidism, including fatigue, sensitivity to cold, constipation, hair loss, slow heart rate, depression, puffy face and weight gain. Pregnant women with undertreated hypothyroidism, elderly patients, and patients with underlying cardiac disease may be at greater risk for complications associated with sub-potent thyroid treatment. RLC Labs Inc. is notifying wholesalers to discontinue distribution of the product, and patients currently taking Nature-Throid® and WP Thyroid® are being asked to contact their health care provider and not discontinue therapy on their own.

COVID-19 Update

FDA Authorizes Antibody Test in Point-of-Care Settings

The FDA announced an emergency use authorization for the first serology (antibody) test for COVID-19 that can be used in point-of-care (POC) settings such as primary care offices, hospitals and emergency rooms. The Assure COVID-19 IgG/IgM Rapid Test Device is available by prescription only, and detects certain antibodies produced by the human body's immune system in response to COVID-19 infection. It can detect these antibodies in venous whole blood, serum, plasma and whole blood acquired by a fingerstick. The acquisition of a blood sample by fingerstick and ability to be tested in POC settings makes this test unique. Previous diagnostics techniques required use of a central lab for testing, which required additional resources and time to transport samples and run tests. The FDA stated that authorizing serology tests in POC settings "will enable more timely and convenient results for individuals who want to understand if they have previously been infected with the virus that causes COVID-19." The FDA also emphasized that antibody tests do not test for active infection, and that patients should not interpret the results of a serology test as confirmed immunity from the virus, as it is unknown how long the antibodies remain in the human body, and whether or not the presence of these antibodies dictates protective immunity. The FDA continues to work on the expansion of COVID-19 testing and reminds the public to continue social distancing and wearing masks in order to protect themselves and others.

FDA Approvals

Recent FDA Approvals

New Dosage Form: Qdolo™ (tramadol hydrochloride)
Oral solution approved for the treatment of pain severe enough to require an opioid analgesic, and for which alternative treatments are inadequate.

New Dosage Form: Onureg® (azacitidine)
Oral tablet approved for the treatment of patients with acute myeloid leukemia (AML) who achieved first complete remission (CR) or complete remission with incomplete blood count recovery (Cri) following intensive induction chemotherapy, and are not able to complete intensive curative therapy [9/1/20 - Orphan Drug; Priority Review – CELGENE CORP]

Novel Drug Approval: Detectnet™ (copper dotatate CU-64)
Intravenous diagnostic agent approved for identification of specific neuroendocrine tumors (NETs) in adult patients [9/3/20 - Orphan Drug; Priority Review – RADIOMEDIX]

Novel Drug Approval: Gavreto™ (pralsetinib)
Oral capsule approved for the treatment of adult patients with select metastatic and RET fusion-positive non-small cell lung cancer [9/4/20 - Orphan Drug; Priority Review – BLUEPRINT MEDICINES]

New Generics

New Generics Entering the Marketplace

Emtriva® (emtricitabine)
Indication: HIV-1 Infection
Dosage Form/Strength: 200 MG oral capsules
Average Wholesale Price (AWP): Generic = $579 | Brand = $819

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