HEM/ONC News

By Devon Schuyler

Venetoclax Approved for Use in Chronic Lymphocytic Leukemia

The US Food and Drug Administration (FDA) approved venetoclax (Venclexta, AbbVie/Genentech) on April 11th for second-line treatment of patients with chronic lymphocytic leukemia (CLL) who have a 17p deletion.

Venetoclax is the first treatment approved by the FDA that targets the B-cell lymphoma 2 (BCL-2) protein. It is approved in combination with the diagnostic Vysis CLL FISH Probe Kit (Abbott) to confirm 17p deletion.

Approval of venetoclax was based on a single-arm phase 2 trial that was reported at the 2015 annual meeting of the American Society of Hematology by Dr Stephan Stilgenbauer. The trial included 107 patients with CLL and the 17p deletion who had received at least one previous therapy. The participants took oral venetoclax once daily, beginning with 20 mg and increasing over 5 weeks to 400 mg. After a median of 12 months, the overall response rate was 79.4%, which included a complete response in 7.5% of patients.

The most common side effects of venetoclax are neutropenia, diarrhea, nausea, anemia, upper respiratory tract infection, thrombocytopenia, and fatigue. Serious complications include pneumonia, febrile neutropenia, autoimmune hemolytic anemia, anemia, and tumor lysis syndrome.

Cola Increases Bioavailability of Erlotinib in Patients Taking a Proton Pump Inhibitor

Approximately 20% to 55% of patients in the United States with cancer are taking a proton pump inhibitor (PPI), which can inhibit the absorption of certain oral drugs. Now, a small study finds that drinking a glass of cola while taking erlotinib (Tarceva, Genentech) can increase the bioavailability of the drug in patients with non–small cell lung cancer (NSCLC) who are also taking the PPI esomeprazole.

The study, which was published in the *Journal of Oncology* on April 20th, included 28 patients with NSCLC who were taking erlotinib. Van Leeuwen and colleagues randomly assigned patients to a PPI or no-PPI group and then further randomized them take erlotinib with either cola or water for 1 week. Patients taking esomeprazole were switched to the alternate beverage during week 2.

The researchers found that drinking cola significantly improved the bioavailability of erlotinib in patients taking the PPI but had little effect in patients not taking the PPI. The study did not evaluate the effect of cola on the efficacy of erlotinib.

Trastuzumab Use Modest in Patients With HER2-Positive Breast Cancer

Just half of patients older than 65 years with stage I, II, or III human epidermal growth factor receptor 2 positive (HER2+) breast cancer received trastuzumab (Herceptin, Genentech) in the year after diagnosis, according to a new study. The rate of trastuzumab use was significantly lower among black women than among white women.

For the study, which was published online in the *Journal of Clinical Oncology* on April 11th, Reeder-Hayes and colleagues used the Surveillance, Epidemiology, and End Results (SEER)-Medicare database to identify 1362 women given a diagnosis of stage I, II, or III HER2+ breast cancer in 2010 and 2011.

The researchers found that 50% of white women and 40% of black women filed a claim for trastuzumab in the year after diagnosis. Among women with stage III disease, the rates were 74% and 56%, respectively. After adjustment for factors such as tumor characteristics, poverty, and comorbidity, black women were 25% less likely than white women to receive trastuzumab.

Trastuzumab is a standard of care for women with HER+ stage II or III disease, and is often prescribed to women with HER+ stage I disease. Potential barriers to use include cost and the fact that trastuzumab must be paired with chemotherapy.

FDA Approves Blood-Based Colorectal Cancer Screening Test

The FDA approved a blood-based colorectal cancer screening test called Epi proColon (Epigenomics) on April 13th. This is the first blood-based colorectal cancer screening test to receive FDA approval.

Epi proColon is indicated for use in patients at average risk for colorectal cancer who have decided against other colorectal cancer screening methods, such as colonoscopy and stool-based fecal immunochemical testing. It works by detecting methylated Septin9 DNA in plasma derived from whole-blood samples.

The blood test can be performed during a routine office visit and requires no changes in diet or medication use. A local or regional diagnostic laboratory can analyze the blood sample.

Approval was based on the results of 3 clinical studies. The test was previously approved for use in Europe and some other countries.