HEM/ONC News

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FDA Expands Ramucirumab Indications to Include Metastatic Colorectal Cancer

The US Food and Drug Administration (FDA) has approved the use of ramucirumab (Cyramza, Eli Lilly) in combination with folinic acid, 5-fluorouracil, and irinotecan (FOLFIRI) to treat patients with metastatic colorectal cancer after progression with bevacizumab (Avastin, Genentech), oxaliplatin, and fluoropyrimidine. Ramucirumab, previously approved for gastric and non–small cell lung cancer, is a human vascular endothelial growth factor receptor 2 (VEGFR2) antibody.

Approval was based on the phase 3 RAISE study, published in *The Lancet Oncology* by Tabernero and colleagues in May 2015. In this study, 1072 patients were randomly assigned to receive FOLFIRI with placebo or ramucirumab (536 patients in each group). Ramucirumab was given intravenously at 8 mg/kg every 2 weeks until disease progression or unacceptable toxicity.

Overall survival was significantly better for patients receiving ramucirumab (13.3 months) vs placebo (11.7 months). Progression-free survival was also improved (5.7 months vs 4.5 months, respectively).

The most common grade 3 or 4 adverse events were neutropenia, hypertension, diarrhea, and fatigue. Boxed warnings also include hemorrhage, gastrointestinal perforation, and impaired wound healing.

Nicotinamide Reduces the Risk for Developing Actinic Cancer

Nicotinamide (vitamin B3) reduces the risk for developing certain types of skin cancer in high-risk patients, according to the phase 3 ONTRAC study (ACTRN12612000625875) presented at the American Society of Clinical Oncology (ASCO) annual meeting by Martin and colleagues (abstract 9000).

This study randomly assigned 386 immunecompetent patients who previously were diagnosed with 2 or more nonmelanoma skin cancers (NMSC) in the past 5 years to receive either oral nicotinamide (500 mg) or placebo twice daily. The incidence of NMSC in the nicotinamide group was 23% lower than the placebo group (incidence rate, 1.77 vs 2.42, respectively). The number of actinic keratosis was 13% lower in the nicotinamide group than the placebo group at 1 year. The rates of basal cell carcinoma and squamous cell carcinoma also were reduced in the nicotinamide group vs the placebo group. The adverse event rates were similar between the groups.

Studies suggest that nicotinamide enhances DNA repair in skin cells damaged by sunlight and protects the skin's immune system. This vitamin is affordable and widely available over the counter. Dr Peter Paul Yu, ASCO President, commented in a premeeting presscast that nicotinamide is "a remarkably simple and inexpensive way to help people avoid repeat diagnosis of some of the most common skin cancers."

Elotuzumab Increases Progression-Free Survival in Relapsed Multiple Myeloma

Elotuzumab, in combination with lenalidomide (Revlimid, Celgene) and dexamethasone, significantly improved progression-free survival in patients with relapsed multiple myeloma compared with lenalidomide and dexamethasone alone, according to the phase 3 ELOQUENT-2 study (NCT01239797) presented by Lonial and colleagues at the ASCO annual meeting (abstract 8508).

This study randomly assigned 646 patients previously treated with 1 to 3 prior therapies to receive lenalidomide and dexamethasone with or without elotuzumab in 28-day cycles until disease progression or unacceptable toxicity. The median progression-free survival time improved for the group given elotuzumab compared with placebo (19.4 months vs 14.9 months, respectively). Two-year progression-free survival was also improved (41% vs 27%, respectively). A similar benefit was seen in high-risk patients who are typically less responsive to therapy, specifically those with del(17p) and t[4;14] genetic abnormalities. Common grade 3 or 4 adverse events included neutropenia and anemia, and infusion reactions occurred in 10% of the elotuzumab group.

Elotuzumab is a monoclonal antibody against signaling lymphocytic activation molecule F7 (SLAMF7). Previous studies have suggested that elotuzumab targets myeloma cells directly and also enhances the ability of immune cells (ie, natural killer cells) to kill myeloma cells. Dr Julie M. Vose, ASCO President-Elect, commented in a premeeting presscast that the "results are very encouraging, giving renewed hope to patients who have relapsed."