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Refractory mCRC Care: A Combination Therapy Approach Improves Survival

Announcer:
You're listening to *Project Oncology* on ReachMD. On this episode, sponsored by Taiho Oncology, we'll hear about the findings from the SUNLIGHT trial, which focused on metastatic colorectal cancer, from study author Dr. Marwan Fakih. Not only is he a Professor in the Department of Medical Oncology and Therapeutics Research, but he's also the Judy and Bernard Briskin Distinguished Director of Clinical Research at City of Hope Comprehensive Cancer Center. Here's Dr. Fakih now.

Dr. Fakih:
The phase III SUNLIGHT trial was designed to evaluate both the efficacy and safety of trifluridine-tipiracil bevacizumab versus trifluridine-tipiracil in patients with refractory metastatic colorectal cancer. This large phase III clinical trial included 246 patients on each arm and was a randomized study that was one-to-one randomization. Trifluridine-tipiracil was given at the standard dose of 35 milligrams per meter square twice daily, day 1 through day 5 and day 8 through day 12 every 28 days. And bevacizumab was dosed at 5 milligrams per kilogram IV every 2 weeks. The primary endpoint was overall survival, and secondary endpoints were progression-free survival, overall response rate, disease control rate, quality of life, and time to worsening performance status.

Now if we look at the results of this study, the primary endpoint of the study—the overall survival—was statistically significantly better with the addition of bevacizumab trifluridine-tipiracil. In fact, the median overall survival was 10.8 months with trifluridine bevacizumab versus 7.5 months with trifluridine alone. And this represents a hazard ratio for death of 0.61, meaning that the addition of bevacizumab prolonged the overall survival by 39 percent over trifluridine-tipiracil alone. In addition, the secondary endpoint of progression-free survival was met here where the median progression-free survival with trifluridine bevacizumab was 5.6 months versus trifluridine alone, 2.4 months. And this represents a hazard ratio of 0.44, meaning that adding bevacizumab delayed progression by 56 percent in patients who have progressed on two lines of therapy. Now the improvement in PFS and overall survival were noted across all subgroups, including patients with RAS mutation or no RAS mutation and patients with prior bevacizumab exposure or no prior bevacizumab exposure.

The adverse events were acceptable on both arms. The arm that received bevacizumab had slightly higher grade 3-4 neutropenia, or 43 percent versus 32 percent. But you have to remember that patients who received bevacizumab remained on treatment with trifluridine quite a bit longer as the median progression-free survival of that group was 5.6 months while the median progression-free survival was less than half of that with trifluridine alone.

Now when we look at the deterioration in ECOG performance status, the addition of bevacizumab also resulted in a benefit. The delay in time to worsening in ECOG performance status from zero or one to two or more was approximately a three-months further delay in comparison to trifluridine alone. It was 9.3 months on the trifluridine bevacizumab arm versus 6.3 months on the trifluridine arm.

Based on the SUNLIGHT trial, the FDA has approved trifluridine bevacizumab as a treatment option for patients who progressed on or following oxaliplatin, irinotecan, fluoropyrimidine, bevacizumab, and anti-EGFR in patients with RAS wild-type tumors. The meaningful clinical benefits with trifluridine bevacizumab seen on SUNLIGHT positioned trifluridine bevacizumab as the treatment of choice for patients with metastatic colorectal cancer who progressed on two lines of therapy.

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