Second-Line Ramucirumab Added to Standard Chemotherapy Delays Disease Progression, Extends Survival for Patients With Advanced Colorectal Cancer

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ASCO Perspective:
“It’s good news that ramucirumab, an angiogenesis inhibitor with proven activity against gastric cancer and lung cancer, has now been found to be active against metastatic colorectal cancer,” said Smitha S. Krishnamurthi, MD, moderator of today’s presscast and ASCO expert. “Now, when a patient’s colorectal cancer has progressed, second line FOLFIRI chemotherapy can be combined with a continuation of bevacizumab or with a change to ziv-aflibercept or, possibly, ramucirumab. Further studies are needed to determine the activity of ramucirumab against colorectal cancer in first-line or other settings.”

ALEXANDRIA, Va. – New findings from an international phase III study of 1,072 patients with advanced colorectal cancer whose disease progressed on or after initial therapy indicate that a combination of the targeted drug ramucirumab and FOLFIRI chemotherapy provides a survival advantage over standard treatment with FOLFIRI alone. On average, patients treated with the ramucirumab combination lived six weeks longer than those treated with FOLFIRI plus placebo. The findings provide proof-of-concept for the development of new second-line treatment strategies for advanced colorectal cancer, especially using a combination of an anti-angiogenic drug with standard chemotherapy in those whose disease progresses after first-line chemotherapy with bevacizumab. The study will be presented at the upcoming 2015 Gastrointestinal Cancers Symposium in San Francisco.

“Advanced colorectal cancer is an incurable disease, and it is particularly difficult to treat after initial therapy stops working,” said lead study author Josep Tabernero, MD, director of the Vall d’Hebron Institute of Oncology in Barcelona, Spain. “Our study also included patients with fast-growing tumors, so the findings are relevant to patients that we typically encounter in practice. It is very
encouraging that we now have another safe option that adds benefit to standard chemotherapy in this second-line setting.”

Ramucirumab belongs to a class of drugs known as angiogenesis inhibitors. It works by blocking the growth of new blood vessels to the tumor, essentially starving it of nutrients. The agent is currently FDA approved only for the treatment of stomach and non-small cell lung cancers, but it is being studied in a range of other cancers.

Patients with metastatic colorectal cancer whose disease progressed on or after initial (first-line) treatment with bevacizumab and chemotherapy consisting of oxaliplatin plus a fluoropyrimidine were randomly assigned to treatment with FOLFIRI plus ramucirumab or FOLFIRI plus placebo (536 patients in each group). FOLFIRI (folinic acid, fluoruracil, and irinotecan) is a standard chemotherapy regimen for colorectal cancer.

Tumor shrinkage rates were similar in the two treatment groups (13.4 percent in the ramucirumab group vs. 12.5 percent in the placebo group), but ramucirumab led to a statistically significant improvement in both progression-free and overall survival, the latter the main objective of the study. The median time to disease progression in the ramucirumab group was 5.7 months compared with 4.5 months in the placebo group. The median overall survival was 13.3 months in the ramucirumab group compared with 11.7 months in the placebo group.

Dr. Tabernero stated that while this study clearly shows that ramucirumab adds benefit to FOLFIRI chemotherapy, the findings should not be extrapolated to other chemotherapy regimens and schedules without formal investigation in clinical trials. Further research is also needed to explore potential benefits of ramucirumab after first-line treatment with the EGFR inhibitor cetuximab.

Other angiogenesis inhibitors that have shown benefit in the second-line treatment of advanced colorectal cancer include bevacizumab and ziv-aflibercept, while regorafenib has shown benefit in the refractory setting. Bevacizumab and ziv-aflibercept are FDA approved for use in combination with chemotherapy, whereas regorafenib is approved as a stand-alone therapy for patients with previously treated metastatic colorectal cancer.

This study received funding from Eli Lilly and Company.

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