Studies show advances in gastrointestinal cancer treatments

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New trial data showing improvements in the treatment of esophageal and gastrointestinal cancers were released today at the ESMO 2012 Congress of the European Society for Medical Oncology in Vienna.

Phase III, randomized, double-blind, placebo-controlled trial of gefitinib versus placebo in esophageal cancer progressing after chemotherapy

The first phase III trial to address the need for second-line treatments in esophageal cancer shows that gefitinib improves important quality-of-life measures and extends progression-free survival, UK researchers report.

Each year, around 50,000 esophageal cancer patients in the European Union relapse after first line chemotherapy. Yet currently, no treatments have been shown to prolong survival or improve quality of life in this second-line setting.

The COG (Cancer Oesophagus Gefitinib) study included 450 patients from 51 UK centers who had already progressed after first line treatment with up to two chemotherapy regimens, and were administered either placebo or the EGFR-inhibitor gefitinib. Median progression-free survival was 35 days for patients who received placebo, and 49 days for those administered gefitinib. Treatment with the drug also improved dysphagia and odynophagia, two important indicators of quality of life in

this patient group.

In addition to the quality-of-life improvements and modest improvements in progression-free survival, some patients saw durable benefits from the treatment. A further study, TRANSCOG, is planned to analyze over 300 patients' biopsies in an effort to identify a molecularly defined subgroup where the benefit is enriched, said study author Prof David Ferry from New Cross Hospital in Wolverhampton, UK.

"If such a benefit can be identified, then given the good tolerance of gefitinib it could potentially be used in relapsed esophageal cancer," Prof Ferry said. "Do the responding patients have activating EGFR mutations like the super-responders in lung cancer? We don't know yet but there would seem to be a dominant role for EGFR in a minority of esophageal patients."

"This trial also shows that in this Cinderella malignancy, large randomized trials can be run and rapidly recruit large numbers of patients," Dr Ferry added. "Performance status is a strong predictor of overall survival and for patients with performance status 2, the median survival of 1.97 months was much worse than for those with performance status 1 or PS 0. Future studies should probably concentrate on PS 0/1 patients."

Commenting on the study, Prof Jean-Yves Douillard, ICO Centre Rene Gauducheau, France, Chair of the ESMO Educational Committee, not involved in the study, said: "This study is interesting and innovative. As stated by the author, there is no standard of care for such disease in second-line. However, more patients nowadays are eligible for second-line chemotherapy. The COG study showed that gefitinib at the high dose of 500mg per day improves progression-free survival, the primary endpoint, with a significant reduction of 21% in the risk of progression, but a modest benefit of the median (2 weeks). The improved progression-

free survival may reflect a benefit in a subgroup of patients sensitive to gefitinib and the ancillary study TRANSCOG is looking at a predictive biomarker, possibly an EGFR mutation as seen in lung cancer. Hopefully a biomarker predicting efficacy will be identified to allow the use of gefitinib in esogastric cancer in a personalized fashion. Considering the present practice however, future studies should have a more active treatment choice than placebo in the control arm."

Combining S-1 and docetaxel improves survival in advanced gastric cancer: update on phase III START trial

An updated analysis of a Japanese trial has shown that the combination of the oral fluoropyrimidine S-1 with docetaxel is beneficial for metastatic gastric cancer patients.

S-1 is used as a standard treatment for advanced and recurrent gastric cancer in East Asia. In 2011, researchers reported the results of a phase III multi-center study that evaluated the potential benefits of adding docetaxel to S-1 in patients with advanced gastric cancer.

The results of this study had been reported through a planned analysis in 2011, however an independent biostatistician pointed out that a large number of censored cases led to an insufficient number of events for proper analysis. Now, Dr Kazuhiro Yoshida and colleagues present an updated analysis. They found that among the 635 patients analyzed, the median survival time was 12.48 months in the combination therapy group compared to 10.78 months in patients who received S-1 alone.

"This combination is much better than S-1 monotherapy which is regarded as one of the standard therapies for metastatic gastric cancer in Japan," Dr Yoshida said.

The earlier SPIRITS trial also showed that S-1 plus cisplatin is a standard therapy for gastric cancer in Asia, Dr Yoshida noted. "However, our data for Japanese patients demonstrated more promising overall survival with a larger number of patients compared to the SPIRITS trial. These data will have an impact on daily practice for gastric cancer patients."

Prof Douillard said: "The START trial is a large study, meeting its primary end-point of improved survival showing a significant 17% reduction of the risk of death and a good median of 12.5 vs 10.8 months in favor of the combination. Progression-free survival and overall response-rate were also significantly better in the combination arm. The START study, with the combination of docetaxel and S-1, might represent an alternative to the platinum-containing regimens widely used in Europe, but would need first to be evaluated in Caucasian populations to assess feasibility and tolerance at doses of docetaxel usually used in Europe, and not at lower doses as routinely done in Japan."

Provided by European Society for Medical Oncology

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