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PROGRAM NAME

Welcome to *Audio Abstracts* on ReachMD. Today, we'll be reviewing a poster that was presented at the 2023 American Society of Clinical Oncology Annual Meeting that was titled, *Subgroup analyses of safety and efficacy by number and types of prior lines of treatment in FRESCO-2, a global phase 3 study of fruquintinib in patients with refractory metastatic colorectal cancer*.

Now for some background, there are limited treatment options available for patients with refractory metastatic colorectal cancer, or mCRC for short. And so the purpose of this global phase 3 cohort, called FRESCO-2, was to analyze the adverse events of a treatment known as fruquintinib in mCRC patients. Fruquintinib is a highly selective, potent, oral tyrosine kinase inhibitor of all three VEGF receptors, with weak or no inhibitory effect on other receptor kinases[1].

In terms of the characteristics of this study, it was performed in the United States, Europe, Japan, and Australia with a total 691 participants, of which 686 received at least one dose of fruquintinib. Before participating in the trial, patients had to have received all standard treatments, which included fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, anti-VEGF therapy, anti-EGFR therapy if they had RAS-wild type mutation status, and trifluridine/ tipiracil or regorafenib. If the patients had MSI-high or MMR-deficient tumors or BRAF V600E-mutant tumors, they must have also received an immune checkpoint inhibitor or BRAF inhibitor.

The randomization of the groups was stratified by the prior treatments of the patients, their RAS mutation status, and the duration of their metastatic disease, with it being less than or equal to 18 months or greater than 18 months. The patients were then put into subgroups according to the number of lines of therapy they had previously received, with the average being four prior lines of therapy. Based on these subgroups and the type of prior anti-cancer treatment they had received, the efficacy and safety of fruquintinib were analyzed.

Now if we look at the results, the average duration of exposure of fruquintinib versus placebo was 2.76 months versus 1.84 months in patients who received less than or equal to four lines of therapy, and 3.45 months versus 1.84 months for those who received greater than four lines of therapy. In patients who had previously been treated with anti-VEGF, regorafenib, or TAS-102, fruquintinib consistently demonstrated overall survival and progression-free survival benefits when compared to placebo. Additionally, fruquintinib improved overall survival and progression-free survival compared to placebo—regardless of the number of previous lines of therapies or types of treatments used.

And in terms of safety, treatment-emergent adverse events were generally balanced between the fruquintinib and placebo arms among patients who had received up to and more than four prior lines of therapy.

These results are consistent with the effect observed in the overall population, which is why the authors concluded that fruquintinib is a safe and effective treatment option for patients with refractory mCRC.

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