JSCO2023 "Frontier" 1
Gastrointestinal Cancer

Thu., October 19, 2023 15:45-17:45 Room2 | 501+502, 5F, Conference Center, Pacifico Yokohama

Moderator : Eiji Oki (Surgery and Science, Graduate School of Medical Sciences, Kyushu University)
Moderator : Ken Kato (National Cancer Center Hospital, Department of Head and Neck, Esophageal Medical Oncology / Department of Gastrointestinal Medical Oncology)
Discussant : Yasue Kimura (Department of Gastroenterological Surgery, National Kyushu Cancer Center)
Discussant : Yoshinori Kagawa (Department of Gastroenterological Surgery, Osaka General Medical Center)

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FR1-1

Pimitespib pooled safety profile analysis in patients with solid tumors, including gastrointestinal stromal tumor

Toshihiko Doi [1], Yukinori Kurokawa [2], Noboru Yamamoto [3]

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Background

Pimitespib (PIMI), a novel heat shock protein (HSP) 90 inhibitor, was approved in Japan for patients (pts) with advanced gastrointestinal stromal tumor (GIST), refractory to standard tyrosine kinase inhibitors based on phase 3 study results (CHAPTER-GIST-301). Here, the pooled safety analysis evaluated the safety of PIMI in pts with GIST and solid tumors.

Methods

This analysis included phase 1 solid tumor including GIST (NCT02965885) and phase 2 and 3 GIST (JapicCTI-163182, JapicCTI-184094) studies. The solid tumor group, including pts with GIST (GIST group), who received PIMI 160 mg once daily on a 5-days-on/2-days-off schedule, were evaluated. Adverse events (AEs), adverse drug reactions (ADRs), and time to resolution (TTR) were analyzed.

Results

As of June 23, 2020, 128 pts in the solid tumor group (including 119 pts in the GIST group) had received PIMI across all studies. The safety profiles in the GIST group were grade (gr) ≧ 3 ADRs (35.3 %), where the most common (≧ 5.0 %) gr ≧ 3 ADRs were diarrhea (17.6 %), anemia (6.7 %), and decreased appetite (5.0 %). ADRs leading to dose interruption and reduction, as well as discontinuation, were observed in 63.0 %, 38.7 %, and 2.5 % of pts (retinal vein occlusion [0.8 %], liver disorder [0.8 %], drug eruption [0.8 %]), respectively. Eye disorder-associated AEs (characteristic of HSP90 inhibitors) were observed in 23.5 % of pts, none of which were gr ≧ 3. These AEs resolved in 20/28 pts (median [m] TTR, 21.0 days). Gastrointestinal disorder-associated AEs were observed in 84.9 % of pts, with gr ≧ 3 observed in 22.7 % of pts. These AEs resolved in 52/100 pts (mTTR, 35.5 days); however, 41/100 pts did not resolve due to overlap with conditions of worsening GIST. The safety profiles of the solid tumors group were consistent with the GIST group.

Conclusions

In this pooled analysis, PIMI had a tolerable safety profile. Most AEs and ADRs, including eye and gastrointestinal disorders, were reversible and manageable with dose adjustments.

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FR1-2

First-line tislelizumab + chemotherapy versus chemotherapy in advanced/ metastatic ESCC: RATIONALE-306 Japanese subgroup analysis

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Background

Tislelizumab (T) + chemotherapy (C) demonstrated a statistically significant and clinically meaningful improvement in overall survival (OS) vs placebo (P) + C (HR:0.66; 95 % CI:0.54-0.80) in patients (pts) with advanced/metastatic esophageal squamous cell carcinoma (ESCC) in the global, phase 3 RATIONALE-306 study. We report results for the Japanese subgroup.

Methods

Eligible pts enrolled in Japan, regardless of PD-L1 expression status, were randomized (1:1) to receive intravenous T 200 mg or P every 3 weeks, both in combination with cisplatin and 5-fluorouracil until disease progression, intolerable toxicity, or withdrawal. The primary endpoint was OS in the intent-to-treat (ITT) population. Secondary endpoints included progression-free survival (PFS), objective response rate (ORR), and duration of response (DoR) per investigator assessment, OS in pts with PD-L1 TAP score $\geq$10 %, safety.

Results

Of 649 randomized pts, 66 (10.2 %) were Japanese (33 pts per arm; ITT population). In the Japanese subset, median age was 67 years; 89.4 % were male and 28.8 % had a PD-L1 score $\geq$10 %. At data cutoff, Feb 28, 2022, median follow-up was 18.8 months (m) in T+C and 15.1m in P+C. Median OS was not reached in T+C and 15.1m in P+C (HR:0.49; 95 % CI:0.24-0.99). The 1-year OS rate was 84.8 % in T+C vs 54.5 % in P+C. Median PFS was 6.8m in T+C vs 4.5m in P+C (HR:0.78; 95 % CI:0.46-1.33). T+C had a higher ORR (63.6 % vs 45.5 %) and longer median DoR (5.3 vs 4.4m) vs P+C. Median OS in pts with PD-L1 score $\geq$10 % was not reached in T+C and 16.8m in P+C (HR:0.51; 95 % CI:0.13-2.04). A similar proportion of pts in T+C and P+C had grade $\geq$3 TEAEs (75.8 % each), dose modifications (87.9 % vs 93.9 %), and discontinuations (21.2 % vs 18.2 %) due to TEAEs. No deaths occurred due to TEAEs.

Conclusion

The OS benefit along with acceptable safety profile in Japanese pts with advanced/metastatic ESCC treated with first-line T+C compared to P+C, is in line with the findings in ITT population from RATIONALE-306.

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FR1-3

High DpR of m-FOLFOXIRI plus cetuximab (Cet) in *RAS/BRAF* wild-type (wt) and left-sided (LT) metastatic colorectal cancer (mCRC) -Updated Analysis of *BRAF* Status in the DEEPER Trial (JACCRO CC-13)-

Dai Manaka [1], Manabu Shiozawa [2], Takashi Kawai [3], Hirofumi Ota [4], Hisateru Yasui [5], Taichi Yabuno [6], Mitsuyoshi Tei [7], Mitsugu Kochi [8], Nobuhisa Matsuhashi [9], Masahiro Takeuchi [10], Wataru Ichikawa [11], Masashi Fujii [12], Yu Sunakawa [13], Akihito Tsuji [14]

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Background: The DEEPER trial compared m-FOLFOXIRI+Cet to bevacizumab (Bev) as initial treatment for *RAS* wt mCRC with Depth of Response (DpR) as the primary endpoint. Improved DpR, prolonged PFS, and OS were observed in the Cet arm for *RAS/BRAF* wt and LT tumors, although *BRAF* status was found in only about half of the cases (JSMO 2023). This updated analysis of *BRAF* status aimed to improve the results in *BRAF* wt mCRC and to explore the correlation between chronological tumor shrinkage from baseline (CTS) and dose density of Cet/Bev.

Methods: DpR was evaluated in the per protocol set (PPS), which consisted of evaluable pts according to the external review board. Secondary endpoints included PFS, OS, ORR, early tumor shrinkage rate, secondary resection rate, and toxicity. Of the 359 pts enrolled, *BRAF* status was determined in 255 (71.0 %) pts with the addition of *BRAF* information in 71 pts from biomarker analysis. The association between CTS and dose density of Cet/Bev was analyzed in pts with *RAS/BRAF* wt and LT tumors.

Results: In 178 pts with *RAS/BRAF* wt and LT tumors of PPS, DpR was significantly better in the Cet arm (n=86) than Bev arm (n=92) (median 59.2 % vs. 47.5 %, P=0.0017). The CTS reached plateau at 24 weeks in both the Cet and Bev arms. It was favorable in the Cet arm compared to the Bev arm throughout the treatment period (median tumor shrinkage from baseline at 8/16/24/32w; 40.7 % vs. 28.4 %/50.5 % vs. 40.0 %/57.1 % vs. 47.1 %/57.3 % vs. 44.8 %). A sub-group analysis by number of cycles until 24 weeks showed that median DpR was 67.4 %/50.5 % for pts with ≧ 16/<16 cycles in the Cet arm, while it was 52.0 %/41.1 % for pts with ≧ 8/<8 cycles in the Bev arm.

Conclusions: This updated analysis showed a significant correlation between dose density of targeted drugs and DpR in m-FOLFOXIRI+Cet/Bev, with a more pronounced effect in Cet. Our data suggest that high dose density of Cet may contribute the deep response and prolonged OS of m-FOLFOXIRI+Cet treatment in *RAS/BRAF* wt and LT mCRC.

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FR1-4

Postoperative molecular residual disease correlates with recurrence in rectal cancer undergoing upfront surgery：update results from the observational GALAXY study

Koji Ando [1], Eiji Oki [2], Daisuke Kotani [3], Yoshiaki Nakamura [3], Saori Mishima [3], Masaaki Miyo [4], Atsushi Hamabe [5], Jun Watanabe [6], Masahito Kotaka [7], Vasily Aushev [8], Hiroya Taiguchi [9], Kentaro Yamazaki [10], Ichiro Takemasa [4], Takeshi Kato [11], Takayuki Yoshino [3]

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Background

Circulating tumor DNA（ctDNA）-based molecular residual disease（MRD）has been shown to predict the risk of recurrence in patients with colorectal cancer. Last year, we presented our first results in rectal cancer（RC）patients（pts）undergoing upfront surgery in GALAXY study. Here, we present our updated results.

Methods

Between April 20, 2021 and August 7, 2023, 730 pts with resectable clinical stage II/III RC were enrolled into the GALAXY study. A personalized tumor-informed assay（Signatera™ bespoke multiplex-PCR NGS assay）was used for ctDNA MRD detection. 12month disease-free survival（12M-DFS）rates were analyzed excluding patients enrolled in the associated, randomized phase III trial（ALTAIR）. Also, the relationship between the benefits of the adjuvant chemotherapy（ACT）and MRD was investigated.

Results

As of August 2023, post-4-week ctDNA-based MRD; 4w-MRD status（4w-MRD+ and 4w-MRD-）, and recurrence data were available for 199 RC pts who underwent upfront surgery, of whom 4w-MRD was positive in 14.1 %（28/199）. A total of 34 pts（16.7 %）experienced recurrences during this period. Among 15 pts with liver recurrence, 14（93.3 %）had 4w-MRD+, while in 12 pts with lung recurrence, 2 pts（16.7 %）were 4w-MRD+ and among the 4w-MRD-, 7 eventually turned ctDNA-positive. With a median follow-up time of 19.5 months, the 12M-DFS rate was 32.4 % in the 4w-MRD+ group and 91.3 % in the 4w-MRD- group, with a hazard ratio（HR）of 14.0（95 % CI 7.0-27.7; P<0.0001）. Considering the use of ACT, among 4w-MRD- pts, 12M-DFS rate was similar in ACT vs. non-ACT: 87.4 % vs. 93.7 %（HR 0.7, 95 % CI 0.2-1.9, P=0.45）. On the other hand, among 4w-MRD+ pts, the 6M-DFS rate was numerically higher tin ACT than in non-ACT（75.0 % vs. 36.5 %）, although the difference was not significant.

Conclusions

This analysis showed the significance of 4w-MRD in relation to recurrence in pts with RC who underwent upfront surgery, suggesting the prognostic value of ctDNA-based 4w-MRD status in pts with RC.

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FR1-5

A biomarker analysis from EFFORT study; a prospective study of FOLFIRI plus aflibercept as second-line treatment after failure of FOLFOXIRI plus BEV in patients with unresectable colorectal cancer

Toshihiko Matsumoto [1], Koji Ando [2], Hironaga Satake [3], Yuji Negoro [4], Tatsuya Kinjo [5], Kotaro Yuge [6], Kenji Baba [7], Hiroyuki Orita [8], Keiji Hirata [9], Mototsugu Shimokawa [10], Akitaka Makiyama [11], Hiroshi Saeki [12], Eiji Oki [2], Hideo Baba [13]

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Background: The EFFORT study investigated whether FOLFIRI plus aflibercept is active following FOLFOXIRI plus BEV in unresectable/metastatic CRC. In EFFORT study, we also evaluated the angiogenic factors and response.

Patients and Methods: EFFORT was an open-label, multicenter, single arm phase II study. Patients with unresectable/metastatic CRC who failed FOLFOXIRI plus BEV as a first-line therapy received aflibercept plus FOLFIRI. The primary endpoint was progression-free survival (PFS) in the full analysis set (FAS). Major secondary endpoints included overall survival (OS), overall response rate (ORR) and safety. A biomarker analysis included nine angiogenic factors; VEGF-A, -B, -C, -D, PlGF, bFGF, Tie2, Flt-1 and IL-8. The expression levels of these proteins were analyzed in the serum of the patients at three points; before the treatment, at the first imaging, and after the failure of the treatment. High level values were defined by values above median.

Results: From April 2019 to May 2021, 35 patients were enrolled and FAS included 34 patients. The primary endpoint was met with a median PFS of 4.3 months [80 % CI: 3.7-5.1]. The median OS was 15.2 months [95 % CI: 8.9-22.7]. Objective tumor responses were CR (n=1), PR (n=4), SD (n=21) or PD (n=8). ORR was 14.7 % (5/34) [95 % CI: 5.0-31.1], and disease control rate was 76.5 % (26/34) [95 % CI: 58.8-89.3]. Of the nine angiogenic factors, the expression levels of VEGF-C, -D and PlGF before the treatment correlated with objective tumor responses. High levels of VEGF-C were associated with higher CR+PR rates versus low levels (P=0.008) and low levels of VEGF-D and PlGF were associated with higher CR+PR rates (P=0.015 and 0.01, respectively).

Conclusions: Aflibercept plus FOLFIRI given after failure of FOLFOXIRI plus BEV is active. Baseline angiogenic factors correlated with response to treatment and may be useful to guide treatment choices.

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FR1-6

Impact of UGT1A1 genotype on the efficacy and safety in QUATTRO-II：A Multicenter Randomized Trial Comparing CAPOXIRI + Bevacizumab to FOLFOXIRI + Bevacizumab for 1st line mCRC patients

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Background: QUATTRO-II is a multicenter randomized phase II study comparing FOLFOXIRI + Bevacizumab (Bev) to CAPOXIRI + Bev. In the primary analysis, the efficacy of CAPOXIRI + Bev was comparable to that of FOLFOXIRI + Bev, although CAPOXIRI + Bev was associated with an increased incidence of certain nonhematologic adverse events (AEs). Here, we investigated the impact of *UGT1A1* polymorphism on efficacy and safety to reveal appropriate patients (pts) for CAPOXIRI + Bev regimen.

Methods: Pts were randomly allocated to FOLFOXIRI + Bev (Arm A) or CAPOXIRI + Bev (Arm B) in a 1:1 ratio. *UGT1A1* polymorphism is divided into wild type (WT) and single hetero (SH) in this post-hoc analysis. SH is defined as G/A SH and 6/7 SH in *UGT1A1 *6* polymorphism in *UGT1A1 *28*, respectively. Pts with double hetero and homo were excluded in QUATTRO-II.

Results: The proportion of *UGT1A1 *6/*28*WT (Arm A/B) was 58.8 %/55.8 %, SH (Arm A/B) was 41.2 %/44.2 %. Regarding the RDI proportion of irinotecan, WT (Arm A/B) was 68.4 %/ 75.9 %, and SH (Arm A/B) was 71.2 %/ 74.1 %, respectively. During a median follow-up of 23.7mo, mPFS (Arm A/B) was 10.6mo /10.9mo (HR 1.119, P= 0.639), 9.7mo /10.8mo, and 12.7mo /11.0mo in the ITT, WT and SH group, respectively. In the additional safety analysis, ≧ grade 3 (G3) diarrhea (Arm A/B) was 13.3 %//20.7 % and 0 % /10.3 % in the WT and SH group, respectively. On the other hand, the rate of G4 neutropenia (Arm A/B) was 13.3 %/13.8 %, 57.1 %/17.4 % in the WT and SH subgroup, and febrile neutropenia (Arm A/B) was 10.0 %/10.3 %, 9.5/13.0 % in the WT and SH subgroup, respectively.

Conclusion: Differences in genetic polymorphisms of *UGT1A1* did not affect the mPFS in both treatment groups. Furthermore, both treatment groups could achieve sufficient RDI of irinotecan by managing diarrhea, neutropenia, and febrile neutropenia, regardless of the *UGT1A1* genotype. In summary, CAPOXIRI+ Bev is an effective and valuable first-line treatment of mCRC, regardless of the *UGT1A1* genotype.

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FR1-7

Pimitespib, an oral inhibitor of heat shock protein 90 in advanced gastrointestinal stromal tumor refractory to standard therapy : Results from the expanded access program

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Background

Pimitespib (PIMI) is a heat shock protein 90 inhibitor. In the phase 3 CHAPTER-GIST-301 (CG301) study involving patients (pts) with advanced gastrointestinal stromal tumor (GIST), PIMI significantly improved progression-free survival (PFS). Median PFS was 2.8 months (mo) with PIMI vs 1.4 mo with the placebo (hazard ratio=0.51, P=0.006). Consequently, this study was initiated as an expanded-access program to evaluate the safety and efficacy of PIMI against GIST, allowing access to PIMI before its commercial availability in Japan.

Methods

Eligible pts had histologically confirmed advanced GIST refractory to standard therapy, measurable lesion, and ECOG PS 0 or 1 or were transitioned from the CG301 study. Pts received PIMI 160 mg once daily on a 5-days-on/2-days-off schedule until disease progression, death, unacceptable toxicity, physician/patient decision, or commercial availability of PIMI. The primary endpoint was patient safety. Secondary endpoints included PFS, overall response rate (ORR), and disease control rate (DCR).

Results

In total, 23 pts received PIMI, and the full analysis set (FAS) included 21 pts, excluding those transferred from the CG301 study. Eleven pts (47.8 %) had an ECOG PS of 1, and 15 patients (65.2 %) had $\geq$4 prior systemic anticancer treatments. The most common ($\geq$10 %) treatment-related adverse events (TRAEs) were diarrhea (73.9 %), nausea (39.1 %), increased blood creatinine (30.4 %), malaise (17.4 %), and night blindness (13.0 %). TRAEs leading to dose interruption and reduction occurred in seven (30.4 %) and five pts (21.7 %), respectively. No TRAE led to study discontinuation or death. In FAS, the median PFS was 4.2 mo (95 % confidence interval 1.9-6.2 mo), ORR was 0 %, and DCR was 66.7 %.

Conclusions

PIMI was well tolerated, with manageable safety. The safety profile was similar to that observed in previous clinical studies of PIMI, without new safety concerns. PIMI showed encouraging efficacy in the fourth line GIST. (jRCT2031210526)

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