

FOLFIRI or NIS793 + bevacizumab + modified FOLFOX6 on Days 1 and 15 of each 28-day cycle. Upon phase II dose confirmation for NIS793 + SOC, an additional safety run-in of NIS793 (starting at 2100 mg Q2W, with the potential for dose de-escalation to 2100 mg Q4W if required) + an anti- PD-1 antibody, tislelizumab (tisle; 300 mg Q4W) + SOC will be performed. Patients ($N = \sim 226$) will then be randomized to continue the same investigational drug(s) + SOC ($n = \sim 150$) or SOC ($n = \sim 76$). In the case that the tisle safety run-in is concurrent with the randomized expansion of the NIS793 + SOC arm, randomization will be modified to also assign patients to the tisle safety run-in cohort. Treatment will continue until unacceptable toxicity, disease progression per RECIST 1.1 (or per iRECIST in the tisle arm), discontinuation by investigator, or withdrawal of consent. The primary objectives are to confirm the recommended phase II dose of NIS793 and to evaluate progression-free survival with NIS793 + tisle + SOC vs SOC alone. Secondary objectives include assessing safety/tolerability, overall survival, and antitumor activity, as well as characterization of immunogenicity and pharmacokinetics. Efficacy will be assessed per RECIST 1.1 (or iRECIST in the tisle arm) every 8 weeks for 1 year, then every 12 weeks until disease progression. Blood will be obtained at baseline and during treatment for immunogenicity and pharmacokinetic assessments. This ongoing study will enroll patients from 87 sites across 20 countries. The study start date was November 15, 2021.

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P-24 Gender differences in overall survival in patients with metastatic pancreatic cancer

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Background: Pancreatic cancer is an aggressive cancer disease and bears a dismal prognosis. Data on gender differences in this tumor entity are scarce.

Methods: In this single center, real-world retrospective analysis of our registry for pancreatic cancer, we investigated and compared the survival data and inflammatory parameters of male and female patients.

Results: In total, we included in this analysis 42 female and 63 male patients with metastatic pancreatic cancer. Liver metastasis was comparable between the genders (69.0% for female and 68.3% for male patients). Female patients were older at time of initial diagnosis (70.5 versus 69.7 years). Median overall survival (OS) rates from initial diagnosis were 13.4 months (95% CI: 7.6-19.1) and 7.0 months (95% CI: 3.2-10.9; $p = 0.013$), respectively. CRP/albumin ratio was significantly lower in female patients ($p = 0.039$). CRP/albumin ratio (HR = 7.7, $p = 0.012$) and CEA (HR = 1.0, $p = 0.821$) were independent prognostic factors for OS.

Conclusions: Based on our retrospective analysis, female patients had a significantly longer OS than male patients with metastatic pancreatic cancer, maybe due to a lower inflammatory activity as reflected by the CRP/albumin ratio.

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P-25 Tislelizumab monotherapy for patients with previously treated advanced hepatocellular carcinoma (HCC): RATIONALE-208 Chinese subpopulation

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Background: Tislelizumab, an anti-programmed cell death protein 1 monoclonal antibody, demonstrated clinical activity and was well tolerated in patients with previously treated advanced HCC in the phase 2 RATIONALE-208 study (NCT03419897). Here, we report results for the Chinese subpopulation.

Methods: Eligible patients who had received ≥ 1 prior line of systemic therapy for advanced HCC, excluding immune checkpoint inhibitors, received tislelizumab 200 mg intravenously once every three weeks. The primary endpoint was objective response rate by independent review committee (IRC) (ORR IRC) per Response Evaluation Criteria in Solid Tumors version 1.1. Secondary endpoints included ORR by investigator (INV) (ORR INV), duration of response by IRC (DoR IRC), DoR by INV (DoR INV), overall survival (OS), PFS by INV (PFS INV), PFS by IRC (PFS IRC), and safety.

Results: As of June 2021, 249 patients were enrolled, and the Chinese subpopulation comprised 122 patients; baseline demographic and disease characteristics were balanced between the Chinese and overall ($N = 249$) populations. Median follow-up duration was 12.9 months for the Chinese subgroup and 12.7 months for the overall population. Response rates were not impacted by region: ORR IRC was 12.3% (95% CI: 7.1, 19.5) and ORR INV was 13.9% (95% CI: 8.3, 21.4) in the Chinese subpopulation, and ORR IRC was 12.9% (95% CI: 9.0, 17.7) and ORR INV was 14.5% (95% CI: 10.3, 19.5) in the overall population. Median DoR IRC in both populations was not reached. Median DoR INV was consistent between the Chinese (21.4 months [95% CI: 7.6, NE]) and overall (21.4 months [95% CI: 11.1, NE]) populations. Median PFS IRC was 1.4 months (95% CI: 1.4, 2.6) and median PFS INV was 1.5 months (95% CI: 1.4, 2.7) for the Chinese subpopulation, while median PFS IRC was 2.7 months (95% CI: 1.4, 2.8) and median PFS INV was 2.8 months (95% CI: 2.6, 4.0) for the overall population. Median OS was 13.7 months (95% CI: 9.9, 17.0) vs 13.2 months (95% CI: 10.8, 15.2) for the Chinese vs overall population, respectively. Treatment-related adverse events (TRAEs) were similar between the Chinese and overall populations; 18.9% vs 15.5% of patients experienced \geq Grade 3 TRAEs, and 4.9% vs 5.2% experienced TRAEs that led to treatment discontinuation in the Chinese vs overall population, respectively. The most common \geq Grade 3 TRAEs were increased aspartate aminotransferase (4.1% vs 2.8%) and increased alanine aminotransferase (1.6% vs 1.2%) for the Chinese vs overall population, respectively.

Conclusions: Tislelizumab is clinically active and well tolerated in Chinese patients with previously treated advanced HCC, and the results are consistent with the overall study population. An ongoing phase 3 clinical trial will continue to investigate the impact of region on the efficacy and safety of tislelizumab monotherapy (NCT03412773).

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