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= ∼226) will then be randomized to continue the same investigational drug(s) + SOC (n= ∼150) or SOC (n= ∼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.

**Clinical trial identification:** NCT04952753.

**Legal entity responsible for the study:** Novartis Pharmaceticals.

**Funding:** Novartis Pharmaceuticals.

**Disclosures:** N. Segal: Advisory / Consultancy: Boehringer Ingelheim; Novartis, Roche/Genentech; GlaxoSmithKline, ABL Bio; Revitope; AstraZenenca; Research grant / Funding (self): Roche/Genentech; Pfizer; Merck; Incyte; Immunocore, BMS; AstraZeneca;; Research grant / Funding (institution): Regeneron, PureTech. C. Tournigand: Honoraria (self): Roche; Sanofi, Bristol-Myers Squibb; Bayer, MSD; Advisory / Consultancy: Bayer; Research grant / Funding (self): Roche; Travel / Accommodation / Expenses: Roche, Bayer, MSD. S. Kasper: Honoraria (self): Merck Serono; Bristol-Myers Squibb; , Amgen; MSD oncology; AstraZeneca; Servier, Roche; Lilly; Sanofi/ Aventis; Novartis; Pierre Fabre; Honoraria (Institution): Merck Serono, Roche; Advisory / Consultancy: Merck Serono; MSD Oncology; Janssen-Cilag, Amgen; Sanofi; Lilly; Servier; Novartis, Roche; Bristol-Myers Squibb; AstraZeneca, Pierre Fabre; Research grant / Funding (self): Merck Serono; Celgene, Roche/ Genentech; Lilly, Bristol-Myers Squibb; Servier; Research grant / Funding (institution): Merck Serono, Roche; Travel / Accommodation / Expenses: Merck Sorono; Lilly; Bristol-Myers Squibb, Amgen; Sanofi, Roche; Pierre Fabre. Y. Chen: Travel / Accommodation / Expenses: Novartis; Shareholder / Stockholder / Stock options: Novartis; Full / Part-time employment: Novartis. P. Deshpande: Shareholder / Stockholder / Stock options: Novartis Pharmaceuticals Corporation; Full / Part-time employment: Novartis Pharmaceuticals Corporation. R. Messmann: Shareholder / Stockholder / Stock options: Novartis; Full / Part-time employment: Novartis. S. Kopetz: Advisory / Consultancy: Roche, Redx Pharma, Jacobio, Merck, Navire Pharma, Holy Stone, Biocartis, Natera, Karyopharm Therapeutics, Repare Therapeutics, Genentech, Lilly, AstraZeneca/MedImmune, EMD Serono, Daiichi Sankyo, Amal Therapeutics, Boehringer Ingelheim, Bayer Health, Lutris, Pfizer, Amgen, Pierre Fabre, Symphogen, Novartis, Boston Biomedical, Ipsen, HalioDx, Inivata, GSK, Jazz pharmaceuticals Iylon, Xilis, Abbvie, Gilead Sciences, Mirati Therapeutics, Flame Biosciences, Servier, Carina Biotechnology, Bicara Therpeutics, Endeavor BioMedicines, Numab Pharma, Johnson & Johnson/Janssen, Genomic Health, Fro; Research grant / Funding (self): Sanofi, Biocartis, Guardant Health, Array BioPharma, Genentech/ Roche, EMD Serono, MedImmune, Novartis, Amgen, Lilly, Daiichi Sankyo; Shareholder / Stockholder / Stock options: MolecularMatch, Frontier Medicines, Lutris, Iylon. The author has declared no conflicts of interest.

https://doi.org/10.1016/j.annonc.2022.04.114

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

H. Taghizadeh, M. Wiesholzer

*University Hospital St. Pölten - Karl Landsteiner University, St. Pölten, Austria*

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

**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.

**Legal entity responsible for the study:** The authors.

**Funding:** Has not received any funding.

**Disclosures:** All authors have declared no conflicts of interest.

https://doi.org/10.1016/j.annonc.2022.04.115

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

Z. Ren[1], Z. Li[2], T. Zhang[3], W. Fang[4], S. Hu[5], H. Pan[6], C. Yen[7], J. Hou[8], Y. Chen[9], G. Shao[10], C. Hsu[11], Y. Bai[12], Z. Meng[13], M. Hou[14], C. Xie[15], Y. Liu[16], J. Wu[17], B. Li[18], S. Chica-Duque[19], A. Cheng[20]

*[1]Liver Cancer Institute, Zhongshan Hospital, Fudan University, Shanghai, China; [2]Division of Hepatobiliary and Pancreatic Surgery, The First Affiliated Hospital, Zhejiang University, Hangzhou, China; [3]Abdominal Oncology Department, Union Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan, China; [4]Department of Medical Oncology, The First Affiliated Hospital, Zhejiang University, Hangzhou, China; [5]Department of Internal Medicine-Oncology, Hubei Cancer Hospital, Wuhan, China; [6]Department of Medical Oncology, Sir Run Run Shaw Hospital, Zhejiang University School of Medicine, Zhejiang, China; [7]Clinical Medicine Research Center, National Cheng Kung University Hospital, Tainan, Taiwan; [8]Southern Medical University, Hepatology Unit, Nanfang Hospital, Guangzhou, China; [9]Department of Hepatobiliary Surgery, Sun Yat-Sen Memorial Hospital, Sun Yat-Sen University, Guangzhou, China; [10]Department of Radiology, Zhejiang Cancer Hospital, Hangzhou, China; [11]National Taiwan University, Taipei, Taiwan; [12]Herbin Medical University, Heilongjiang, China; [13]Department of Integrative Oncology, Shanghai Cancer Hospital, Fudan University, Shanghai, China; [14]Chang Gung Memorial Hospital, Taipei, Taiwan; [15]Radiation and Medical Oncology Department, The First Affiliated Hospital of Wenzhou Medical University, Wenzhou, China; [16]Xuzhou Central Hospital, Xuzhou, China; [17]BeiGene (Ridgefield Park) Co., Ltd., Ridgefield Park, United States; [18]BeiGene (Beijing) Co., Ltd., Beijing, China; [19]BeiGene (San Mateo) Co., Ltd., San Mateo, United States; [20]National Taiwan University Cancer Center, Taipei, Taiwan*

**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 ≥ 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 ≥ 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).

**Clinical trial identification:** NCT03419897.

**Editorial acknowledgement:** This study is sponsored by BeiGene, Ltd. Medical writing support, under direction of the authors, was provided by Kirsty Millar, MSc, of Ashfield MedComms, an Ashfield Health company, and was funded by BeiGene, Ltd.

**Legal entity responsible for the study:** BeiGene, Ltd.

**Funding:** BeiGene, Ltd.

**Disclosures:** B. Li: Shareholder / Stockholder / Stock options: BeiGene; Full / Part-time employment: BeiGene. S. Chica-Duque: Shareholder / Stockholder / Stock options: BeiGene. All other authors have declared no conflicts of interest.

https://doi.org/10.1016/j.annonc.2022.04.116