323P Early safety and efficacy from the phase IIIb TOURMALINE study of durvalumab (D) in combination with gemcitabine (G)-based chemotherapy in advanced biliary tract cancer (aBTC)

D-Y. Oh[1], M. Ikeda[2], T. Macarulla Mercade[3], A.R. He[4], J.O. Park[5], M. Kitano[6], A. Lamarca[7], D.W.M. Tai[8], F. Dayyani[9], T. Pressiani[10], G. Wetherill[11], A. Stell[12], P. Sun[13], B. Baur[13], A. Vogel[14]

[1]Division of Medical Oncology, Department of Internal Medicine, Seoul National University Hospital; Cancer Research Institute, Seoul National University College of Medicine, Seoul, Republic of Korea; [2]Department of Hepatobiliary and Pancreatic Oncology, National Cancer Center Hospital East, Kashiwa, Japan; [3]Vall d'Hebron Institute of Oncology (VHIO), Vall d'Hebron University Hospital, Barcelona, Spain; [4]Division of Hematology and Oncology, Lombardi Comprehensive Cancer Center, Georgetown University, Washington, United States of America; [5]Department of Medicine, Division of Hematology-Oncology, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, Republic of Korea; [6]Second Department of Internal Medicine, Wakayama Medical University, Wakayama, Japan; [7]Department of Oncology — Onco-Health Institute, Fundación Jiménez Díaz University Hospital, Madrid, Spain; [8]Duke-National University of Singapore Graduate Medical School; Division of Medical Oncology, National Cancer Centre Singapore, Singapore; [9]Division of Hematology/Oncology, University of California Irvine, Orange, United States of America; [10]Medical Oncology and Hematology Unit, Humanitas Cancer Center, IRCCS Humanitas Research Hospital, Milan, Italy; [11]Oncology Biostatistics Unit, AstraZeneca, Cambridge, United Kingdom; [12]Global Medical Affairs, AstraZeneca, Cambridge, United Kingdom; [13]Global Medical Affairs, AstraZeneca, Gaithersburg, United States of America; [14]Toronto General Hospital, University Health Network; Princess Margaret Cancer Center, Toronto, Canada

Background: The global, single-arm, phase 3b TOURMALINE study (NCT05771480) assesses the safety and efficacy of D + G-based chemotherapy as first-line treatment (tx) in aBTC. Early safety and efficacy data are reported.

Methods: Participants (pts) received D 1500 mg with an investigator-selected G-based chemotherapy (D + G alone or in combination with oxaliplatin, carboplatin, cisplatin [cis], tegafur-gimeracil-oteracil [S-1], cis + S-1, or cis + nab-paclitaxel). The primary endpoint is the number of pts with Grade 3/4 possibly related adverse events (PRAEs) within 6 months of initiation of any study tx. Safety and objective response rate (ORR; per RECIST 1.1) were evaluated (data cut-off [DCO]: 7 Aug 2024) by non-platinum (non-plat; D + G, D + G + S-1) vs plat groups, and double vs triple tx within the plat group (double: D + G + cis, D + G + oxaliplatin, D + G + carboplatin; triple: D + G + cis + nab-paclitaxel, D + G + cis + S-1).

Results: By DCO, 121 pts (with a median age of 68, 74.4% being from Asia, and 16.5% with ECOG PS 2) were recruited. Pts received a median 5 cycles of D with a median follow-up of 4.9 months. Grade 3/4 PRAEs within 6 months of initiation of any study tx occurred in 45.5% of pts overall (Table). Safety was generally comparable between non-plat vs plat and plat double vs triple groups. However, in the non-plat vs plat group, rates of serious AEs (SAEs; 41.7% vs 30.9%, respectively) and PRSAEs (20.8% vs 7.2%) were higher. Overall, 3 pts had AEs with an outcome of death not related to any study tx and 7 pts had an infusion-related AE, all within the plat group (Table). ORRs were numerically higher in plat vs non-plat group (25.8% [95% confidence interval, 17.4—35.7] vs 4.2% [0.1—21.1]) and plat double vs triple group (29.3% [18.1—42.7] vs 20.5% [9.3—36.5]).

Table: 323P

	Plat double	Plat triple	Plat total	Non-plat	Total*
N	58	39	97	24	121
Any grade 3/4 PRAE within 6 months of tx initiation,† n (%)	29 (50.0)	16 (41.0)	45 (46.4)	10 (41.7)	55 (45.5)
Any AE, n (%)	52 (89.7)	38 (97.4)	90 (92.8)	22 (91.7)	112 (92.6)
Any PRAE†	47 (81.0)	38 (97.4)	85 (87.6)	21 (87.5)	106 (87.6)
Any AE leading to discontinuation	8 (13.8)	5 (12.8)	13 (13.4)	2 (8.3)	15 (12.4)
Any AE with an outcome of death	3 (5.2)	0	3 (3.1)	0	3 (2.5)
Any SAE, n (%)	18 (31.0)	12 (30.8)	30 (30.9)	10 (41.7)	40 (33.1)
Any PRSAE†	4 (6.9)	3 (7.7)	7 (7.2)	5 (20.8)	12 (9.9)
Any infusion-related AE, n (%)	2 (3.4)	5 (12.8)	7 (7.2)	0	7 (5.8)
ORR, n (%)	17 (29.3)	8 (20.5)	25 (25.8)	1 (4.2)	26 (21.5)

*Plat total plus non-plat. †As assessed by the investigator.

Conclusions: The safety profiles of all study tx were manageable. ORR data are immature but overall ORR is comparable to the TOPAZ-1 study.

Clinical trial identification: NCT05771480.

Editorial acknowledgement: Medical writing support, under the direction of the authors, was provided by Sarah Leneghan, PhD, CMC Connect, a division of IPG Health Medical Communications, funded by AstraZeneca.

Legal entity responsible for the study: AstraZeneca.

Funding: AstraZeneca.

Disclosure: D. Oh: Financial Interests, Personal, Advisory Board: AstraZeneca, Novartis, Genentech/Roche, Merck Serono, Bayer, Taiho, Aslan, Halozyme, Zymeworks, BMS/Celgene, BeiGene, Basilea, Turning Point, Yuhan, Arcus Biosciences, IQVIA, MSD, LG Chem, Astellas, AbbVie, J-Pharma, Mirati Therapeutics, Eutilex, Moderna, Idience, Alligator Bioscience AB, Hana pharm; Financial Interests, Institutional, Research Grant: AstraZeneca, Novartis, Array, Eli Lilly, Servier, BeiGene, MSD, Handok. M. Ikeda: Financial Interests, Personal, Advisory Board: AstraZeneca, Chugai, Eisai, Nihon Servier, Novartis, Bristol Myers Squibb, MSD, Boehringer Ingelheim, Astellas Pharma, GSK, AbbVie, Guardant Health Japan; Financial Interests, Personal, Invited Speaker: AstraZeneca, Chugai, Eli Lilly Japan, Eisai, Nihon Servier, Novartis, Taiho, Yakult, Teijin Pharma, Incyte Biosciences Japan, Takeda, Ono, MSD, Guardant Health Japan, Nobelpharma, EA Pharma, Chugai, Eisai, Rakuten Medical, AstraZeneca, Delta-Fly Pharma; Financial Interests, Institutional, Invited Speaker: Bristol Myers Squibb, Eisai, AstraZeneca, Eli Lilly Japan, Chugai Pharmaceutical, MSD, Ono, Novartis, J-Pharma, Chiome Bioscience, Nihon Servier, Syneos Health, Merus. N.V., Merck Biopharma, Boehringer Ingelheim, Invitae, Nobelpharma, AbbVie, Incyte Biosciences Japan. T. Macarulla Mercade: Financial Interests, Personal, Advisory Board: Ability Pharmaceutical, SL, Arcus Biosciences, AstraZeneca, Basilea Pharma, Baxter, BioLineRx Ltd, Celgene SLU, Eisai, Ipsen Pharma, Incyte, MSD, Novocure; Financial Interests, Personal, Invited Speaker: Bioncotech Therapeutics, Daiichi Sankyo, Esteve, Janssen, Jazz Pharmaceuticals, Lilly, Novartis; Financial Interests, Personal, Other, Direct research fund: Merck, Sharp and Dohme, Novocure, QED Therapeutics Inc, Roche, Sanofi-Aventis, Servier, Zymeworks; Financial Interests, Personal, Other, Travel and accommodation: AstraZeneca; Financial Interests, Personal, Other, Travel and accommodation: Servier, Incyte, Lilly, MSD, Roche; Financial Interests, Personal, Other, Travel and accommodation: Sanofi; Financial Interests, Institutional, Research Grant: Amc Medical Research, Armo Biosciences, Basilea, BioKeralty Research Institute, Merck Sharp & Dohme, Oncomed Pharmaceuticals, QED Therapeutics, VCN Biosciences, AbbVie Farmaceútica, Ability Pharmaceuticals, Agios, Amgen, Aslan, AstraZeneca, Bayer, Beigene, BioLineRx, Blueprint Medicines, Boston Biomedical, Bristol Myers Squibb (BMS), Cantargia, Celgene, Eisai, Erytech Pharma, F. Hoffmann-la Roche, FibroGen, Genentech, Halozyme, Immunomedics, Incyte, Ipsen, Lab. Menarini, Lilly, Loxo Oncology, MedImmune, Merrimack, Millenium, Nelum, Novartis, Novocure, Pfizer, Pharmacyclics, Roche, Zymeworks; Non-Financial Interests, Member: American Society of Clinical Oncology - ASCO, "Sociedad Española de Oncología Médica" — SEOM, Sociedad Europea de Oncología Médica - ESMO; Other, Editorial Board: GI Annals og¡f Oncology. A.R. He: Financial Interests, Personal, Invited Speaker, Speaker's Bureau: Eisai; Financial Interests, Personal, Invited Speaker, Speaker's bureau: AstraZeneca; Financial Interests, Institutional, Research Grant: AstraZeneca. J.O. Park: Financial Interests, Personal, Advisory Board: Servier, MediRama, Adicet Bio, AstraZeneca, Merck Sereno, ImmuneOncia, Merck, Arcus biosciences; Financial Interests, Personal, Other, Travel support for a poster presentation at ASCO GI 2023: Minneamrita Therapeutics LLC; Financial Interests, Personal, Research Grant, Clinical research grant: MedPacto, Servier, BMS (Celgene); Financial Interests, Personal, Research Grant: Eutilex, ABL Bio. M. Kitano: Financial Interests, Personal, Invited Speaker, Fee for lecture: AstraZeneca; Financial Interests, Institutional, Funding, Funding for Clinical Trial: AstraZeneca. A. Lamarca: Financial Interests, Personal, Invited Speaker: AAA, AstraZeneca, Eisai, GenFit, Incyte, Incyte, Ipsen, Merck, Pfizer, QED, QED, Servier, Servier, Advanz Pharma, Roche; Financial Interests, Personal, Advisory Board: Albireo Pharma, AstraZeneca, Boston Scientific, Eisai, GenFit, Ipsen, Nutricia, QED, Roche, Servier, Taiho; Financial Interests, Institutional, Other, Access to FM molecular profiling: Roche; Financial Interests, Institutional, Other, educational event: AstraZeneca; Non-Financial Interests, Principal Investigator, PI of trial: QED, Merck, AstraZeneca, Boehringer Ingelheim, Roche, Servier, Jazz Therapeutics, CAMURUS, Novocure, Taiho, Panbela Therapeutics; Other, Travel and educational support: Ipsen, Pfizer, Bayer, AAA, SIrTex, Novartis, Mylan, Delcath, Advanz Pharma, Roche. D.W.M. Tai: Financial Interests, Institutional, Advisory Board: Novartis, Celgene, SIRTEX, MSD, BMS, Eisai, Bayer, GSK. F. Dayyani: Financial Interests, Personal, Advisory Board: Eisai, AstraZeneca; Financial Interests, Personal, Invited Speaker: Ipsen, Sirtex, Takeda; Financial Interests, Institutional, Invited Speaker: AstraZeneca, BMS, Bayer, Exelixis, Roche, Ipsen, Signatera, Merck, Taiho. T. Pressiani: Financial Interests, Personal, Invited Speaker: AstraZeneca; Financial Interests, Institutional, Invited Speaker: Roche, AstraZeneca. G. Wetherill: Financial Interests, Personal, Other, Contracted employee: AstraZeneca. A. Stell, P. Sun, B. Baur: Financial Interests, Personal, Full or part-time Employment: AstraZeneca; Financial Interests, Personal, Stocks/Shares: AstraZeneca. A. Vogel: Financial Interests, Personal, Advisory Board: Amgen, AstraZeneca, Boehringer Mannheim, Eisai, Incyte, Ipsen, MSD, Roche, Servier, Tyra, Tahio, AbbVie; Financial Interests, Personal, Invited Speaker: BMS, Eisai, Ipsen, MSD, Roche, AstraZeneca, Roche, MSD, Beigene, Boehringer Ingelheim.

https://doi.org/10.1016/j.annonc.2025.05.338

325P Epidemiological profile of biliary tract cancer (BTC) in Argentina: A real-world study by Latin American intergroup of gastrointestinal oncology (ILOGI)

A.C. Ituarte[1], G.F. Arroyo[2], S.V. Rojo[3], H. Caceres[4], I.V. Herrera[5], A.G. Soria[6], L. Basbus[7], R. Sifon[8], A. Botana[9], V.S. Barbereau[10], B. Freile[11], F. Quintana[12], A.I. Oviedo[13], S.A. Ostoich[14], L. Toselli[12], M.C. Baiud[15], V. Faura[16], J.O. Castillo[17], M.H. Dioca[18]

[1]Oncology, Pablo Soria Hospital, San Salvador de Jujuy, Argentina; [2]Oncology, CeDIT (Centro de Diagnóstico, Investigación y Tratamiento), Salta, Argentina; [3]Oncology, National Clinical Hospital, Cordoba, Argentina; [4]Oncology, Pasteur Sanatorium, San Fernando del Valle de Catamarca, Argentina; [5]Oncology, Zenón Santillán Hospital Health Center, San Miguel de Tucuman, Argentina; [6]Oncology, Private University Hospital of Córdoba, Cordoba, Argentina; [7]Oncology, Italian Hospital of Buenos Aires, Buenos Aires, Argentina; [8]Oncology Department, Dr. Norberto Quirno Center for Medical Education and Clinical Research CEMIC, Buenos Aires, Argentina; [9]Oncology, Churruca Visca Hospital, Buenos Aires, Argentina; [10]Oncology, Cancer Missionary Institute, Buenos Aires, Argentina; [11]Gastrointestinal Oncology, Alexander Fleming Institute, Buenos Aires, Argentina; [12]Oncology, Allende Sanatorium, Cordoba, Argentina; [13]Medical Oncology, Gastroenterology Hospital Dr. Bonorino Udaondo, Buenos Aires, Argentina; [14]Oncology, Rosario Private Hospital, Rosario, Argentina; [15]Oncology, Queen Fabiola University Clinic, Cordoba, Argentina; [16]Oncology, British Hospital of Buenos Aires, Buenos Aires, Argentina; [17]Oncology, German Hospital, Buenos Aires, Argentina; [18]Gastrointestinal and Neuroendocrine Tumors, Angel H. Roffo Oncology Institute, Buenos Aires, Argentina

Background: BTC includes a heterogeneous group of tumors with increasing incidence and mortality. This study addresses the need to characterize these rare neoplasms in an Argentine cohort.

Methods: Multicenter observational study of patients with histological diagnosis of cholangiocarcinoma (intrahepatic: ICC, extrahepatic: ECC) and gallbladder cancer (GBC) between 2013 and 2023. Follow-up until December 2024. The data were