659MO Preliminary results from a phase I/II study of 9MW2821, an antibody-drug conjugate targeting nectin-4, in patients with advanced solid tumors

J. Zhang[1], R. Liu[1], S. Gao[1], X. Li[2], J. Chen[3], X. Yao[4], Y. fang[5], R. Li[6], M. Zhang[7], F. Qiu[8], Y. Li[9], T. Liu[10], H. Huang[11], X. Zhang[12], H. Guo[13], B. Hu[14], J-Y. Liu[15], Q. Yang[16], P. Zhao[17], P. Wang[18]

[1]Phase I Clinical Trial Center, Fudan University Shanghai Cancer Center, Shanghai, China; [2]Department of Oncology, The First Affiliated Hospital of Zhengzhou University, Zhengzhou, China; [3]Department of Medical Oncology, Yantai Yuhunagding Hospital, Yantai, China; [4]Department of Urologic Oncology, Tianjin Cancer Hospital, Tianjin, China; [5]Department of Urology, Affiliated Cancer Hospital of Chongqing University, Chongqing, China; [6]Gynecological Oncology Center, Chongqing University Cancer Hospital, Chongqing, China; [7]Department of Medical Oncology, The Second Hospital of Anhui Medical University, Hefei, China; [8]Department of Medical Oncology, The Second Affiliated Hospital of Zhejiang University School of Medicine-East Gate 1, Hangzhou, China; [9]Department of Oncology, Shenyang Tenth People's Hospital, Shenyang, China; [10]Department of Medical Oncology, Zhongshan Hospital Affiliated to Fudan University, Shanghai, China; [11]Department of Urinary Surgery, The First Affiliated Hospital of Wenzhou Medical University-Nanbaixiang Site, Wenzhou, China; [12]Department of Urology, Wuhan Union Hospital, Wuhan, China; [13]Department of Urology, The Affiliated Drum Tower Hospital of Nanjing University Medical School, Nanjing, China; [14]Department of Urology, Liaoning Cancer Hospital and Institute, Shenyang, China; [15]Department of Biotherapy, West China School of Medicine/West China Hospital of Sichuan University, Chengdu, China; [16]Phase I Clinical Trial Center, The Second Affiliated Hospital of Sun Yat-sen University, Guangzhou, China; [17]Department of Medical Oncology, The First Affiliated Hospital of Medical School of Zhejiang University, Hangzhou, China; [18]Clinical Medicine Department, Mabwell (Shanghai) Bioscience Co., Ltd., Shanghai, China

Background: Nectin-4 is an adhesion molecule that highly expressed in variety of solid tumors and could be a potent therapeutic target. 9MW2821 is a monoclonal antibody-drug conjugate (ADC) that delivers monomethyl auristatin E to cells expressing Nectin-4. Here we report the first-in-human, multicenter, phase I/II study designed to explore the safety, pharmacokinetics and efficacy of 9MW2821 in advanced solid tumors.

Methods: 9MW2821 was administered by intravenous infusion on days 1, 8 and 15 of each 28-day cycle. The study included dose escalation, dose expansion and cohort expansion period which included urothelial cancer (UC) and other Nectin-4 positive solid tumors. Primary objectives were assessment of safety and preliminary efficacy.

Results: As of April 27, 2023, 97 patients (pts) were enrolled with doses ranging from 0.33 to 1.5mg/kg. Median age was 57 years (range, 32-78). Only 1 dose limiting toxicity of grade 4 neutropenia lasted more than 5 days was observed at 1.5mg/kg group. Maximum tolerated dose was not yet reached. Treatment related adverse events (TRAEs) of any grade occurred in 64.9% pts. The most common TRAEs were white blood cell (WBC) count decreased (36.1%), neutropenia (35.1%), nausea (22.7%), aspartate aminotransferase increased (22.7%), rash (19.6%), alopecia (19.6%), fatigue (18.6%), decreased appetite (18.6%), anemia (17.5%), vomiting (16.5%), peripheral sensory neuropathy (16.5%). Grade 3/4 TRAEs occurred in 35.1% pts. The most common grade 3/4 TRAEs were WBC count decreased (18.6%) and neutropenia (18.6%). Treatment related death was not observed. Among 39 pts treated with 9MW2821 at 1.25mg/kg or above and evaluable for tumor assessment, objective response rate (ORR) and disease control rate (DCR) was 38.5% and 84.6%, respectively. In 18 pts with UC who progressed after platinum-based chemotherapy and immune checkpoint inhibitors and dosed at 1.25mg/kg, ORR and DCR was 55.6% and 94.4%, respectively. Objective responses were also observed in pts with breast cancer and cervical cancer.

Conclusions: The results showed that 9MW2821 had manageable safety profile and promising antitumor activity. Enrollment continues to determine efficacy of 9MW2821 in certain solid tumors.

Clinical trial identification: NCT05216965.

Legal entity responsible for the study: Mabwell (Shanghai) Bioscience Co., Ltd.

Funding: Mabwell (Shanghai) Bioscience Co., Ltd.

Disclosure: P. Wang: Financial Interests, Institutional, Full or part-time Employment: Mabwell (Shanghai) Bioscience Co., Ltd. All other authors have declared no conflicts of interest.

https://doi.org/10.1016/j.annonc.2023.09.1845

660MO First-in-human study of SGN-B7H4V, a B7-H4-directed vedotin ADC, in patients with advanced solid tumors: Preliminary results of a phase I study (SGNB7H4V-001)

C.A. Perez[1], J.T. Henry[2], N. Lakhani[3], J.A. Call[4], E.P. Hamilton[5], G. Colon-Otero[6], J.R. Diamond[7], B. O'Neil[8], A. Kalyan[9], G.P. Sonpavde[10], I. Moreno Candilejo[11], A.A. Awan[12], E. Fontana[13], P. Xu[14], F. Zhang[15], N. Nazarenko[16], A. Patnaik[17]

[1]Sarah Cannon Research Institute at Florida Cancer Specialists, University of Central Florida Lake Nona Cancer Center, Orlando, FL, USA; [2]Drug Development Unit, Sarah Cannon Research Institute at HealthONE, Denver, CO, USA; [3]Developmental Therapeutics, START Midwest, Grand Rapids, MI, USA; [4]Developmental Therapeutics, START Mountain Region, West Valley City, UT, USA; [5]Sarah Cannon Research Institute, Tennessee Oncology, Nashville, TN, USA; [6]Medical Oncology, Mayo Clinic, Jacksonville, FL, USA; [7]University of Colorado Hospital, University of Colorado, Aurora, CO, USA; [8]Hematology and Medical Oncology, Community Health Network, Indianapolis, IN, USA; [9]Division of Hematology and Oncology, Robert H. Lurie Comprehensive Cancer Center, Northwestern University, Chicago, IL, USA; [10]Genitourinary Oncology, AdventHealth Cancer Institute, Celebration, FL, USA; [11]START Madrid-CIOCC, Centro Integral Oncológico Clara Campal, Madrid, Spain; [12]Medical Oncology, Ottawa Hospital Research Institute, Ottawa, ON, Canada; [13]Drug Development, Sarah Cannon Research Institute SCRI UK, London, UK; [14]Biostatistics, Seagen Inc., Bothell, WA, USA; [15]Quantitative Pharmacology and Disposition, Seagen Inc., Bothell, WA, USA; [16]Global Drug Development, Seagen Inc., Bothell, WA, USA; [17]Developmental Therapeutics, START San Antonio, San Antonio, TX, USA

Background: B7-H4 is a B7 immune checkpoint ligand expressed at low levels in normal tissue and is upregulated in solid tumors, including breast, ovarian, and endometrial cancers. SGN-B7H4V is an investigational vedotin ADC comprising a B7-H4-directed monoclonal antibody conjugated to monomethyl auristatin E via a protease-cleavable linker. We report first results from dose escalation (Part A) of this ongoing phase 1 study.

Methods: SGNB7H4V-001 is a first-in-human, multicenter study evaluating the safety, tolerability, pharmacokinetics, and antitumor activity (objective response rate per RECIST v1.1) of SGN-B7H4V in patients with advanced solid tumors. Part A enrolled patients with histologically or cytologically confirmed locally advanced unresectable or metastatic solid tumors irrespective of B7-H4 expression. Patients received SGN-B7H4V on Days 1 and 8 of a 21-day cycle (2Q3W, 0.75, 1.0, 1.25, or 1.5 mg/kg), or on Days 1 and 15 of a 28-day cycle (2Q4W, 1.25, 1.5, 1.75, or 2.0 mg/kg).

Results: As of 10 March 2023, 75 patients were enrolled and received SGN-B7H4V. In 2Q3W (n=35), 3 patients (8.6%) had dose-limiting toxicities (DLTs) of hyperglycemia (1.25 mg/kg), arterial embolism (1.5 mg/kg), and neutropenia (1.5 mg/kg). The most common TEAEs across doses were fatigue (20.0%), peripheral sensory neuropathy (20.0%), and neutropenia (17.1%). The most common grade $\geq$3 TEAE was neutropenia (14.3%). In 2Q4W (n=40), 2 of 39 DLT-evaluable patients (5.1%) had DLTs of peripheral sensory neuropathy (1.5 mg/kg) and transaminitis (2.0 mg/kg). The most common TEAEs were fatigue (27.5%), peripheral sensory neuropathy (27.5%), and nausea (22.5%). The most common grade $\geq$3 TEAEs were anemia, dyspnea, hypotension, and pneumonia (5.0% each). Confirmed objective responses (starting at 0.75 mg/kg) were observed in evaluable patients with breast (7/25 patients), ovarian (2/15 patients), endometrial (1 [complete response]/16 patients), and biliary tract cancers (2/9 patients).

Conclusions: SGN-B7H4V showed a manageable safety profile in patients with advanced solid tumors. Responses were observed at all tested dose levels and across various tumor types. Dose expansion in select tumor types is planned.

Clinical trial identification: EudraCT 2021-002107-35, NCT05194072; Release date: 03 April 2023.

Editorial acknowledgement: Irina Mordukhovich, PhD (MMS Holdings, Canton, MI), provided medical writing.

Legal entity responsible for the study: Seagen Inc.

Funding: Study funding was provided by Seagen Inc., Bothell, WA, USA.

Disclosure: C.A. Perez: Financial Interests, Institutional, Principal Investigator: Accutar Biotech, Dracen Pharmaceuticals, Elpiscience Biopharmaceuticals, Elucida Oncology, Genentech Inc., Hyamab Inc., Jazz Pharmaceuticals, Kinnate Biopharma, Kura Oncology, Mirati Therpeutics, Relay Therapeutics, Ribbon Therapeutics, Seagen Inc., Tallac Therapeutics, Xilio Therapeutics, Zhuhai Yufan Biotechnologies Co. J.T. Henry: Financial Interests, Personal, Full or part-time Employment, Associate Director/Oncologist: Sarah Cannon Research Institute; Financial Interests, Personal, Stocks/Shares: HCA; Financial Interests, Institutional, Invited Speaker: Abbiscko Therapeutics, ABl bio, Accutar biotech ADC therapeutics, Agenus, Aileron Therapeutics, Amgen Inc., Artios, Astrazenaca, Bicycle therapeutics, BioAlta, BioInvent pharma, Biosplice therapeutics, Black diamond therapeutics, Boehringer, Ingelheim, Cyteir, Daiichi Sankyo, Eli Lilly, Epizyme, Erasca, Exelixis, FujiFilm, GSK, Hutchison MediPharma, ICON plc, IGM Biosciences, Immunogen, Jacobio pharmaceuticals, Jounce pharma, Jubilant therapeutics, Loxo Oncology, Merck& CO, Metabomed, Molecular templates, Navire Pharma, Nikang pharmaceuticals, Oncorus, Prelude therapeutics, Poseida, PureTech, Pyramid, Rascal Therapeutics, Regeneron, Relay Therapeutics, Rgenix Inc., Ribon therapeutics, Sapience, Sarah Cannon Development Innovations, Sarah Cannon Research Institute, Seagen, Simcha Therapeutics, Siranomics, Stingthera, Synthorx Inc., Teneothree, Takeda pharmaceuticals, Tallac therapeutics, Tarveda, Tesaro, Turning point pharma, Xencor. N. Lakhani: Financial Interests, Personal, Advisory Board: Innovent Biologics; Financial Interests, Personal, Advisory Board, Participation in Ad Board: Ikena, SK Life Sciences; Financial Interests, Institutional, Invited Speaker: ALX Therapeutics, Ascentage, Constellation Pharma, Alpine Biosciences, Forty Seven, Merck, Pfizer, Regeneron, Symphogen, InhibRx, Seagen, Sapience Therapeutics, Jounce, Northern Biologics, Odonate, Loxo/Lilly, Ikena, Mersana Therapeutics, Astellas, Celgene, Helsinn, Shattuck Labs, Samumed, GSK, Alkermes, Servier, Samumed, Tizona Therapeutics, Gilead, Repare Therapeutics, Alkermes, InhibRx, Janssen, cytomX, KSQ Therapeutics, Repare Therapeutics. E.P. Hamilton: Financial Interests,

Institutional, Other, Consulting/Advisory Role: Genentech/Roche, Novartis, Lilly, Pfizer, Mersana, iTeos, Janssen, Loxo, Relay Therapeutics, Olema Pharmaceuticals, Orum Therapeutics, Stemline Therapeutics, Arcus, AstraZeneca, Daiichi Sankyo, Seagen, Ellipses Pharma, Greenwich LifeSciences, Tubulis, Verascity Science, Theratechnologies; Financial Interests, Institutional, Research Grant: Oncomed, Genentech/Roche, Zymeworks, Rgenix, Arqule, Clovis, Millennium, Acerta Pharma, Sermonix Pharmaceuticals, Black Diamond, Karyopharm, Curis, Syndax, Novartis, Boehringer Ingelheim, Immunomedics, FujiFilm, Taiho, Deciphera, Molecular Templates, Onconova Therapeutics, Dana Farber Cancer Hospital, Hutchinson MediPharma, MedImmune, Seagen, Compugen, TapImmune, Lilly, Pfizer, H3 Biomedicine, Merus, Regeneron, Arvinas, StemCentRx, Verastem, eFFECTOR Therapeutics, CytomX, InventisBio, Lycera, Mersana, Radius Health, AbbVie, Nucana, Leap Therapeutics, Zenith Epigenetics, Harpoon, Orinove, EMD Serono, AstraZeneca, Tesaro, Macrogenics, Daiichi Sankyo, Syros, Sutro, G1 Therapeutics, PharmaMar, Olema, Immunogen, Plexxicon, Amgen, Akesobio Australia, Shattuck Labs, ADC Therapeutics, Aravive, Atlas MedX, Ellipses, Incyte, Jacobio, Mabspace Biosciences, ORIC Pharmaceuticals, Pieris Pharmaceuticals, Pionyr Immunotherapeutics, Repertoire Immune Medicine, Treadwell Therapeutics, Accutar Biotechnology, Cascadian Therapeutics, Artios, BeiGene; Financial Interests, Institutional, : Bliss BioPharmaceuticals. G. Colon-Otero: Financial Interests, Institutional, Full or part-time Employment, employed full time by the Mayo Clinic: Mayo Clinic; Financial Interests, Institutional, Invited Speaker, NIH grant 2022-2027: NIH; Financial Interests, Institutional, Invited Speaker, Co-Investigator for U54 grant with FAMU: National Institute of Minority Health; Financial Interests, Institutional, Invited Speaker, Research grant for clinical trial Y40482: A phase 1b study of cobimetinib in combination with niraparib 2019- August 2023: Hoffmann-LaRoche; Financial Interests, Institutional, Invited Speaker, Research funding for phase 1b/2trial of TG4001 and avelumab in patients with HV-16 positive recurrent or metastatic malignancies 11/21- 12/23: Transgene SA; Financial Interests, Institutional, Invited Speaker, A Phase 1 Study of SGN-B7H4V in Advanced Solid Tumors.Funded by Seagen. (SGNB7H4V-001) August 2022- July 2026: Seagen; Financial Interests, Institutional, Invited Speaker, A Randomized, Phase 2 Study of Pembrolizumab AndChemotherapy With or Without MK-4830 as NeoadjuvantTreatment for High-Grade Serous Ovarian Cancer. Funded byMerck & Co., Inc. November 2022- November 2024: Merck; Financial Interests, Institutional, Invited Speaker, (ECTx) RP-6306-02 (MCF): Phase 1 Study of the PKMYT1Inhibitor RP-6306 in Combination with Gemcitabine for theTreatment of Advanced Solid Tumors (MAGNETIC Study).Funded by Repare Therapeutics. (RP-6306-02) June 2022- May 2024: REPARE; Non-Financial Interests, Advisory Role, May 2023- no personal renumeration: REPARE; Non-Financial Interests, Member of Board of Directors: Florida Society of Clinical Oncology; Non-Financial Interests, Officer: AACR MICR Council; Non-Financial Interests, Member, Member of MICR Council: AACR. J.R. Diamond: Financial Interests, Institutional, Other, Consultant, Chief Medical Officer: OnKure Therapeutics; Financial Interests, Institutional, Advisory Board: Gilead; Financial Interests, Institutional, Other, stock options: OnKure Therapeutics; Financial Interests, Institutional, Invited Speaker, PI of clinical trial at my institution with payments to my institution: HutchMed, Gilead, Merck, Cosmo, Adlai Nortye, Takeda, Seattle Genetics, BMS. B. O'Neil: Financial Interests, Personal, Speaker's Bureau: AstraZeneca. A. Kalyan: Financial Interests, Personal, Advisory Board, Consulting and advisory board: AstraZeneca; Financial Interests, Personal, Advisory Board, Consulting and Advisory Board: Genentech; Financial Interests, Personal, Invited Speaker, Speaking for Nurses and Doctors: Genentech; Financial Interests, Personal, Advisory Board: Exelixis, Boston Scientific; Financial Interests, Personal, Other, Consulting: Boston Scientific; Financial Interests, Institutional, Invited Speaker: Boston Scientific, Exelixis; Non-Financial Interests, Principal Investigator, Investigator: Exelixis; Non-Financial Interests, Principal Investigator: Boston Scientific. G.P. Sonpavde: Financial Interests, Personal, Advisory Board: Bicycle Therapeutics, Bristol Myers Squibb, EMD Serono/Pfizer, Exelixis, G1 Therapeutics, Genentech, Janssen, Loxo Oncology, Lucence, Merck, Sanofi, Scholar Rock, Seagen, Syapse, Tempus, Immunomedics/Gilead; Financial Interests, Personal, Advisory Board, Editor of Bladder cancer virtual center of excellence for Practice Update: Elsevier; Financial Interests, Personal, Advisory Board, to develop a trial in bladder cancer: Servier Pharmaceuticals; Financial Interests, Personal, Invited Speaker: Exelixis, Gilead, Research to practice, Seagen, Janssen; Financial Interests, Personal, Other, Member of data safety monitoring board: Mereo; Financial Interests, Personal, Other, Author of chapter: Uptodate; Financial Interests, Institutional, Research Grant, Financial interest: EMD Serono; Financial Interests, Institutional, Research Grant, No financial interest: Gilead, Jazz Pharma, Predicine, QED, Sanofi; Non-Financial Interests, Personal, Principal Investigator, Steering committee of trial: Bristol Myers Squibb; Non-Financial Interests, Personal, Principal Investigator: G1 Therapeutics; Non-Financial Interests, Personal, Other, Steering committee of trial: Merck; Non-Financial Interests, Personal, Leadership Role, Steering committee of trial: QED; Other, Personal, Other, Spouse employment: Myriad Genetics. A.A. Awan: Financial Interests, Personal, Other, Honorarium: Apotex, Roche Canada, AstraZeneca Canada, Oncology Education, Eli Lilly, Exactis Innovation, Novartis; Financial Interests, Personal, Speaker, Consultant, Advisor: Exact Sciences, Pfizer, Novartis Canada Pharmaceuticals Inc., Exact Sciences, Eli Lilly, Foundation Medicine, AstraZeneca Canada, Roche Canada, AstraZeneca, Gilead Sciences; Financial Interests, Institutional, Research Funding: Roche, Sermonix Pharmaceuticals, Seagen, Exactis Innovation, Intensity Therapeutics, Astellas Pharma, Canexia Health; Financial Interests, Institutional, Other, Travel/Accomodations/Expenses: Roche/Genentech. E. Fontana: Financial Interests, Personal, Invited Speaker: CARIS Life Science, Repair Therapeutics; Financial Interests, Personal, Other, Conference attendance: Sapience Pharma; Financial Interests, Personal, Full or part-time Employment: Hospital Corporation of America (HCA) International; Financial Interests, Personal, Officer: EORTC; Financial Interests, Institutional, Coordinating PI: Repair Therapeutics, Amgen, Taiho Pharmaceutical; Financial Interests, Institutional, Local PI: Bicycle Therapeutics, Artios Pharma, Seagen, Nurix Therapeutics, BioNTech SE, Relay Therapeutics, Pfizer, Roche, Daiichi Sankyo, Gilead Science, Basilea Pharmaceutica, Jiangsu Hengrui Medicine, Mereo Biopharma, HUTCHMED, Merus, Crescendo Biologics, GSK plc, BeiGene, Turning Point Therapeutics, Sapience Pharma; Non-Financial Interests, Advisory Role: Vivan Therapeutics. P. Xu, F. Zhang, N. Nazarenko: Financial Interests, Institutional, Full or part-time Employment: Seagen Inc.; Financial Interests, Institutional, Stocks/Shares: Seagen Inc. A. Patnaik: Financial Interests, Institutional, Other, Institutional research funding: Compugen. All other authors have declared no conflicts of interest.

https://doi.org/10.1016/j.annonc.2023.09.1846

661MO Anti-tumor activity of belvarafenib in combination with cobimetinib in patients with metastatic solid tumors harboring BRAF fusions or BRAF class II/III mutation

T.W. Kim[1], J. Lee[2], S.J. Shin[3], S-W. Han[4], Y.J. Kim[5], J-S. Kim[6], S.Y. Oh[7], D.H. Lee[1], M.H. Kim[3], S.T. Kim[2], Y. Hong[8], S. Kim[8], T. Kim[8], B. Lee[8], J. Eng-Wong[9], Y. Yan[10], C. Chou[9], Y.S. Noh[8]

[1]Oncology Department, Asan Medical Center-University of Ulsan College of Medicine, Seoul, Republic of Korea; [2]Division of Hematology/Oncology, Department of Internal Medicine, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, Republic of Korea; [3]Division of Medical Oncology, Department of Internal Medicine, Yonsei University College of Medicine, Seoul, Republic of Korea; [4]Department of Internal Medicine, Seoul National University Hospital, Seoul, Republic of Korea; [5]Internal Medicine Department, Seoul National University Bundang Hospital, Seoul National University College of Medicine, Seongnam, Republic of Korea; [6]Internal Medicine Department, Boramae Medical Center, Seoul, Republic of Korea; [7]Departments of Internal Medicine, Dong-A University College of Medicine, Busan, Republic of Korea; [8]Clinical Research and Development, Hanmi Pharmaceutical Co., Ltd., Seoul, Republic of Korea; [9]Early Clinical Development, Genentech, Inc., South San Francisco, CA, USA; [10]Translational Medicine, Genentech, Inc., South San Francisco, CA, USA

Background: Belvarafenib (Belva) is a type II selective RAF dimer inhibitor that, in combination with Cobimetinib (Cobi) has shown clinical activity in patients with NRAS-mutant melanoma (ASCO 2021 , ESMO 2021). One cohort in this phase I trial evaluated BRAF fusions (including indel/rearrangement) or class II/III point mutations, which are considered potential therapeutic targets for Belva +/- Cobi. Here, we present findings on activity and safety of Belva and Cobi in patients with BRAF fusion including indel/rearrangement.

Methods: A total of 23 patients harboring BRAF non-canonical aberration were enrolled and treated with Belva 300mg PO BID and Cobi 20mg PO TIW (3 times a week) in the HM-RAFI-103 study (NCT03284502). Sub-cohort A (SC-A) enrolled patients with BRAF fusions and sub-cohort B (SC-B) enrolled patients with BRAF class II/III point mutations. Safety results were updated based on 133 patients who were treated with Belva and Cobi as of Jan 31, 2023.

Results: In SC-A, a total of 15 patients harboring BRAF fusions (Melanoma (10), NSCLC (3), CRC (1), Pancreatic cancer (1)) and 8 patients with BRAF class II/III point mutation were in SC-B (Biliary tract cancer (3), CRC (3), SCLC (1), Glioblastoma (1)) were enrolled. The confirmed objective response rate (ORR), assessed by investigators' assessment, for SC-A was 60.0%, median progression-free survival (mPFS) was 13.7 months, and median duration of response was 12.0 months (95% CI: 7.43 to 22.34) with median follow-up time 12.9 months, while patients in SC-B showed best response of stable disease. As of cut-off date, the most common treatment related adverse events from 133 patients is dermatitis acneiform (54.1%), rash (28.6%), and blood creatine phosphokinase increased (24.1%). No new safety signals were found.

Table: 661MO

		SC-A: BRAF fusion (N = 15)	SC-B: Point mutation (N = 8)
Best overall response	CR	0	0
	PR	9 (60.0)	0
	SD	5 (33.3)	4 (50.0)
	PD	1 (6.7)	4 (50.0)
ORR	n (%)	9 (60.0)	0
	95% CI	32.29, 83.66	0, 36.94
Disease control rate (PR+SD)	n (%)	14 (93.3)	4 (50.0)
	95% CI	68.05, 99.83	13.70, 78.80
mPFS	month	13.7	2.1
	95% CI	7.36, 18.23	1.61, 7.16

Conclusions: The combination of Belva with Cobi showed promising anti-tumor activity as well as durable responses in patients with BRAF fusions regardless of cancer type.

Clinical trial identification: NCT03284502.

Legal entity responsible for the study: Hanmi Pharmaceutical.

Funding: Hanmi Pharmaceurical.

Disclosure: T.W. Kim: Financial Interests, Institutional, Research Grant: Genentech. J. Lee: Financial Interests, Steering Committee Member: Seattle Genetics, AZ; Non-Financial Interests, Principal Investigator: AstraZeneca, Daiichi Sankyo, Merck MSD, BMS, Leaptherapeutics; Non-Financial Interests, Project Lead: Samsung Bioepis, Genome and Company, Oncxerna; Non-Financial Interests, Advisory Role: Mirati Therapeutics; Non-Financial Interests, Member: KSMO; Non-Financial Interests, Other, AP Council: ASCO. S. Han: Financial Interests, Institutional, Local PI: Hanmi, Genentech, Roche, Loxo, Mirati, MSD, Janssen, Lilly, Seagen, Arcus. J. Kim: Financial Interests, Personal, Invited Speaker: CJ Healthcare, AstraZeneca, GeneCKer, Sanofi/Aventis, Gencurix, Boryung; Financial Interests, Personal, Advisory Board: ABION, CJ Healthcare; Financial Interests, Personal, Member of Board of Directors: IMBdx; Financial Interests, Local PI: AstraZeneca, Boehringer Ingelheim, Sanofi, Lilly, CJ Healthcare, Hanmi, Ono Pharmaceutical, Pfizer, Novotech, Astellas Pharma, Merck, Alpha Biopharma, Yuhan, MSD, IL-Yang Pharm, AbbVie, Boryung, ChongKeunDang Healthcare, Daiichi Sankyo, BeiGene. D.H. Lee: Financial Interests, Personal, Advisory Board, honoraria for lectures and