ORAL SESSIONS

SESSION ORAL 01: CHEMOTHERAPY DEVELOPMENTS FOR LUNG CANCER MONDAY, SEPTEMBER 7, 2015

CHEMOTHERAPY DEVELOPMENTS FOR LUNG CANCER
MONDAY, SEPTEMBER 7, 2015 - 10:45-12:15

ORAL01.01 Randomized Phase III Study of Nedaplatin plus Docetaxel versus Cisplatin plus Docetaxel for Advanced Squamous Cell Lung Cancer (WJOG5208L) Takashi Seto[1], Takehito Shukuya[2], Takeharu Yamanaka[3], Tomonori Hirashima[4], Terufumi Kato[5], Yoshitsugu Horio[6], Shinji Atagi[7], Takako Inoue[8], Yoshinobu Ohsaki[9], Tadashi Maeda[10], Koichi Nishi[11], Toshiyuki Sawa[12], Morihito Okada[13], Daichi Fujimoto[14], Taishi Harada[15], Kazuhiko Nakagawa[16], Yoichi Nakanishi[15], Nobuyuki Yamamoto[17] [1]*National Kyushu Cancer Center, Fukuoka/Japan,* [2]*Juntendo University, Tokyo/Japan,* [3]*Yokohama City University, Yokohama/Japan,* [4]*Osaka Prefectural Medical Center for Respiratory and Allergic Diseases, Habikino/Japan,* [5]*Kanagawa Cardiovascular and Respiratory Center, Yokohama/Japan,* [6]*Aichi Cancer Center, Nagoya/Japan,* [7]*Kinki-Chuo Chest Medical Center, Sakai/Japan,* [8]*Osaka Medical for Cancer and Cardiovascular Disease, Osaka/Japan,* [9]*Asahikawa Medical University, Asahikawa/Japan,* [10]*Yamaguchi-Ube Medical Center, Ube/Japan,* [11]*Ishikawa Prefectural Central Hospital, Kanazawa/Japan,* [12]*Gifu Municipal Hospital, Gifu/Japan,* [13]*Hiroshima University, Hiroshima/Japan,* [14]*Kobe City Medical Center General Hospital, Kobe/Japan,* [15]*Kyushu University, Fukuoka/Japan,* [16]*Kinki University Faculty of Medicine, Osaka-Sayama/Japan,* [17]*Wakayama Medical University, Wakayama/Japan*

Background: Nedaplatin (N) is a second-generation platinum compound with lower nausea/vomiting and nephrotoxicity than cisplatin (C). Nedaplatin plus docetaxel (ND) showed a promising efficacy with acceptable toxicity for advanced squamous cell lung cancer (SqLC) in the previous phase II study. **Methods:** Eligible patients (pts) were those with pathologically proven SqLC with stage IIIB/IV or postoperative recurrence, aged 20-74 years and ECOG PS 0-1. Pts were randomized 1:1 to ND (N 100 mg/m^2 and docetaxel (D) 60mg/m^2 iv, q3w, up to 6 cycles) or C plus D (CD) (C 80 mg/m^2 and D 60mg/m^2 iv, q3w, up to 6 cycles) according to stage, gender and institution. The primary endpoint was overall survival (OS), and secondary endpoints included progression-free survival (PFS), response rate (RR) and adverse events (AEs). Target sample size of 350 provided 90% statistical power to detect a hazard ratio of 0.71 with one-sided type I error of 0.05. **Results:** Between July 2009 and July 2012, 355 pts were randomized. Of 349 for efficacy analysis (ND 177; CD 172), baseline characteristics were well-balanced between two arms. ND had a significantly longer OS (p=0.037, one-sided stratified log-rank test). The OS HR was 0.81 (90%CI, 0.67-0.98) with a median OS of 13.6 months [m] for ND and 11.4 for CD. ND had a longer PFS (p=0.050) with a HR of 0.83 (0.69-1.00) and a median PFS of 4.9 m in ND and 4.5 in CD. RR was 54.5% in ND vs 52.9% in CD (p=0.829). Grade 3 or higher AEs of nausea (4.0% vs 14.3%), fatigue (3.4% vs 10.9%), hyponatremia (13.6% vs 30.3%) and hypokalemia (2.3% vs 8.6%) are more frequent in CD. Grade 3 or higher AEs of neutrophils (82.5% vs 70.3%) and platelets (9.0% vs 0.0%) are more frequent in ND, but there was no difference in grade 3 or higher febrile neutropenia (13.6% vs 15.4%). Treatment related deaths occurred in 4 and 3 pts in ND and CD, respectively. **Conclusion:** ND showed a significantly longer OS as compared to CD with different toxicity profile. ND will be considered as a new standard treatment for advanced or relapsed SqLC. Clinical trial information: UMIN000002015.
Keywords: Advanced Non-Small Cell Lung Cancer, Squamous cell lung cancer, Nedaplatin, docetaxel

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ORAL01.02 Therapy of Advanced Metastatic Lung Cancers with an Anti-Trop-2-SN-38 Antibody-Drug Conjugate, IMMU-132: Interim Phase II Clinical Results
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Background: Sacituzumab govitecan (IMMU-132) is a new Antibody Drug Conjugate (ADC) comprising SN-38, the active metabolite of the topoisomerase I inhibitor, camptothecin (irinotecan), conjugated to an anti-Trop-2 humanized antibody at a high drug-antibody ratio (7.6). In vitro and in vivo preclinical data suggest that IMMU-132 delivers up to 136-fold more SN-38 than its parental drug, irinotecan, in a human cancer xenograft. Trop-2 is widely expressed in most epithelial cancers, including non-small and small-cell lung cancers (NSCLC and SCLC).The safety and efficacy of this new ADC is being examined in advanced metastatic lung cancers. Methods: A Phase II clinical trial (ClinicalTrials.gov, NCT01631552) is ongoing in subsets of previously-treated patients with metastatic lung cancer, administering IMMU-132 on days 1 and 8 of 21-day treatment cycles. A phase 1 run-in phase selected 8 and 10 mg/kg weekly dosage as safe for tumor cohort phase 2 expansion. Treatment is continued based on tolerance or until progression, with safety and response assessments made every week and 8-12 weeks, respectively. Results: Forty-four lung cancer patients were given IMMU-132 doses at 8 mg/kg (N = 23) or 10 mg/kg (N = 21); 38 patients (18 NSCLC and 20 SCLC) are assessable for efficacy. Patients were heavily pretreated (median of 3 prior lines). Objective tumor responses (all partial responses by RECIST1.1) and median progression-free survival (PFS) are reported below per tumor. These studies are being expanded.

Tumor type	Prior lines of therapy: median (range)	Objective Response Rate (PR)	Median PFS (maturity) in months
NSCLC (N=18)	3 (1-8)	33%	5.4 (56%)
SCLC (N=20)	2.5 (1-7)	25%	2.4 (70%)

IMMU-132 was well tolerated with limited grade 3/4 toxicities above the 3% threshold per patient. Neutropenia was the only Grade 3/4 toxicity (G3, 14%; G4, 7%) together with hyponatremia (G3, 2%; G4, 2%). Other drug-related G3 toxicities included diarrhea (7%), anemia (5%), leukopenia (5%), hyperglycemia (5%) and atrial fibrillation (5%); no patient developed antibodies to the conjugate. Conclusion: Repeated cycles of IMMU-132 monotherapy are well tolerated. Objective response rate and progression-free survival data in previously-treated metastatic lung cancer (5.4 months in NSCLC) are encouraging and warrant further evaluation of IMMU-132 in these lung cancers.
Keywords: non small cell lung cancer, small cell lung cancer, antibody drug conjugate, IMMU-132

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ORAL01.03 A Randomized Phase 2 Trial of Vintafolide and Docetaxel in Folate-Receptor Positive (FR+) Advanced NSCLC Patients: Final Efficacy Results
Nasser Hanna[1], Erzsebet Juhasz[2], Calin Cainip[3], Oleg Gladkov[4], Óscar Juan Vidal[5], Rodryg Ramlau[6], Oscar J. Vidal[5], Rohit Lal[7], James Symanowski[8], Romnee Clark[9], Wael Harb[10] [1]*Indiana University Simon Cancer Center, Indianapolis/AL/United States of America,* [2]*Prof. Dr. Ion Chiricuta Institute of Oncology, Budapest/Hungary,* [3]*Prof. Dr. Ion Chiricuta Institute of Oncology, Cluj-Napoca/Romania,* [4]*Chelyabinsk Regional Clinical Oncology Center, Chelyabinsk/Russian Federation,* [5]*Le Fe University Hospital, Valencia/Spain,* [6]*Med Polonia Sp. Z O.O., Warsaw/Poland,* [7]*Guys and St. Thomas Hospital NHS Foundation, London/United Kingdom,* [8]*Levine Cancer Institute, Charlotte/United States of America,* [9]*Endocyte, Inc, Indianapolis/IN/United States of America,* [10]*Horizon Oncology Research, Lafayette/United States of America*

Background: Vintafolide (folic acid-vinca alkaloid conjugate) binds to the folate receptor (FR), which is overexpressed in approximately 80% of patients with NSCLC, including patients with squamous cell and adenocarcinoma. Using the molecular imaging agent 99mTc-etarfolatide for SPECT imaging, the FR status of malignant lesions can be determined. Vintafolide has demonstrated single agent activity in patients with advanced NSCLC whose tumors all expressed FR [FR(100%)] compared to patients not FR(100%) (Edelman et al, 2012). **Methods:** This study randomized patients with advanced NSCLC whose tumors were FR(100%) to vintafolide, vintafolide + docetaxel, or docetaxel. Key eligibility criteria: age ≥ 18 years; 1 prior systemic therapy for advanced disease; ECOG PS 0-1. Patients underwent ^{99m}Tc-etarfolatide SPECT screening for FR assessment. Vintafolide (2.5 mg) was administered on days 1, 4, 8, 11 every 21 days and docetaxel (75 mg/m^2) on day 1 every 21 days. The primary endpoint was progression-free survival (PFS). Pre-specified PFS comparisons were performed for vintafolide vs docetaxel and vintafolide+docetaxel vs docetaxel in all patients as well as those with adenocarcinoma. Significance testing for each PFS analysis was one-sided without adjustment for multiplicity (alpha=0.10). Overall survival (OS) was a secondary endpoint. **Results:**Over 14 months, 199 FR(100%) patients were randomized and treated (vintafolide: 63; vintafolide+docetaxel: 68; docetaxel: 68). Patient and disease characteristics were well-balanced between arms. The vintafolide+docetaxel arm met the primary endpoint of superior PFS over the docetaxel arm in all patients regardless of histology (17.0% censored; unstratified Cox model hazard ratio [HR] =0.75; unstratified one-sided p-value=0.0696) as well as in the prespecified 133 patient adenocarcinoma subgroup (18.8% censored; HR=0.73; p-value=0.0899). Trends in OS favored the vintafolide+docetaxel arm over the docetaxel arm in all patients (37.7% censored; HR=0.88; p-value=0.2874) and showed the greatest benefit in the adenocarcinoma subgroup (42.8% censored; HR=0.70; p-value=0.1018). The single-agent vintafolide arm was not superior to docetaxel. Vintafolide+docetaxel treatment was associated with more neutropenia (all grades: 77% versus 62%), febrile neutropenia (13% versus 6%), and peripheral neuropathy (34% versus 21%) compared to docetaxel alone. **Conclusion:** The addition of vintafolide to docetaxel resulted in a statistically significant improvement in PFS in FR(100%) NSCLC patients regardless of histology (PFS HR= 0.75) and in the adenocarcinoma subset (PFS HR= 0.73). Additionally, there was a trend towards improvement in OS in all patients regardless of histology (OS HR= 0.88) and in the adenocarcinoma subset (OS HR= 0.70). Vintafolide +docetaxel was generally well tolerated, although rates of neutropenia, neutropenic fever, and neuropathy were higher than with docetaxel alone. Final survival results will be presented at the conference.
Keywords: vintafolide, SPECT, etarfolatide

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ORAL01.05 Phase I/II Dose Escalation Study of Immunoconjugate L-DOS47 as a Monotherapy in Non-Squamous Non-Small Cell Lung Cancer Patients
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Poland, [2]Military Institute of Health Institute, Warsaw/Poland, [3]Mazovian Centre of Pulmonary Diseases and Tuberculosis, Otwock/Poland, [4]Department of Oncology, Poznan University of Medical Sciences, Poznan/Poland, [5]National Tuberculosis and Lung Diseases Research Institute, Warsaw/Poland, [6]Helix Biopharma Corp., Aurora/ON/Canada

Background: L-DOS47, a cancer therapeutic designed to exploit the acidic tumour extracellular environment, is a protein conjugate consisting of a urease conjugated to a camelid monoclonal antibody (AFAIKL2) that is targeted to the CEACAM6 antigenic tumour marker. The AFAIKL2 antibody serves as a targeting agent to deliver the enzyme to the tumor sites while the urease enzyme converts urea, an abundant natural metabolite, into ammonia and generates a local pH increase. The combined effect of ammonia toxicity and pH increase is cytotoxic to cancer cells in culture and in xenograft models. This first in human study of L-DOS47 was designed to define the maximum tolerated dose of multiple doses of L-DOS47 administered intravenously to patients with non-squamous NSCLC when given as a monotherapy. **Methods:** Stage IIIb or IV histologically confirmed non-squamous NSCLC patients (aged ≥ 18 yrs, ECOG PS ≤2) receive multiple cycles of L-DOS47 during the study treatment period. L-DOS47 is administered once weekly over 14 days followed by 7 days rest in each treatment cycle. Patients are recruited into cohorts and received the same dose of L-DOS47 on Days 1 and 8 of each treatment cycle. Dose levels of L-DOS47 are escalated in further cohorts following a review of safety data by the Trial Steering Committee. **Results:** Thirty-three (33) pts (median age 61, 58% male) were enrolled in the first ten cohorts (dose levels: 0.12, 0.21, 0.33, 0.46, 0.59, 0.78, 1.04, 1.38, 1.84, 2.45 µg/kg) in four Polish centers. L-DOS47 was well tolerated at the dose levels reviewed. No DLTs were reported. Adverse events reported to date were expected for the population under study. None of the patients treated to date have had a partial or complete response as defined by RECIST v1.1. Sixteen (16) patients had an overall response of stable disease after completing two cycles of L-DOS47. One patient in cohort 9 was dosed for 9 cycles without disease progression. **Conclusion:** L-DOS47 monotherapy is well tolerated at dose levels up to 2.45 µg/kg. ClinicalTrials.gov identifier: NCT02340208

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ORAL01.06 S-1 and Cisplatin versus Docetaxel and Cisplatin in Patients with Untreated Advanced NSCLC: An Randomised, Multicenter, Phase 3 Trial

Yuankai Shi[1], Mengzhao Wang[2], Jianxing He[3], Jianhua Chang[4], Baohui Han[5], Xiaoqing Liu[6], Gongyan Chen[7], Caicun Zhou[8], Jiwei Liu[9], Hongming Pan[10], Cheng Huang[11], Shucai Zhang[12], Jifeng Feng[13], Xiaoyan Lin[14], Jie Wang[15], Jianjin Huang[16], Fang Li[17], Shukui Qin[18], Zhehai Wang[19], Liwei Wang[20], Nong Xu[21] *[1]Department of Medical Oncology, Cancer Institute and Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College,National Center for Anticancer Drugs Clinical Study, Beijing Key Laboratory of Clinical Study on Anticancer Molecular Targeted Drugs, Beijing/China, [2]Peking Union Medical College Hospital, Beijing/China,[3]The First Affiliated Hospital of Guangzhou Medical College, Guangzhou/China, [4]Fudan University Shanghai Cancer Center, Shanghai/China, [5]Shanghai Chest Hospital, Shanghai/China, [6]Military Academy of Medical Sciences Affiliated Hospital, Beijing/China, [7]The Affiliated Tumor Hospital of Harbin Medical University, Harbin/China, [8]Shanghai Pulmonary Hospital, Shanghai/China, [9]The First Affiliated Hospital of Dalian Medical University, Dalian/China, [10]Sir Run Run Shaw Hospital, Hangzhou/China, [11], Fujian Provincial Tumor Hospital, Fuzhou/China, [12]Beijing Chest Hospital, Beijing/China, [13]Jiangsu Cancer Hospital, Nanjing/China, [14]Fujian Medical University Union Hospital, Fuzhou/China, [15]Beijing Cancer Hospital, Beijing/China, [16]The First Affiliated Hospital Zhejiang University College of Medicine, Hangzhou/China, [17]Chinese PLA General Hospital, Beijing/China, [18]No.81 Hospital of People'S Liberation Army, Nanjing/China, [19]Shandong Cancer Hospital, Jinan/China, [20]Shanghai First People'S Hospital, Shanghai/China, [21]The Second Affiliated Hospital Zhejiang University College of Medicine, Hangzhou/China*

Background: Platinum-based doublet chemotherapy is the standard chemotherapeutic regimen for treatment-naïve advanced non-small cell lung cancer (NSCLC). S-1, an oral fluoropyrimidine, combined with carboplatin or cisplatin (CDDP) has demonstrated the non-inferiority to the standard platinum doublet chemotherapy in Japanese NSCLC patients. However, its effectiveness in Chinese NSCLC patients is uncertain. The purpose of this study is to compare the efficacy and safety of these chemotherapeutic regimens in Chinese NSCLC patients. **Methods:** We did this randomized controlled study in 21 sites in China. Eligible patients were those aged 18-70 years who was histologically or cytologically confirmed with locally advanced or metastatic NSCLC with no prior radiotherapy, molecular targeted therapy or chemotherapy. Patients were randomized to receive either S-1 orally 80 mg/m^2/day (40 mg/m^{2}2 b.i.d., 80–120 mg/day) with 60 mg/m^2 CDDP on day 8 every 5 weeks (SP) or docetaxel and CDDP (both 75 mg/m^2) on day 1 every 3 weeks (DP) for up to 6 cycles. Randomisation was stratified by centre, pathological classification, disease stage and gender. The primary endpoint was progression free survival (PFS), analyzed in the full analysis set. The study is registered at ClinicalTrials.jp, number Japic CTI-111479. **Results:** Between March 2011 and November 2012, 246 patients from 21 institutions in China were randomly assigned and received SP or DP treatment (124 vs 122) with 18-month follow-up period from the last patient randomized. In the SP and DP group, median PFS was 5.9 and 5.7 months (HR=0.68; 95% CI, 0.48-0.96) respectively, median overall survival was 19.1 and 14.8 months, respectively (HR=0.84; 95% CI, 0.61-1.14). The most common grade 3 or worse adverse events in both treatment groups were neutropenia 3.3% vs 55.1%, leukopenia 1.7% vs 39.0%, and febrile neutropenia 0.8% vs 5.9%, of 121 patients in the SP group and of 118 patients in the DP group, respectively. **Conclusion:** The efficacy of SP was non-inferior to DP with a better safety profile. SP would be a new standard first-line chemotherapy regimen for Chinese patients with advanced NSCLC.
Keywords: S-1, phase 3 trial, Therapy, NSCLC

SESSION ORAL 02: PD1 AXIS IMMUNOTHERAPY 2 MONDAY, SEPTEMBER 7, 2015

PD1 AXIS IMMUNOTHERAPY 2
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ORAL02.01 Phase 3, Randomized Trial (CheckMate 017) of Nivolumab (NIVO) vs Docetaxel in Advanced Squamous (SQ) Cell Non-Small Cell Lung Cancer (NSCLC)

Karen Reckamp[1], Julie R. Brahmer[2], David R. Spigel[3], Naiyer A. Rizvi[4], Elena Poddubskaya[5], Howard West[6], Wilfried E.E. Eberhardt[7], Paul Baas[8], Scott J. Antonia[9], Adam Pluzanski[10], Everett Vokes[11], Esther Holgado[12], David Waterhouse[13], Neal Ready[14], Justin F. Gainor[15], Osvaldo Arén Frontera[16], Leora Horn[17], Luis Paz-Ares[18], Ang Li[19], Mark Lynch[20] *[1]City of Hope Comprehensive Cancer Center, Duarte/CA/United States of America, [2]The Sidney Kimmel Comprehensive Cancer Center at John Hopkins, Baltimore/MD/United States of America, [3]Sarah Cannon Research Institute/Tennessee Oncology, PLLC, Nashville/TN/United States of America, [4]Memorial Sloan Kettering Cancer Center, New York/NY/United States of America, [5]N.N. Blokhin Russian Cancer Research Center, Moscow/Russian Federation, [6]Swedish Cancer Institute, Seattle/WA/United States of America, [7]University Hospital Essen, West German Cancer Centre, Ruhrlandklinik, University Duisburg-Essen, Essen/Germany, [8]The Netherlands Cancer Institute-Antoni Van Leeuwenhoek Hospital, Amsterdam/Netherlands, [9]H. Lee Moffitt Cancer Center & Research Institute, Tampa/FL/United States of America, [10]Centrum Onkologii - Instytut Im. Marii Sklodowskiej-Curie, Warsaw/Poland, [11]University of Chicago Medicine & Biological Sciences, Chicago/IL/United States of America, [12]Hospital de Madrid, Norte Sanchinarro/Spain, [13]Oncology Hematology Care, Cincinnati/OH/United States of America, [14]Duke University Medical Center, Durham/NC/United States of America, [15]Massachusetts General Hospital, Boston/MA/United States of America, [16]Centro Internacional de Estudios Clinicos, Santiago/Chile, [17]Vanderbilt University Medical Center, Nashville/TN/United States of America, [18]Hospital Universitario Virgen Del Rocio, Sevilla/Spain, [19]Global Biometric Sciences/Statistical Programming and Technologies, Bristol-Myers Squibb, Princeton/NJ/United States of America, [20]Bristol-Myers Squibb, Princeton/NJ/United States of America*

Background: Treatment options for patients with advanced SQ NSCLC who fail platinum-based doublet chemotherapy (PT-DC) are limited. NIVO, a fully human IgG4 programmed death-1 (PD-1) immune checkpoint inhibitor, demonstrates activity across NSCLC histologies and is approved in the US for treatment of metastatic SQ NSCLC with progression on or after platinum-based chemotherapy. We report results from a randomized, open-label, global phase 3 study (CheckMate 017; NCT01642004) comparing NIVO vs docetaxel in patients with previously treated SQ NSCLC and disease progression during/after one prior PT-DC regimen. **Methods:** Patients (N=272) were randomized 1:1 to receive either NIVO 3 mg/kg every 2 weeks (Q2W; n=135) or docetaxel 75 mg/m2 Q3W (n=137) until disease progression or discontinuation due to toxicity or other reasons. For NIVO patients, treatment after initial progression was permitted at the investigator's discretion, per protocol criteria. The primary objective was overall survival (OS). Secondary objectives included investigator-assessed objective response rate (ORR; per RECIST v1.1), progression-free survival (PFS), efficacy by PD-L1 expression (PD-L1 testing not required for enrollment), patient-reported outcomes (PRO), and safety. PRO analyses are presented in a separate abstract. **Results:** Treatment with NIVO led to 41% reduction in risk of death (hazard ratio [HR]=0.59; 95% CI: 0.44, 0.79; *P*=0.00025) and improved ORR (20% vs 9%; *P*=0.0083) and PFS (HR=0.62; 95% CI: 0.47, 0.81; *P*=0.0004) vs docetaxel (Table). Twenty-eight patients were treated with NIVO beyond initial progression, nine of whom demonstrated a non-conventional pattern of benefit (ie, reduction in target lesions with simultaneous appearance of new lesions, initial progression followed by tumor reduction, or no further progression for ≥ 2 tumor assessments). Across pre-specified cut-points (1%, 5%, and 10%), PD-L1 expression was neither prognostic nor predictive of benefit. OS HRs favored NIVO across most predefined patient subgroups. Grade 3–4 drug-related adverse events (AEs) were reported in 7% (9/131) of NIVO and 55% (71/129) of docetaxel patients. Grade 3–4 drug-related select AEs are shown below (Table). No deaths were related to NIVO vs 3 docetaxel-related deaths.