MINI ORAL SESSIONS
SATURDAY, SEPTEMBER 24, 2016

MINI01.01
Whole Body and Intracranial Efficacy of Ceritinib in ALK-inhibitor Naïve Patients with ALK+ NSCLC and Brain Metastases: Results of ASCEND 1 and 3
Topic: Medical Oncology

Alice T. Shaw,1 David R. Spigel,2 Daniel S.-W. Tan,3 Dong-Wan Kim,4 Ranee Mehra,5 Sergey Orlov,6 Keunchil Park,7 Chong-Jen Yu,8 Tony Mok,9 Makoto Nishio,10 Giorgio Scagliotti,11 Santosh Sutradhar,12 Dajana Csesic,12 Enriqueta Felip13 1Massachusetts General Hospital, Boston/United States of America, 2Sarah Cannon Research Institute, Nashville, TN/United States of America, 3National Cancer Centre Singapore, Singapore/Singapore, 4Seoul National University Hospital, Seoul/Korea, Republic of, 5Fox Chase Cancer Center, Philadelphia, PA/United States of America, 6St. Petersburge State Medical University, St. Petersburge/Russian Federation, 7Innovative Cancer Medicine Institute, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul/Korea, Republic of, 8National Taiwan University Hospital, Taipei City/Taiwan, 9Chinese University of Hong Kong, Sha Tin/China, 10Japanese Foundation for Cancer Research, Tokyo/Japan, 11University of Torino, Torino/Italy, 12Novartis Pharmaceuticals Corporation, East Hanover, NJ/United States of America, 13Vall d’Hebron University, Barcelona/Spain

Background: Here we present efficacy outcomes in ALK-rearranged (ALK+) NSCLC patients with baseline (BL) brain metastases (BM) treated with the selective oral ALKi ceritinib in the ASCEND-1 (phase 1; NCT01283516) and ASCEND-3 (phase 2; NCT01685138) trials.

Methods: ALKi-naïve patients with ALK+ NSCLC and stable BL BM received ceritinib 750 mg/day. Efficacy analyses (by blinded independent review committee [BIRC]) assessed whole body responses for ASCEND-1 and -3 according to RECIST 1.0 and 1.1, respectively. Pooled intracranial responses were evaluated by BIRC (ASCEND-1, retrospectively; ASCEND-3, prospectively) in patients with measurable BL BM (RECIST 1.1).

Results: Of 26 and 50 ALKi-naïve patients with BL BM enrolled in ASCEND-1 and -3, respectively, 88.5% and 100% had prior chemotherapy and 57.7% and 54.0% had prior brain radiotherapy (RT); median times from prior RT to first ceritinib dose were 4.6 and 2.7 months. Ceritinib showed whole body and intracranial efficacy (Table). The most common AEs (ASCEND-1; ASCEND-3) were nausea (84.6%; 78.0%), diarrhea (92.3%; 76.0%) and vomiting (76.9%; 72.0%); 46 patients (ASCEND-1: 19; ASCEND-3: 27) had dose reductions and 4 patients (ASCEND-1: 3; ASCEND-3: 1) discontinued due to AEs.

Conclusion: Clinically meaningful whole body and intracranial activity with an acceptable tolerability profile were observed in ALKi-naïve patients with ALK+ NSCLC and BL BM treated with ceritinib.

MINI01.02
Response and Plasma Genotyping from Phase I/II Trial of Ensartinib (X-396) in Patients (pts) with ALK+ NSCLC
Topic: Medical Oncology

Leora Horn,1 Heather Wakelee,5 Karen L. Reckamp,3 George Blumenschein Jr.,4 Jeffrey R. Infante,5 Corey A. Carter,6 Saaima N. Waqar,7 Joel W. Neal,2 Kimberly Harrow,8 Jon P. Gockerman,9 Gary Dukart,10 Chris Liang,10 James L. Gibbons,10 Jennifer Hernandez,11 Tera Newman-Eerkes,11 Lee Lim,11 Christine M. Lovly1 1Vanderbilt University Medical Center, Nashville, TN/United States of America, 2Stanford Cancer Institute, Stanford, CA/United States of America, 3City of Hope Comprehensive Cancer Center, Duarte/United States of America, 4Department of Thoracic/Head & Neck Medical Oncology, The University of Texas MD Anderson Cancer Center, Houston, TX/United States of America, 5Sarah Cannon Research Institute, Nashville, TN/United States of America, 6Walter Reed National Military Medical Center, Germantown, MD/