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

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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-naive 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 criteria, respectively. Pooled intracranial responses were evaluated by BIRC (ASCEND-1, retrospectively; ASCEND-3, prospectively) in patients with measureable 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.

	ASCEND-1	ASCEND-3	Pooled
Data cut-off	14 Apr 14	27 Jun 14	-
ALK-naïve patients with BL BM	26	50	-
Median duration of follow-up (range), months	12.3 (0.6–22.1)	7.5 (0.6–13.8)	-
Whole body response (BIRC)			
ORR [CI], %	65.4 [44.3, 82.8]	60.0 [45.2, 73.6]	-
Disease control rate [CI], %	76.9 [56.4, 91.0]	78.0 [64.0, 88.5]	-
Median DOR[a] [CI], months	NR [4.2, NR]	9.4 [5.6, NR]	-
Median PFS [CI], months	18.4 [4.6, NR]	11.0 [7.2, NR]	-
Intracranial response (BIRC)			
Patients with measurable BL BM	8	17	25
Intracranial ORR [CI], %	62.5 [24.5, 91.5]	58.8 [32.9, 81.6]	60.0 [38.7, 78.9]
Intracranial disease control rate [CI], %	62.5 [24.5, 91.5]	82.4 [56.6, 96.2]	76.0 [54.9, 90.6]
Median intracranial DOR[a] [CI], months	8.2 [5.6, NR]	NR [5.6, NR]	8.2 [5.6, NR]

[a]Calculated for patients with confirmed CR or PR
CI, 95% confidence interval; NR, not reached

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

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