

Presidential Session IV

Tuesday 27 September 2011, 09:00–11:00

12LBA LATE BREAKING ABSTRACT

Cognitive and Cardiac Outcome After Prenatal Exposure to Chemotherapy in Children 18 Months or Older

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13LBA LATE BREAKING ABSTRACT

Efficacy of Veliparib (ABT-888) Plus Temozolomide Versus Temozolomide Alone: a Randomized, Double-blind, Placebo-controlled Trial in Patients with Metastatic Melanoma

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assessed by NCI-CTCAE v3.0. Efficacy endpoints included PFS, overall survival (OS), and objective response rate (ORR). Tumor response and disease progression were evaluated every 8 weeks (per RECIST), with CT scans reviewed centrally.

Results: Between February 2009 and January 2010, 346 pts were randomized. Although median PFS nearly doubled numerically in the veliparib groups vs pbo (table), these differences were not statistically significant.

Efficacy endpoints	Pbo +TMZ (N = 115)	Veliparib 20 mg +TMZ (N = 116)	Veliparib 40 mg +TMZ (N = 115)	Hazard Ratio (HR); P-value	
				Veliparib 20 mg vs Pbo	Veliparib 40 mg vs Pbo
Median PFS, days [95% CI]	60 [57,111]	113 [92,168]	110 [57,125]	HR = 0.737 p = 0.071 ^a	HR = 0.822 p = 0.233 ^a
Median OS, days [95% CI]	390 [299,436]	327 [274,399]	412 [346,483]	HR = 1.009 p = 0.955 ^a	HR = 0.790 p = 0.162 ^a
ORR, n (%)	8 (7.0)	12 (10.3)	10 (8.7)	p = 0.372 ^b	p = 0.598 ^b

^aStratified log-rank test. ^bStratified CMH test.

Toxicities were as expected for TMZ. The frequency of thrombocytopenia, neutropenia and leukopenia increased significantly in the veliparib groups. Grade 3/4 adverse events (AEs), mainly of hematological toxicities, were seen in 38% (pbo), 54% (veliparib 20 mg), 57% (veliparib 40 mg) of pts. Veliparib-/pbo-related AEs were reported by 79% (pbo), 89% (veliparib 20 mg), 93% (veliparib 40 mg) of pts, and TMZ-related AEs were reported by 89% (pbo), 93% (veliparib 20 mg), 96% (veliparib 40 mg).

Conclusion: Veliparib-treated pts had numerically increased median PFS (20 and 40 mg) and median OS (40 mg), but these trends were not significant. No new toxicity signals were identified.

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14LBA LATE BREAKING ABSTRACT

A Phase I/II, Open-label, Randomised Study of BIBF 1120 Plus mFOLFOX6 Compared to Bevacizumab Plus mFOLFOX6 in Patients with Metastatic Colorectal Cancer

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