**1033P** **Efficacy and safety of bosutinib vs imatinib in Indian and non-Indian patients with newly diagnosed chronic phase chronic myeloid leukemia: Subgroup analysis from the BELA trial**

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**Background:** The international, phase 3 BELA trial (NCT00574873) evaluated first-line bosutinib vs imatinib in Philadelphia chromosome–positive patients (pts) with chronic phase chronic myeloid leukemia.

**Methods:** Pts were randomized to receive bosutinib 500 mg once daily (QD) or imatinib 400 mg QD; the primary endpoint was complete cytogenetic response (CCyR) rate at 12 mo. We compared efficacy and safety of bosutinib and imatinib in Indian and non-Indian pts after 48 mo of follow-up. Efficacy was assessed in the intent-to-treat population; safety was assessed in all pts who received ≥1 dose of study drug.

**Results:** In all, 54 Indian pts (median age 34.5 y; 61% male) and 448 non-Indian pts (median age 48.5 y; 56% male) were randomized to receive bosutinib (n = 25 and n = 225 [2 untreated], respectively) or imatinib (n = 29 and n = 223 [1 untreated]). At 12 mo, major molecular response (MMR) and CCyR rates, respectively, for bosutinib vs imatinib were 44% vs 24% and 72% vs 86% in Indian pts, and 37% vs 26% and 70% vs 66% in non-Indian pts (Table). After 48 mo of follow-up, cumulative MMR and CCyR rates, respectively, for bosutinib vs imatinib were 64% vs 69% and 84% vs 97% in Indian pts, and 68% vs 67% and 78% vs 79% in non-Indian pts. The most frequently reported treatment-emergent adverse events (TEAEs; any grade) with bosutinib were diarrhea (44%) and thrombocytopenia (36%) in Indian pts, and diarrhea (73%) and nausea (39%) in non-Indian pts. 8 pts in the entire study were lost to follow-up while on-treatment; 7 (6 bosutinib; 1 imatinib) were from Indian sites.

**Table: 1033P**

| | Indian pts | | Non-Indian pts | |
|---|---|---|---|---|
| | Bosutinib n = 25 | Imatinib n = 29 | Bosutinib n = 225 | Imatinib n = 223 |
| Sokal Risk Group, n (%) | | | | |
| Low | 11 (44) | 13 (45) | 77 (34) | 76 (34) |
| Medium | 11 (44) | 13 (45) | 106 (47) | 105 (47) |
| High | 3 (12) | 3 (10) | 42 (19) | 42 (19) |
| Cumulative response, any time on–treatment, % (95% CI) | | | | |
| MMR | 64 (45–83) | 69 (52–86) | 68 (61–74) | 67 (61–73) |
| CCyR | 84 (70–98) | 97 (90–100) | 78 (73–84) | 79 (74–84) |
| Response at 12 mo, % (95% CI) | | | | |
| MMR | 44 (25–64) | 24 (9–40) | 37 (31–44) | 26 (20–31) |
| CCyR | 72 (54–90) | 86 (74–99) | 70 (64–76) | 66 (60–72) |
| Probability of retaining response at 48 mo (95% CI)* | | | | |
| MMR | 80 (49–93) | 100 (100–100) | 93 (86–96) | 98 (93–99) |
| CCyR | 89 (62–97) | 78 (58–90) | 93 (88–96) | 91 (85–95) |
| Transformation to AP/BP CML, n (%) | 1 (4) | 2 (7) | 4 (2) | 10 (5) |
| Overall survival | | | | |
| Deaths, n (%) | 1 (4) | 1 (3) | 14 (6) | 14 (6) |
| At 48 mo (95% CI)* | 96 (72–99) | 96 (77–100) | 95 (91–97) | 94 (89–96) |

*Kaplan-Meier estimate

AP=accelerated phase; BP=blast phase; CCyR=complete cytogenetic response; CI=confidence interval; CML=chronic myeloid leukemia; MMR=major molecular response

**Conclusions:** Response rates for bosutinib were comparable between Indian and non-Indian pts. MMR rates were higher for bosutinib vs imatinib at 12 mo, but not 48 mo, in Indian pts; comparison of bosutinib vs imatinib was limited by the small number of Indian pts. TEAEs were consistent with the known bosutinib safety profile, although Indian pts had a lower rate of diarrhea than non-Indian pts.

**Clinical trial identification:** NCT00574873.

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