Bosutinib vs imatinib for newly diagnosed chronic myeloid leukemia in the BFORE trial: 24-month follow-up.

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Abstract Disclosures

Research Funding:

Background: Bosutinib is a dual Src/Abl tyrosine kinase inhibitor approved for the treatment of newly diagnosed chronic phase (CP) chronic myeloid leukemia (CML) and CML resistant/intolerant to prior therapy. Here we compare efficacy of first-line bosutinib and imatinib after ≥24 mo (median: 27 mo) of follow-up.**Methods:**In the ongoing, open-label, phase 3 BFORE trial (NCT02130557), 536 patients were randomized 1:1 to bosutinib (n = 268) or imatinib (n = 268 [3 untreated]).**Results:**Higher molecular and complete cytogenetic response (MR and CCyR) rates were observed for bosutinib vs imatinib at 12 mo; these differences continued after ≥24 mo (**Table**). The between-arm difference in major MR (MMR) rate was retained at 24 mo; however, differences in rates of deeper MRs (MR^4 and $MR^{4.5}$) were smaller. Times to MR and CCyR were shorter for bosutinib vs imatinib, consistent with 12-mo data. There were 6 transformations to accelerated/blast phase with bosutinib and 7 with imatinib. 71% vs 66% remained on bosutinib vs imatinib treatment.**Conclusions:**At 24 mo, a higher MMR rate was maintained with bosutinib vs imatinib. The results support the use of bosutinib as first-line therapy for CP CML. Clinical trial information: NCT02130557

	Intent-to-treat (ITT) Population		
	Bosutinib n = 268	Imatinib n = 268	*P**
Cumulative, any time on-treatment, %			
MMR	68.7	59.3	.024
MR[4]	39.9	31.3	.040
MR4.5	25.7	19.0	.063
CCyR[†]	82.5	76.8	.113
MMR by 24 mo, %	67.2	57.5	.020

MMR, %

At 12 mo	46.6	36.2	.013
At 24 mo	61.2	50.7	.015
MR4, %			
At 12 mo	20.5	11.6	.005
At 24 mo	32.8	25.7	.073
MR4.5, %			
At 12 mo	7.5	3.0	.020

At 24 mo	13.1	10.8	.428
Time to response (based on cumulative incidence), hazard ratio (HR)[‡]			
MMR	1.37		.004
CCyR[†]	1.34		.005
MR[4]	1.39		.025
MR[4.5]	1.42		.054
Overall survival (OS),[§] %			–

At 12 mo	99.6	98.1
At 24 mo	99.2	97.0

* 2-sided *P* values not adjusted for multiple comparisons; *P* value for OS not provided until 5-y analysis

† Modified ITT population (bosutinib n = 246; imatinib n = 241); Philadelphia chromosome-positive patients with e13a2/e14a2 transcripts

‡ Bosutinib vs imatinib; HR > 1 indicates shorter time to response for bosutinib

§ 3 and 9 deaths in the bosutinib and imatinib arm, respectively, due to adverse event related (0 vs 1) or unrelated (2 vs 2) to study drug, disease progression (1 vs 3), and other causes (0 vs 3)