Six-year (yr) follow-up of patients (pts) with imatinib-resistant or -intolerant chronic-phase chronic myeloid leukemia (CML-CP) receiving dasatinib.

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Background: Dasatinib, a potent BCR-ABL inhibitor, is approved for use as 1st- and 2nd-line therapy for CML pts with newly diagnosed disease or resistance/intolerance to imatinib. This ongoing study in pts with imatinib-resistant/-intolerant CML provides the longest follow-up of a second-generation BCR-ABL inhibitor.**Methods:**Study design has been described (Shah, J Clin Oncol 2008). Pts with imatinib-resistant/-intolerant CML (N=670) were randomized to dasatinib 100 mg once daily (QD), 50 mg twice daily (BID), 140 mg QD, or 70 mg BID.**Results:**Five-yr data are reported here; 6-yr data will be presented. After a minimum of 5 yrs, 151 pts (74%) remain on QD dosing, 85 of whom (56%) are on ≥100 mg QD dosing. Overall, 205 pts (31%) remain on study therapy with 55 pts (53%) originally randomized to BID dosing having switched to QD dosing. For pts randomized to the 100 mg QD arm (n=167), progression-free survival (PFS) at 5 yrs is 57%, overall survival (OS) is 78% with an overall 5% rate of transformation to advanced disease. In exploratory analyses, 42% and 60% of pts had BCR-ABL levels ≤10% (International Scale) at 1 and 3 months (mos), respectively. In a landmark analysis, BCR-ABL ≤10% at 1 or 3 mos was associated with higher 5-yr PFS. For dasatinib 100 mg QD, nonhematologic adverse events (AEs; all grades) generally first occurred in <24 mos. Cumulative rates of AEs in the 100 mg QD arm were headache (33%), diarrhea (28%), fatigue (26%), and pleural effusion (24%). For dasatinib 100 mg QD, cytopenias (grades 3/4) generally first occurred in <12 mos. The most common hematologic AEs (grades 3/4) in the 100 mg QD arm were neutropenia (36%) and thrombocytopenia (24%). AEs were managed by dose/schedule modifications.**Conclusions:**Five-yr follow-up of pts who switched to dasatinib 100 mg QD after imatinib-resistance/intolerance shows high rates of PFS, and OS with an overall low rate of transformation. Exploratory

analyses suggest that achievement of a fast and deep response (≤10% BCR-ABL) at 1 or 3 mos after initiation of dasatinib 100 mg QD may be associated with a higher PFS. Dasatinib 100 mg QD was generally well tolerated over 5 yrs. Six-yr data will be presented.