

# ETY OF HEMATOLOGY NG AND EXPOSITION

## [428] SIX YEAR FOLLOW-UP RESULTS OF A PHASE II STUDY OF IMATINIB IN LATE CHRONIC PHASE (L-CP) CHRONIC MYELOID LEUKEMIA (CML) POST INTERFERON- $\alpha$ (IFN) REFRACTORINESS/INTOLERANCE. SESSION TYPE: ORAL SESSION

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**BACKGROUND:** Imatinib is a selective inhibitor of the Bcr-Abl tyrosine kinase indicated for the treatment of all phases of Ph+ CML. This study updates the results up to more than 60 months (mos) after last patient (pt) started treatment.

**METHODS:** Imatinib 400 mg/d was first administered to 454 patients with L-CP CML between December 1999 and May 2000. Median time since diagnosis was 34 months (mos). Pts had received a median of 14 mos of prior IFN treatment before entering the

study but were hematologically (n=133) or cytogenetically resistant/refractory (n=160) or intolerant (n=161) to IFN. Dose escalation up to 800 mg/d was allowed for lack of efficacy. Pts were evaluated for best major and complete cytogenetic response (MCyR and CCyR), time to progression to accelerated phase (AP) or blast crisis (BC), and overall survival (OS). Beyond July 31, 2002, no adverse events or laboratory values were collected.

**RESULTS:** As of July 31, 2005, median duration of treatment was 60 mos (with average of 48 mos). A total of 244 (54%) pts had their dose increased to 600 or 800 mg/d, 42% received 800 mg/d at least once. Of 227 pts who are still on treatment, 85 (37%) had their dose increased to 600 mg/d or 800 mg/d for lack of efficacy. Overall actual dose intensity was 444 mg/d (median 400mg/d). The table summarizes reasons for discontinuation, best observed responses rates and estimated long term outcomes at 60 mos.

The MCyR (CCyR) rate was 57% (48%) for hematologic failures to IFN, 70% (60%) in

	N (%) [95% CONF. INTERVALS] N=454
STILL ON TREATMENT	227 (50)
DISCONTINUED	227 (50)
UNSATISFACTORY THERAPEUTIC EFFECT	117 (26)
DEATHS FROM ANY CAUSE	18 (4)
AES ABNORMAL LABORATORY VALUES	33 (7)
BMT	5 (1)
WITHDREW CONSENT/LOST/OTHERS	54 (12)
PTS WITH MCYR (INCL CCYR)	304 (67)
PTS WITH CCYR	259 (57)
% ESTIMATED FREEDOM OF PROGRESSION TO AP/BC AT 60 MOS	69% [64-74]
% ESTIMATED OS AT 60 MOS	79% [75-83]

*Continued on Page 23*