

Continuous versus interruption of imatinib (IM) in responding patients with advanced GIST after three years of treatment: A prospective randomized phase III trial of the French Sarcoma Group.

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Abstract: **Background:** IM the first-line targeted therapy for advanced GIST, must not be interrupted after one year (yr) in responding patients (pts) and has to be given continuously until disease progression (PD) or intolerance (Blay, Le Cesne et al, ASCO 2004 and 2005). The impact on progression free survival (PFS) of IM discontinuation in long lasting responding pts is unknown. **Methods:** This prospective national multicenter BFR14 study was initiated in June 2002. After 3 yrs of IM 400mg/day, pts free from progression were randomly offered to continue (C arm) or interrupt (I arm) IM, with the exception of pts initially randomized in the I arm after 1 yr of IM (32 pts). Pts allocated to the I arm could restart IM (same dose) in case of PD. Primary endpoint was PFS. Pts declining randomization proceed with IM. **Results:** As of december 2006, 286 pts were included in this trial and up to date, 35 non progressive pts at 3 yrs were randomized, 19 and 16 in the I and C arm respectively. Pt characteristics were well balanced between the two arms. Nine progressions were reported after a median follow-up of 5.3 months (range 0-14) in this cohort of patients. IM reintroduction in the I arm after a re-progression allowed again a tumor control (OR or SD) in all evaluable pts so far. **Conclusions:** An increase in the rate of PD was observed in patients randomized after 3 years of IM. The final analysis will be performed after the randomization of 50 pts. Updated results including mutational analysis will be presented at the meeting.

