Six-year follow-up of patients receiving imatinib for the first-line treatment of chronic myeloid leukemia.

Imatinib mesylate is considered standard of care for first-line treatment of chronic phase chronic myeloid leukemia (CML-CP). In the phase III, randomized, open-label International Randomized Study of Interferon vs STI571 (IRIS) trial, previously untreated CML-CP patients were randomized to imatinib (n=553) or interferon-alpha (IFN) plus cytarabine (n=553). This 6-year update focuses on patients randomized to receive imatinib as first-line therapy for newly diagnosed CML-CP. During the sixth year of study treatment, there were no reports of disease progression to accelerated phase (AP) or blast crisis (BC). The toxicity profile was unchanged. The cumulative best complete cytogenetic response (CCyR) rate was 82%; 63% of all patients randomized to receive imatinib and still on study treatment showed CCyR at last assessment. The estimated event-free survival at 6 years was 83%, and the estimated rate of freedom from progression to AP and BC was 93%. The estimated overall survival was 88% -- or 95% when only CML-related deaths were considered. This 6-year update of IRIS underscores the efficacy and safety of imatinib as first-line therapy for patients with CML.