Long-term outcome of a phase 2 trial with nilotinib 400 mg twice daily in first-line treatment of chronic myeloid leukemia

GIMEMA multicenter phase II single arm
73 patients with chronic-phase chronic myeloid leukemia
First-line treatment nilotinib 400 mg twice daily



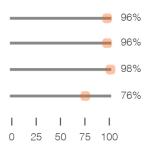
Overall survival

Progression-free survival

Cumulative incidence of

Cumulative incidence of deep molecular response (MR 4.0)

major molecular response



High efficacy

Cardiovascular adverse events mainly due to arterial thrombosis

- in 11/73 patients (15%)
- none was fatal
- after 24 to 76 months of therapy
- frequent in elderly patients and patients with baseline cardiovascular risk factors