

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

6 year follow-up

75% of patients were still on nilotinib



High efficacy

Overall survival 96%

Progression-free survival 96%

Cumulative incidence of major molecular response 98%

Cumulative incidence of deep molecular response (MR 4.0) 76%



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