Evaluation of masitinib in the treatment of canine mast cell tumors: Long-term follow-up efficacy data from phase III clinical study

O Hermine, JP Kinet, P Dubreuil, A Moussy, KA Hahn
ESVONC 2009 (26-29 March 2009 – Budapest, Hungary)

Purpose: We evaluated masitinib for the treatment of canine grade 2/3 mast cell tumors (MCT) in multicenter, randomized, placebo-controlled, double-blind study. Previously reported data at 6-month showed that masitinib significantly improved time-to-progression (Log-Rank p=0.033). Here we report a follow-up at 24-months.

Design: Two-hundred-and-two dogs having recurrent or non-resectable grade 2/3 cutaneous MCT without lymph node or visceral metastases received either masitinib (12.5 mg/kg/day, *per os*, 161 dogs) or placebo (41 dogs). Endpoints were tumor response/progression (WHO criteria) and overall survival (OS).

Results: Two-year follow-up data confirmed the improvement of time-to-progression and showed that masitinib induces long-lasting tumor control. Masitinib was especially efficient on non-resectable tumors. At 12-month, 31.6% of dogs under masitinib had controlled disease (versus no dogs under placebo, p<0.001) and 15.8% were in complete remission. At 24-months, 11.8% of dogs remained in complete remission. Masitinib also improved survival. It increased survival rate at 12-months (61.3% versus 37.5% under placebo, p=0.041) and at 24-months (36.4% versus 15.0% under placebo) and almost doubled the survival time with a median survival of 617 days (versus 322 days under placebo). Masitinib was also particularly efficient on tumors expressing a mutated c-Kit. At 12-month, 31.8% of dogs under masitinib had tumor response (versus no dogs under placebo) and 27.3% were in complete remission. Moreover, at 24-months, 23.8% of dogs remained in complete remission. Masitinib also improved survival. It increased survival rate at 12-months (62.9% versus 11.1% under placebo, p=0.008) and at 24-months (29.3% versus no dogs under placebo) and almost tripled the survival time with a median survival of 498 days (versus 182 days under placebo, hazard ratio: 2.91, p=0.009).

Conclusions and clinical importance: Masitinib induced a long-lasting control of tumor progression and was curative (complete remission at 24-months) in a subset of patients. When masitinib was used on non-resectable tumors and on tumors expressing a mutated c-Kit, it was particularly efficient and significantly improved long-term survival.