The pharmaceutical company AB Science SA announced on the 4th of October 2012 that the European Medicines Agency (EMA) has accepted for review a Marketing Authorization Application (MAA) for Masitinib in the treatment of patients with Imatinib-(Glivec®)-resistant GIST.

Filing for the Marketing Authorization of Masitinib in GIST resistant to Imatinib was accepted by EMA on the basis of results from a phase II study that showed Masitinib to improve overall survival in patients with Imatinib-resistant GIST as compared with Sunitinib (Sutent®), which is currently the standard of care for second-line treatment of GIST. In this study, 44 patients with inoperable, locally advanced or metastatic GIST and showing disease progression while treated with Imatinib (400 to 800 mg/day) received either Masitinib (23 patients) at 12 mg/kg/day or Sunitinib (21 patients) at 50 mg/day until progression. After a median follow-up of 17 months, the median overall survival was not reached for Masitinib versus 16 months for Sunitinib (hazard ratio:0.27 - 95% CI [0.09)(hazard ratio:0.78]). The Overall Survival rate estimates at 6, 12, and 18 months were respectively, 95.7%, 81.9%, and 81.9% in Masitinib-treated patients, versus 76.2%, 57.1%, and 42.3% in Sunitinib-treated patients. Masitinib was well tolerated, with 17% of patients reporting non-hematological grade 3 related adverse events, as compared with 62% of patients in the Sunitinib treatment arm. No patients receiving Masitinib reported any related serious adverse events compared with 19% of patients in the Sunitinib treatment arm.

Masitinib is an orally administered tyrosine kinase inhibitor that targets mast cells, important cells for immunity, as well as a limited number of kinases that play key roles in various cancers. Masitinib, has already been registered in veterinary medicine in Europe and in the USA, and is pursuing different studies in human medicine - including on-going studies in GIST. Masitinib is still an investigational agent and currently not approved by EMA, FDA or other health authorities. Please remember: An approval of an application means that a review for a potential Marketing Authorization will be done. This means not - that the approval of the application is guaranteed.