

Preliminary efficacy and safety results of Masitinib administered, front line in patients with advanced GIST. A phase II study.

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Abstract: **Background:** Masitinib mesylate (MM; AB1010) is a protein tyrosine kinase inhibitor (tki) which, *in vitro*, has greater activity and selectivity than imatinib mesylate (IM) against the wild-type c-Kit receptor and the mutated form in the juxtamembrane region. MM also inhibits the PDGF and FGFR3 receptors. A phase I trial has shown MM safety and tolerability in patients (pts) with different tumor types. One pathological complete response was observed in a pt intolerant to IM. This evidence led to a multicenter phase II trial in non pretreated GIST pts. **Methods:** Twenty-six pts with advanced or metastatic GIST tumors naive to IM treatment were recruited by the end of October 2006. MM was given orally at the dose of 7.5 mg/Kg/d. **Results:** Preliminary results are available from 21/26 pts enrolled so far. There were 13 male, 8 female) with a median age of 61 years (range 33-81). The mean tumor size was 104 mm (29- 254), primary tumor origin was in the stomach in 8 cases and small intestine in 9 cases. At pathological review one patient was found to have a low grade stromal uterine sarcoma. After a median follow up of 9 months (4-15), 11/21 (52.4%) patients achieved a partial response, 8(38.1%) are in stable disease; 2 (9.5%) were considered in progression. Three PR were observed in patients with a primary in the lower GI tract and 7 in patients with gastric primary GIST. The low grade uterine sarcoma also showed PR. The progression occurred after 8 weeks in a pt with primary gastric origin, who failed also IM treatment afterwards. The most frequent AEs related to the study drug were Asthenia (observed in 15% of patients), Periorbital oedema, Muscle spasm, Nausea (40% each), Abdominal pain (35%), Rash, Abdominal pain upper, Diarrhea (30 % each) and Vomiting (25 %). Two patients stopped treatment at 87 and 189 days due to skin toxicity G3. **Conclusions:** These preliminary results, obtained in a small homogeneous population of patients with GIST naïve to IM treatment, show high efficacy of MM and warrant further trials to confirm the

efficacy and complete the safety evaluation of this promising TKI. Definitive results and analysis of KIT/PRGFR mutational status will be presented during meeting.