Patient baseline characteristics and prior treatment history are summarized in Table 1. Treatment-related AEs related to cardiac function included heart failure, congestive heart failure, myocardial ischemia, and myocardial infarction (Table 2). Only 1 patient (0.1%) died of cardiac failure. Nine hundred and six patients (81%) discontinued treatment for any reason. As of December 2007, 1,126 patients were enrolled in the study and followed up for a median of 51 weeks (range, 0.1–159). The ITT population was followed up for a median of 51 weeks (range, 0.1–159). The safety profile observed in this study was similar to that seen with sunitinib (NCT 00367049) and suitinib (NCT 00367049) (NCT 00367049) (NCT 00367049). The number of patients to be enrolled was not predetermined and no inferential analysis was performed. Subgroup analysis suggested that age, ECOG PS, and prior imatinib dosage were significant predictors of OS (Table 3).

Statistical Analysis

The number of patients to be enrolled was predetermined and no inferential analysis was planned due to the nature of this study.

The study population comprises patients aged 18 years or older whose disease fulfills the following key patient inclusion criteria: – overall survival (OS).

The safety profile observed in this study was similar to that seen with sunitinib and sunitinib (NCT 00367049) and suitinib (NCT 00367049) (NCT 00367049). The number of patients to be enrolled was not predetermined and no inferential analysis was performed. Subgroup analysis suggested that age, ECOG PS, and prior imatinib dosage were significant predictors of OS (Table 3).

Conclusions

Based on results from the treatment use trial, sunitinib appears to be safe and tolerated in patients with imatinib-resistant or -intolerant advanced GIST who were ineligible for other sunitinib clinical trials. The safety profile observed in this study was not different from that seen in a prior phase II GIST study (with most AEs mild to moderate in severity).

Sunitinib was effective in the treatment of patients with advanced GIST after sunitinib failure, correlating with previous studies. The median estimated TTP and OS from this ongoing study are 41 and 75 weeks, respectively.

Subgroup analysis suggested that age, ECDOS® and prior imatinib dosage may be important prognostic factors affecting the clinical outcomes in this patient population, but further studies are required to confirm this.

References


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Detailed Analysis of Survival and Safety with Sunitinib in a Worldwide Treatment-use Trial of Patients with Advanced Imatinib-resistant/intolerant GIST

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The study population comprises patients aged 18 years or older whose disease fulfills the following key patient inclusion criteria: – age as of December 2007, 1,126 patients were enrolled in the study and followed up for a median of 51 weeks (range, 0.1–159). The ITT population was followed up for a median of 51 weeks (range, 0.1–159). The safety profile observed in this study was similar to that seen with sunitinib and sunitinib (NCT 00367049) and suitinib (NCT 00367049) (NCT 00367049). The number of patients to be enrolled was not predetermined and no inferential analysis was performed. Subgroup analysis suggested that age, ECOG PS, and prior imatinib dosage were significant predictors of OS (Table 3).

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