

EDUCATIONAL HIGHLIGHTS FROM DATA PRESENTED AT THE  
**33<sup>RD</sup> EUROPEAN SOCIETY  
FOR MEDICAL ONCOLOGY (ESMO) CONGRESS**

9–16 SEPTEMBER 2008, STOCKHOLM, SWEDEN

**EXPANDING THE BOUNDARIES OF CLINICAL PRACTICE:  
BUILDING ON EXPERIENCE WITH TARGETED THERAPIES**

Targeted therapies have dramatically improved the management of advanced renal-cell carcinoma (RCC) and gastrointestinal stromal tumours (GIST). Since 2006, three targeted therapies have been approved for RCC: sunitinib, sorafenib, and temsirolimus. First-line therapy with sunitinib improves overall survival compared with historical treatment of metastatic RCC, prolonging survival beyond two years. GIST, a rare and difficult-to-treat cancer, has had a poor prognosis historically. The introduction of targeted therapies improved one-year survival from 30% in the pre-targeted-therapy era to 90% with current agents. Imatinib, approved for GIST in 2003, is recommended as first-line therapy; sunitinib is now recommended for second-line therapy of GIST refractory to or progressing on imatinib. Speakers at a satellite symposium and at poster sessions discussed role of sunitinib in the management of advanced RCC and GIST.

**Improved survival in metastatic colorectal cancer with first-line sunitinib**

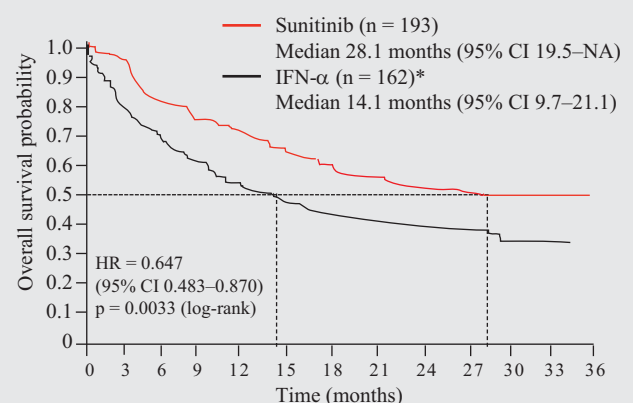
First-line therapy with sunitinib achieved more than two years overall survival in patients with metastatic RCC and was superior to standard therapy with interferon- $\alpha$  (IFN- $\alpha$ ), according to final survival results of a Phase III study presented at ESMO at a poster session by Sylvie Negrier of the Department of Medical Oncology, Centre Leon Berard Lyon, France <sup>[1]</sup>. “Sunitinib remains a reference standard of care for the first-line treatment of patients with metastatic RCC,” Prof. Negrier stated.

The study enrolled 375 patients randomised to sunitinib and 360 randomised to IFN- $\alpha$ . Median overall survival in the sunitinib group was 26.4 months versus 21.8 months for IFN- $\alpha$ , which was marginally significant ( $p = 0.051$ ). Prof. Negrier and colleagues suggested that the real survival benefit with sunitinib may have been greater. The survival end point could have been confounded by the 117 (33%) of patients assigned to the IFN- $\alpha$  arm who crossed over to sunitinib and by other anti-cancer drugs that patients took after the trial was ended. An exploratory analysis of patients who received study treatment only showed that median overall survival with sunitinib was twice that of IFN- $\alpha$ : 28.1 months versus 14.1 months, respectively ( $p = 0.003$ ; Figure 1).

*Cost-effectiveness of sunitinib*

Three different posters presented at ESMO showed that sunitinib is cost-effective as first-line therapy for metastatic RCC according to economic modelling in Sweden <sup>[2]</sup>, Spain <sup>[3]</sup>, and the United States <sup>[4]</sup>.

Figure 1 KAPLAN-MEIER ESTIMATES OF OVERALL SURVIVAL FOR PATIENTS WHO DID RECEIVE ANY POST-STUDY TREATMENT



\* Includes 20 patients who crossed over to sunitinib on study  
CI = confidence interval; NA = not available; HR = hazard ratio

Source: Negrier S, et al. Data presented at the 33rd European Society for Clinical Oncology (ESMO) Congress, Stockholm, Sweden, 2008.

The economic model predicted superior outcomes with sunitinib compared to sorafenib, bevacizumab plus IFN- $\alpha$ , and temsirolimus for life years, progression-free life years, and quality-adjusted life years (QALYs). Moreover, sunitinib was found to be cost-saving compared with these agents.

The Markov cost-effectiveness model used in the three studies had a 10-year time horizon and simulated disease progression and survival and cost outcomes in a hypothetical cohort of adult patients with histologically confirmed metastatic RCC.