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Sunitinib

A Viewpoint by Robert J. Motzer

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The recent introduction of targeted therapies with activity against cell signalling pathways fundamental to tumour growth has led to a new era in the treatment of several cancers. Sunitinib malate (SU11248; SUTENT®),[1] an oral, multitargeted tyrosine kinase inhibitor with antitumour and antiangiogenic activities, has received approval from the US FDA for the treatment of advanced renal cell carcinoma (RCC) and of gastrointestinal stromal tumour (GIST) after disease progression on or intolerance to imatinib mesylate therapy. Recently, in the EU, sunitinib has received conditional approval for use in patients with unresectable and/or metastatic malignant GIST following unsuccessful imatinib treatment, and patients with advanced and/or metastatic RCC after failure of interferon-α or interleukin-2 therapy.

Sunitinib has demonstrated substantial single-agent antitumour activity in metastatic RCC, a notoriously difficult-to-treat cancer, with a high level (approximately 40%) of objective responses and prolonged progression-free survival. This activity compares favourably with that observed for other second-line therapies. Sunitinib therapy has generally been well tolerated, and toxicities are manageable with dose reduction. Haematological toxicity has been observed but has rarely been severe. However, this will need to be closely monitored when assessing the feasibility of sunitinib combination therapy. Sunitinib is currently under investigation in a randomized phase III study as a first-line therapy versus interferon-α. Early indications are that sunitinib will provide a new standard of care, replacing cytokine therapy in the management of advanced RCC in the first-line setting.

In GIST, sunitinib provides an effective treatment option for patients following failure of imatinib due to resistance or intolerance. Compared with placebo, significantly longer time to disease progression (>4-fold) and better overall survival have been demonstrated in a phase III trial. This is an important therapeutic advance, as almost 50% of patients treated with imatinib develop secondary resistance over a period of approximately 2 years.

Overall, sunitinib is an extremely important and exciting new agent that will change the face of treatment for many cancer patients who previously had few if any treatment options. ▲

1 The use of trade names is for product identification purposes only and does not imply endorsement.