

Patient Interest Groups

Submission of Evidence Template

Name of organisation submitting information	James Whale Fund for Kidney Cancer
Contact Details: Name Designation Address Telephone Number	Nicholas E. Turkentine Chief Operations Officer 46 – 48 King Street Cambridge CB1 1LN 01799 585033
Product to which this submission relates	SUNITINIB
Date of SMC meeting (if known)	5 June 2007.

Should you have any queries regarding the completion of this form,
please contact the SMC secretariat:

Telephone: 0141 225 6989/6874

Please also send a copy of your completed submission form, by post, to the following address:

Scottish Medicines Consortium
 Secretariat
 Delta House
 50 West Nile Street
 GLASGOW
 G1 2NP

26/09/2007

Secretariat - Delta House, 50 West Nile Street
 Glasgow G1 2NP
 Telephone 0141 225 6874
 E-mail maureen.stark@nhshealthquality.org

Chairman Professor David Webb

Section 1 – General Information

1.1 Submitting Organisation

Please provide an overview of the organisation making the submission, including the aims of the organisation and an outline of membership. Although SMC has access to epidemiological data, you may wish to provide additional information on numbers affected.

The James Whale Fund for Kidney Cancer, has the dual aim of raising awareness of Kidney Cancer within and beyond the medical professions and, by raising funds, to assist in research into the condition with the aim of establishing causes and improving treatments for patients with the disease. Representative membership is in the region of 1,200 patient/carers in Scotland

1.2 Declarations of Interest

It is essential that you read the information on *declarations of interest* contained within the *Patient Interest Group Guidance* on submission of evidence before you complete this section.

- A. *We have no declaration of interest to make*
- B. *We have the following declaration(s) of interest in respect of corporate members and joint working/sponsorship:*
- C. *We have the following declaration(s) of interest in respect of those playing a significant role in compiling this submission:*

- 1.3 In its advice to NHS Boards and their Area Drug and Therapeutics Committees, SMC normally makes reference to having considered a patient interest group submission. If you would prefer your organisation not to be named, please tick this box.

1.4 Currently available medicines

From a patient/carer perspective, please outline their experiences in respect of medicines currently available, including perceived advantages and disadvantages, preferences and needs both met and currently unmet. Provide us with any information that you feel will help SMC understand how this health problem affects patients/carers. Please identify how you obtained this information, e.g. helpline, existing database, published/unpublished research and user-perspective literature, focus groups, one-to-one conversations with a number of patients, etc.

Current treatment for metastatic renal cancer is alpha-interferon. This is a toxic treatment with severe side effects, a low response rate which at best will prolong survival for a few months. This has been shown by the results of the MRC REO1 trial.

New agents such as tyrosine kinase inhibitors have shown a much higher activity with much greater duration of progression-free survival than interferon and they have lower side effects.

Our members who have been treated with these drugs in clinical trials have reported much greater benefit and lower side effects than interferon.

Section 2 – Product Specific Details

2.1 Potential Impact

If this new medicine were to be made available how would it match up to user needs and preferences; what would be its advantages and disadvantages over currently available medicines; and how might it impact upon the lives of patients and carers? Please identify how you obtained this information, e.g. helpline, existing database, published/unpublished research and user-perspective literature, focus groups, one-to-one conversations with a number of patients, etc.

Survival for patients with metastatic kidney cancer is short. A significant proportion of patients are young with families. Any drug which will prolong survival whilst maintaining quality of life is put as the highest priority from our members.

2.2 Additional information

Please include any additional information you believe would be helpful to SMC.

The response rate from interferon is so poor and the side effects so great that our members feel it hardly qualifies as a treatment at all. Regulatory bodies such as the SMC should view metastatic renal cancer as a disease for which there is currently no effective treatment.

Further, we would refer members of SMC to a paper from NCRI 4 October 2006 headed:

‘Expert Opinion from Clinicians on the NCRI Renal Cancer Clinical Studies Group’

The side headings for which are;

Introduction.

Metastatic Renal Cell Carcinoma and Efficacy of Current Standard Treatments.

Evidence for Activity of Multi-targeted Kinase Inhibitors.

Sorafenib.

Sunitinib, quoted here in full.

Two 2nd line phase II studies in metastatic RCC are published and interim data from a phase III randomised 1st line study against interferon-alpha were presented this year.

Results from both phase II studies (Motzer, Michaelson et al, 2006; Motzer, Rini et al, 2006) have been combined giving a total of 168 patients. The combined response rate was 42% with an additional 24% having stable disease for greater than three months. The combined median progression free survival was 8.2 months. The median PFS for patients attaining a complete or partial response was 14.8 months. Median overall survival for the first study was 16.4 months and at the time of reporting had not yet been reached for the second study.

Interim data from the phase III study (Motzer 2006) demonstrated a median PFS of 47.3 weeks (95% CI 40.9, not yet reached) for sunitinib vs. 24.9 weeks (95% CI 21.9, 37.1) for IFN-alpha [hazard ratio 0.394 (95%CI 0.297,0.521) ($p < 0.000001$)]. The objective response was 24.8% (95% CI 19.7, 30.5) for sunitinib vs. 4.9% (95% CI 2.7, 8.1) for IFN-alpha ($p < 0.000001$). In summary, both sorafenib and sunitinib significantly prolong progression free survival in this refractory disease and should now be made routinely available.

Recommendations.
References.

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