

-----Original Message-----

From: James Whale Fund [mailto:]

Sent: 22 December 2010 09:00

To:

Cc:

Subject: Everolimus Appeal by JWF

Dear

The James Whale Fund for Kidney Cancer wishes to Appeal against the initial decision of NICE not to recommend the Drug Everolimus as a 2nd line treatment of Kidney Cancer for the following reasons: The outlook for metastatic kidney cancer patients who have failed initial treatment (sunitinib in the UK) is bleak. Everolimus is the only agent with positive randomized data in the 2nd line setting. Trials have shown the drug is well tolerated and has an impressive progression free survival advantage (HR 0.3). In Trails patients were able to cross over into the active treatment arm for compassionate reasons invalidating any overall survival analysis.

Everolimus is established worldwide as an essential part of kidney cancer management. The absence of 2nd line therapy in the UK puts patients at a disadvantage in terms of outcome. We know Clinicians feel this will have a negative impact on survival in audits which are ongoing.

References

Motzer RJ, Escudier B, Oudard S, Hutson TE, Porta C, Bracarda S, Grünwald V, Thompson JA, Figlin RA, Hollaender N, Urbanowitz G, Berg WJ, Kay A, Lebwohl D, Ravaud A; RECORD-1 Study Group.

Efficacy of everolimus in advanced renal cell carcinoma: a double-blind, randomised, placebo-controlled phase III trial. Lancet. 2008 Aug 9;372(9637):449-56.

Appeal of the James Whale Fund for Kidney Cancer