



EORTC
European Organisation for Research
and Treatment of Cancer

1962-2002

40 years of excellence in developing new standards of cancer care

Patrick THÉRASSE, MD, MSc
Director - EORTC Data Center
Direct Phone : +32 2 774 16 14
Direct Fax : +32 2 772 61 97
E-mail : pth@eortc.be

Dr. Takashi Aiko
Head
General Rules' Committee of the Japanese Gastric
Cancer Association
c/o Secretariat, Japanese Gastric Cancer Association
Department of Digestive Surgery, Kyoto Prefectural
University of Medicine
465 Hirokoji-kajiicho, Kawaramachi, Kamigyo-ku, Kyoto
602-8566
JAPAN

Brussels, 28 February 2003

Ref. : PT/z03/Aiko 014.doc

Dear Prof. Aiko,

During the last ASCO meeting (Orlando, May 2002) the RECIST working group met with Dr. Kurihara and colleagues to discuss the implementation of specific criteria as proposed by the Japanese Cancer Society for the evaluation of gastric cancer.

After a long and fruitful discussion, we agreed that it is yet too early to include these criteria in the RECIST guidelines as golden standards for the evaluation of gastric cancer because it requires an expertise that is available, so far, mainly in Japan. Moreover, no validation of the proposed guidelines have been published outside Japan.

However, due to the frequency of gastric cancer in Japan, we believe that the criteria developed by Dr. Kurihara and colleagues could be useful for the evaluation of new anticancer agents for gastric cancer in Japan. Since the RECIST guidelines have been developed as a tool to facilitate cancer research and not specifically as a set of rules to be followed rigidly by regulatory agencies, we do not perceive a conflict for the Japanese authority to accept the criteria proposed by Dr. Kurihara et al for the evaluation of gastric cancer and the RECIST criteria for the other tumor types.

We remain at your disposal for any further information you may need.

Yours sincerely,

Patrick Therasse

On behalf of the RECIST WG

CC : Dr. Elizabeth Eisenhauer
Dr. Jantien Wanders