

bortezomib (Velcade®)

(No. 126/04)

Ortho Biotech

Summary of Advice

11 October 2004

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and advises NHS Boards and ADTCs on its use in NHS Scotland. The advice is summarised as follows:

ADVICE: following a full submission.

Bortezomib (Velcade®) is accepted for use within NHS Scotland for the treatment of patients with multiple myeloma who have received at least two prior therapies, have demonstrated disease progression on the last therapy and who are refractory to alternative licensed treatments for this stage of the disease.

Bortezomib produced a disease response in approximately one third of these patients in an open-label uncontrolled study. Any other use of bortezemib should only take place within the context of a controlled study.

The manufacturers are encouraged to mount an observational study in collaboration with haemato-oncologists to gain more information on the benefits and risks of this therapy.

Professor David H Lawson
Chairman