New oncology reimbursements in Belgium

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OVERVIEW OF BELGIAN REIMBURSEMENT NEWS

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DENOSUMAB (XGEVA®)

Denosumab (Xgeva®) is now reimbursed for the treatment of adults and skeletally mature adolescents presenting with a giant cell tumour of bone (GCTB) which cannot be resected or in case surgical resection would be associated with serious morbidity.

Approval for this indication was based on the outcome of two open-label single arm studies. The dosing regimen was 120 mg denosumab administered SC Q4W, with 120 mg loading doses on days eight and fifteen of treatment.

Study 20040215 was an open-label, single-arm, phase II study to evaluate the tumour response to treatment with denosumab, measured by histopathology (at least 90% elimination of giant cells relative to baseline, or complete elimination of giant cells in cases where giant cells represented <5% of tumour cells) or radiography (lack of progression of the target lesion at week 25 as determined by the investigator). To be included, patients needed to have histologically confirmed GCTB, measurable (≥10 mm in the greatest dimension) recurrent GCTB confirmed by radiology, or unresectable GCTB. Response, as defined by the primary endpoint, was 86% with a considerable difference whether based on histology (100%) or radiology (66.7%).

Study 20062004 is an ongoing phase II, open-label study designed to primarily evaluate the safety of denosumab, as well as tumour response as determined by the investigator. Two cohorts are included: cohort one with primary unresectable tumours and cohort two where surgery would lead to substantial morbidity. The efficacy endpoints were, for the cohorts respectively, time to disease progression and proportion of subjects without any surgery at month six. The median time to objective tumour response was three months. At the interim analysis, only 4% in cohort one had progressive disease and 90% in cohort two had not undergone surgery by month six. At the data 'snap-shot' with cut-off date August 20th, 2013, the corresponding numbers were 8.1% and 92%, respectively. Almost 20% of the patients had a complete resection over the study.

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Conflict of interest: The author has nothing to disclose and indicates no potential conflict of interest.