New oncology reimbursements in Belgium

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OVERVIEW OF BELGIAN REIMBURSEMENT NEWS

(BELG J MED ONCOL 2018;12(3):145-146)

LENVIMA® (LENVATINIB)

Lenvima® (lenvatinib) is reimbursed for the treatment of adult patients with rapidly progressing (>20% over one year), symptomatic, locally advanced or metastatic differentiated, radioactive iodine resistant thyroid cancer with a tumour diameter of at least 1 cm. Reimbursement should be requested via the eHealth system.

The SELECT study was a multicentre, randomised, double-blind, placebo-controlled trial in which 392 patients with measurable radioiodine-refractory differentiated thyroid cancer with independently, centrally reviewed, radiographic evidence of disease progression within twelve months (+1 month window) prior to enrolment were randomly assigned 2:1 to receive lenvatinib 24 mg once daily or matched placebo. Radioiodine-refractory was defined as one or more measurable lesions either with a lack of iodine uptake or with progression in spite of radioactive-iodine (RAI) therapy, or having a cumulative activity of RAI of >600 mCi or 22 GBq with the last dose at least six months prior to study entry. The primary endpoint was progression-free survival (PFS) as determined by blinded independent radiologic review using RECIST 1.1. Secondary endpoints included overall response rate (ORR) and overall survival (OS). Patients in the placebo arm could opt to receive lenvatinib at the time of confirmed disease progression.

Of the 392 patients randomised, 76.3% were naïve to prior VEGF/VEGFR-targeted therapies. A statistically significant prolongation in PFS was demonstrated in lenvatinib-treated patients compared with those receiving placebo (Hazard Ratio [HR] 0.21; 99% CI 15.1, not estimable [NE], p<0.0001). Median PFS was 18.3 months (95% CI 15.1, NE) and 3.6 months (95% CI 2.2, 3.7, respectively.

Following independent review confirmation of disease progression, 83.2% of patients randomised to placebo had crossed over to open-label lenvatinib at the time of the primary efficacy analysis. The objective response rate per independent radiological review was significantly (p<0.0001) higher in the lenvatinib-treated group (64.8% [95% CI 59.0, 70.5]) than in

the placebo-treated group (1.5% [95% CI 0.0, 3.6]). The median time to objective responsive was 2.0 (95% CI 1.9, 3.5) months. The overall survival analysis was confounded by the fact that placebo-treated subjects with confirmed disease progression had the option to cross over to open-label lenvatinib. There was no statistically significant difference in OS between the treatment groups at the time of the primary efficacy analysis (HR=0.73; 95% CI 0.50, 1.07; p=0.1032). The median OS had not been reached for either the lenvatinib group or the placebo crossover group.

The most frequently reported adverse reactions (occurring in ≥30% of patients) are hypertension (68.6%), diarrhoea (62.8%), decreased appetite (51.5%), weight decreased (49.1%), fatigue (45.8%), nausea (44.5%), proteinuria 36.9%), stomatitis (35.8%), vomiting (34.5%), dysphonia (34.1%), headache (34.1%), and palmar-plantar erythrodysesthesia syndrome (PPE) (32.7%). The majority of Grade 3 to 4

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

adverse reactions occurred during the first six months of treatment except for diarrhoea, which occurred throughout treatment, and weight loss, which tended to be cumulative over time. The most important serious adverse reactions were renal failure and impairment (2.4%), arterial thromboembolisms (3.9%), cardiac failure (0.7%), intracranial tumour haemorrhage (0.7%), PRES/RPLS (0.2%), hepatic failure (0.2%), and arterial thromboembolisms (cerebrovascular accident (1.1%)), transient ischaemic attack (0.7%), and myocardial infarction (0.9%). Adverse events led to dose reduction in 63.1% of patients and to discontinuation in 19.5% of patients. Adverse reactions that most commonly led to dose reductions (in ≥5% of patients) were hypertension, proteinuria, diarrhoea, fatigue, PPE, weight decreased, and decreased appetite. The median time to first dose reduction was 2.8 months. Adverse reactions that most commonly led to discontinuation of lenvatinib were proteinuria, asthenia, hypertension, cerebrovascular accident, diarrhoea, and pulmonary embolism.

DECAPEPTYL® (TRIPTORELIN)

Decapeptyl® (triptorelin) is reimbursed in combination with tamoxifen or an aromatase inhibitor or chemotherapy for the adjuvant treatment of high risk hormone receptor positive breast cancer.