New oncology reimbursements in Belgium

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OVERVIEW OF BELGIAN REIMBURSEMENT NEWS

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TEMOZOLOMIDE® (TEMODAR/TEMODAL)

Some companies have transferred temozolomide from chapter IV to chapter I. These can now be prescribed without restrictions. In the near future, other temozolomide brands are also expected to be transferred.

LOMUSTINE (CCNU)

The reimbursement criteria for lomustine have been modified and are entirely concordant with the recently modified criteria for procarbazine, except for the indication Hodgkin's disease, which only applies for procarbazine.

CABOMETYX® (CABOZANTINIB)

Cabometyx® (cabozantinib) can be reimbursed for patients with advanced renal cell carcinoma (RCC) after at least one prior anti-VEGF directed agent. Prior treatment with cytokines and anti-PD1 is allowed. In the METEOR trial, 658 patients with advanced renal cancer (RCC) with a clear cell component who had previously received at least one prior VEGF receptor tyrosine kinase inhibitor were randomised to receive cabozantinib or everolimus. The median duration of treatment was 7.6 months (range 0.3 – 20.5) for patients receiving cabozantinib and 4.4 months (range 0.21 – 18.9) for patients receiving everolimus. A statistically significant improvement in progression-free survival (PFS; primary endpoint) was demonstrated for cabozantinib compared to everolimus. Median PFS by independent radiology review committee in the primary PFS analysis population was 7.4 months (95% confidence interval [CI] 5.6-9.1) with cabozantinib versus 3.8 months (95% CI 3.7-5.4) with everolimus with a hazard ratio (HR) of 0.58 (95% CI 0.45-0.74; p<0.0001). Similar data were observed in the intent-to-treat population. A planned interim analysis of overall survival (OS) was conducted at the time of the PFS analysis and did not reach the interim boundary for statistical significance (HR=0.68 [0.51, 0.90], p=0.006). However, in a subsequent unplanned interim analysis of OS, a statistically significant improvement was demonstrated (median 21.4 months versus 16.5 months; HR=0.66; 95% CI 0.53-0.83; p=0.0003). The overall response rate (ORR) was 17% (95% CI 13-22) for cabozantinib and 3% (95% CI 2-6) for everolimus (p<0.0001).

COTELLIC® (COBIMETINIB)

Cotellic® (cobimetinib) can be reimbursed in association with vemurafenib (Zelboraf®) for the treatment of patients with advanced non-resectable or metastatic melanoma with a *BRAF*V600 mutation. In the coBRIM trial, 495 previously untreated patients with unresectable locally advanced or metastatic melanoma with confirmed *BRAF* V600 mutation, using the Cobas® 4800 *BRAF* V600 mutation test, were randomised to receive vemurafenib 960 mg twice daily on days 1-28 plus either cobimetinib 60 mg or matched placebo once daily on days 1-21 of each 28 day treatment cycle. Progression-free survival as assessed by the investigator was the primary endpoint. After a median follow up of 14.2 months, median PFS was 12.3 months (95% CI 9.5-13.4) with cobi-

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metinib plus vemurafenib and 7.2 months (95% CI 5.6-7.5) with placebo plus vemurafenib (HR 0.58; 95% CI 0.46-0.72). Median OS was 22.3 months (95% CI 20.3-not evaluable [NE]) and 17.4 months (95% CI 15.0-19.8), respectively (HR 0.70; 95% CI 0.55-0.90; p=0.005). The objective response was 69.6% (95% CI 63.5-75.3) rate in the cobimetinib plus vemurafenib arm and 50.0% (95% CI 43.6-56.4) in the placebo plus vemurafenib arm. Median duration of response was thirteen months (95% CI 11.1-16.6) and 9.2 months (95% CI 7.5-12.8), respectively (p<0.0001).

IBRANCE® (PALBOCICLIB)

Ibrance® (palbociclib) is reimbursed in combination with a non-steroidal aromatase inhibitor for patients with hormone-receptor positive, HER2-negative, locally advanced or metastatic breast cancer recurring during or within twelve months after prior adjuvant hormonal treatment with tamoxifen. In the PALOMA-2 trial, 666 postmenopausal women with ER-positive, HER2-negative locally advanced breast cancer not amenable to resection or radiation therapy with curative intent or metastatic breast cancer who had not received prior systemic treatment for their advanced disease, were randomised 2:1 to receive letrozole plus either palbociclib or placebo. The primary endpoint was PFS as assessed by investigator. The observed HR was 0.576 (95% CI 0.46-0.72) in favour of palbociclib plus letrozole, with a stratified log-rank test one-sided p-value of <0.000001. The median PFS was 24.8 months (95% CI 22.1-NE) in the palbociclib plus letrozole arm and 14.5 months (95% CI 12.9-17.1) in the placebo plus letrozole arm.