New haematology reimbursements in Belgium

P. Specenier, MD, PhD

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MIDOSTAURIN (RYDAPT®)

Midostaurin (Rydapt®) can be reimbursed for the treatment of adult patients with newly diagnosed FLT3-mutated (ITD or TKD) acute myelocytic leukaemia (AML), with the exception of acute promyelocytic leukaemia (M3), when it is combined with an anthracycline and cytarabine as induction chemotherapy and cytarabine as consolidation therapy. Patients who achieve a complete remission qualify for maintenance therapy with midostaurin. In a randomised phase III trial, 717 patients with newly diagnosed FLT3-mutated AML as determined by a clinical study assay were randomised (1:1) to receive midostaurin 50 mg twice daily or placebo sequentially in combination with standard daunorubicin (60 mg/m^2 daily on days 1-3)/cytarabine (200 mg/m^2 daily on days 1-7) induction and high-dose cytarabine (3 g/m^2 every twelve hours on days 1, 3, and 5) consolidation, followed by continuous midostaurin or placebo treatment according to initial assignment for up to twelve additional cycles (28 days/cycle). The primary analysis was conducted after a minimum follow-up of approximately 3.5 years after the randomisation of the last patient. The study demonstrated a statistically significant improvement in overall survival (OS; primary endpoint) with a hazard ratio (HR) of 0.774 (95% confidence interval [CI] 0.629-0.953; p=0.0078). Median OS was 74.7 months with midostaurin and 25.6 months with placebo. The key secondary endpoint was event-free survival (EFS; an EFS event is defined as a failure to obtain a complete remission (CR) within 60 days of initiation of protocol therapy, or relapse, or death from any cause). Event-free survival was significantly improved with the addition of midostaurin (HR: 0.78; 95% CI 0.66-0.93; p=0.0024) with a median EFS of 8.2 months and 3.0 months, respectively. The most frequent adverse drug reactions (ADRs) in the midostaurin arm were febrile neutropenia (83.4%), nausea (83.4%), exfoliative dermatitis (61.6%), vomiting (60.7%), headache (45.9%), petechiae (35.8%), and pyrexia (34.5%). The most frequent grade 3/4 ADRs were febrile neutropenia (83.5%), lymphopenia (20.0%), device-related infection (15.7%), exfoliative dermatitis (13.6%), hyperglycaemia (7.0%), and nausea (5.8%). The most frequent laboratory abnormalities were haemoglobin decreased (97.3%), ANC decreased (86.7%), ALT increased (84.2%), AST increased (73.9%), and hypokalaemia (61.7%). The most frequent grade 3/4 laboratory abnormalities were ANC decreased (85.8%), haemoglobin decreased (78.5%), ALT increased (19.4%), and hypokalaemia (13.9%). Midostaurin is also indicated as monotherapy for the treatment of adult patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated haematological neoplasm (SM-AHN), or mast cell leukaemia (MCL). However, the market authorisation holder did not request reimbursement for this rare condition. Hence, midostaurin is not reimbursed for patients with mastocytosis or mast cell leukaemia.

LENALIDOMIDE (REVLIMID®)

Lenalidomide (Revlimid®) can be reimbursed as monotherapy for adult patients with recurrent or refractory mantle cell lymphoma after at least one chemo(immuno)therapy-based treatment with the exception of a Bruton's kinase inhibitor. Patients with high tumour burden (>1 lesion with a diameter of >5 cm or >3 lesions with a diameter of >3 cm) or for whom alternative treatment options are available are excluded from reimbursement. In study MCL-002, 254 patients, who were refractory to their last regimen or had relapsed one to three times and who were ineligible for intensive chemotherapy and/or stem cell transplant, were randomly assigned (2:1) to receive lenalidomide 25 mg once daily for the first 21 days of repeating 28-day cycles until progression, unacceptable toxicity or single agent of investigator's choice (IC). Median progression-free survival (PFS; primary endpoint) was 37.6 months (95% CI 24.0-52.6) with lenalidomide and 22.7 months (95% CI 15.9-30.1) with IC. The hazard ratio for PFS was 0.61 (95% CI 0.44-0.84; p=0.004).

Department of Oncology, University Hospital Antwerp, Edegem, Belgium.

Please send all correspondence to: T. Feys, MSc, MBA, Ariez international BV, Oude Houtlei 118, 9000 Ghent, Belgium, tel: +32 479 56 78 90, email: t.feys@ariez.com.

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