The IMiD® Foundation Provides Proven OS Benefit across the Continuum in MM

REVLIMID and POMALYST have improved OS for patients across the continuum of care in MM[1-7]*:

- From a meta-analysis, continuous REVLIMID + dex provides significant OS advantages in **NSCT NDMM** vs melphalan-containing triplets including MPT and VMP[1-3]
- REVLIMID maintenance achieves a median OS of more than 9 years **after ASCT in NDMM**, representing a more than 2 year improvement compared with no maintenance[4]
- The POMALYST + dex regimen provides a survival benefit for **RRMM** patients who are refractory to REVLIMID[7]

* In Hong Kong, REVLIMID is indicated for maintenance following ASCT, in combination for the treatment of previously untreated MM, and in combination with dex for previously treated MM[8]. POMALYST in combination with bortezomib and dex is indicated for the treatment of MM after ≥1 prior treatment regimen (including REVLIMID), and in combination with dex for the treatment of RRMM after ≥2 prior treatment regimens (including REVLIMID and bortezomib) and with disease progression on the last therapy[9].

ASCT=autologous stem cell transplantation. dex=dexamethasone. IMiD=immunomodulatory imide drug. MM=multiple myeloma. MPT=melphalan-prednisone-thalidomide. NDMM=newly diagnosed multiple myeloma. NSCT=non-stem cell transplantation. OS=overall survival. RRMM=relapsed and refractory multiple myeloma. VMP=bortezomib-melphalan-prednisone.

Abbreviated Prescribing Information: Revlimid® 5 mg, 10 mg, 15 mg, 25 mg hard capsules. Refer to the full Prescribing Information (PI) before prescribing. Full PI is available on request.
Name of medicine: Revlimid® 5 mg, 10 mg, 15 mg, 25 mg hard capsules. Active ingredient: Lenalidomide. Available dosage forms: Hard capsules containing lenalidomide 5 mg, 10 mg, 15 mg or 25 mg. Authorized indications: Revlimid® as monotherapy is indicated for the maintenance treatment of adult patients with newly adiagnosed multiple myeloma who have undergone autologous stem cell transplantation. Revlimid® as combination therapy is indicated for the treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant. Revlimid® in combination with dexamethasone is indicated for the treatment of multiple myeloma in adult patients who have received at least one prior therapy. Posology and method of administration: For all indications described below: Dose is modified based upon clinical and laboratory findings. Dose adjustments, during treatment and restart of treatment, are recommended to manage grade 3 or 4 thrombocytopenia, neutropenia, or other grade 3 or 4 toxicity judged to be related to lenalidomide. In case of neutropenia, the use of growth factors in patient management should be considered. If less than 12 hours has elapsed since missing a dose, the patient can take the dose. If more than 12 hours has elapsed since missing a dose at the normal time, the patient should not take the dose, but take the next dose at the normal time on the following day. Newly diagnosed multiple myeloma (Lenalidomide maintenance in patients who have undergone autologous stem cell transplantation (ASCT)): Lenalidomide maintenance should be initiated after adequate haematologic recovery following ASCT in patients without evidence of progression. Lenalidomide must not be started if the Absolute Neutrophil Count (ANC) is < 1.0 x 10^9/L, and/or platelet counts are < 75 x 10^9/L. The recommended starting dose is lenalidomide 10 mg orally once daily continuously (on days 1 to 28 of repeated 28-day cycles) given until disease progression or intolerance. After 3 cycles of lenalidomide maintenance, the dose can be increased to 15 mg orally once daily if tolerated. Newly diagnosed multiple myeloma (Lenalidomide in combination with dexamethasone until disease progression in patients who are not eligible for transplant): Lenalidomide treatment must not be started if the ANC is < 1.0 x 10^9/L, and/or platelet counts are < 50 x 10^9/L. The recommended starting dose of lenalidomide is 25 mg orally once daily on days 1 to 21 of repeated 28-day cycles. The recommended dose of dexamethasone is 40 mg orally once daily on days 1, 8, 15 and 22 of repeated 28-day cycles. Patients may continue lenalidomide and dexamethasone therapy until disease progression or intolerance. For hematologic toxicity the dose of lenalidomide may be re-introduced to the next higher dose level (up to the starting dose) upon improvement in bone marrow function (no hematologic toxicity for at least 2 consecutive cycles: ANC ≥ 1,5 x 10^9/L with a platelet count ≥ 100 x 10^9/L at the beginning of a new cycle). Newly diagnosed multiple myeloma (Lenalidomide in combination with melphalan and prednisone followed by lenalidomide maintenance in patients who are not eligible for transplant): Lenalidomide treatment must not be started if the ANC is < 1.5 x 10^9/L, and/or platelet counts are < 75 x 10^9/L. The recommended starting dose is lenalidomide 10 mg orally once daily on days 1 to 21 of repeated 28-day cycles for up to 9 cycles, melphalan 0.18 mg/kg orally on days 1 to 4 of repeated 28-day cycles, prednisone 2 mg/kg orally on days 1 to 4 of repeated 28-day cycles. Patients who complete 9 cycles or who are unable to complete the combination therapy due to intolerance are treated with lenalidomide monotherapy as follows:10 mg orally once daily on days 1 to 21 of repeated 28-day cycles given until disease progression. Multiple myeloma with at least one prior therapy: Lenalidomide treatment must not be started if the ANC < 1.0 x 10^9/L, and/or platelet counts < 75 x 10^9/L or, dependent on bone marrow infiltration by plasma cells, platelet counts < 30 x 10^9/L. The recommended starting dose of lenalidomide is 25 mg orally once daily on days 1 to 21 of repeated 28-day cycles. The recommended dose of dexamethasone is 40 mg orally once daily on days 1 to 4, 9 to 12 and 17 to 20 of each 28-day cycle for the first 4 cycles of therapy and then 40 mg once daily on days 1 to 4 every 28 days. Prescribing physicians should carefully evaluate which dose of dexamethasone to use, taking into account the condition and disease status of the patient. All indications: For other grade 3 or 4 toxicities judged to be related to lenalidomide, treatment should be stopped and only restarted at next lower dose level when toxicity has resolved to ≤ grade 2 depending on the physician's discretion. Lenalidomide interruption or discontinuation should be considered for grade 2 or 3 skin rash. Lenalidomide must be discontinued for angioedema, grade 4 rash, exfoliative or bullous rash, or if Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) or Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) is suspected, and should not be resumed following discontinuation from these reactions. Special populations (refer to section 4.2 of the PI for full details): Paediatric population, elderly, patients with renal impairment, patients with hepatic impairment. Contraindications: Pregnancy. Women of childbearing potential unless all of the conditions of the Pregnancy Prevention Programme (PPP) are met. Hypersensitivity to the active substance or to any of the excipients. Warnings (refer to section 4.4 of the PI for full details): Pregnancy warning: If lenalidomide is taken during pregnancy, a teratogenic effect in humans is expected. All female patients or male patients with a female partner of childbearing potential must fulfil the conditions of the PPP. Counselling: For women of childbearing potential, lenalidomide is contraindicated unless all of the following are met: She understands the expected teratogenic risk to the unborn child and the need for effective contraception without interruption, 4 weeks before starting treatment, throughout the entire duration of treatment, and 4 weeks after the end of treatment. She must be capable of complying with effective contraceptive measures and understand the need to undergo medically supervised pregnancy tests. Contraception: Women of childbearing potential must use one effective method of contraception for 4 weeks before therapy, during therapy, and until 4 weeks after lenalidomide therapy and even in case of dose interruption unless the patient commits to absolute and continuous abstinence confirmed on a monthly basis. Combined oral contraceptive pills are not recommended because of the increased risk of venous thromboembolism in multiple myeloma patients taking lenalidomide and dexamethasone. Refer to section 4.4 of the PI for full details. Pregnancy testing: According to local practice, medically supervised pregnancy tests with a minimum sensitivity of 25 mIU/mL must be performed for women of childbearing potential. Male patients must understand the teratogenic risk of sexual activity with a pregnant woman or a woman of childbearing potential not using effective contraception and as a precaution, he must use a condom throughout treatment duration, during dose interruption and for 4 weeks after cessation of treatment. Additional precautions: Patients should be instructed never to give this medicinal product to another person and to return any unused capsules to their pharmacist at the end of treatment. Patients should not donate blood during therapy or for 4 weeks following discontinuation of lenalidomide. Other special warnings and precautions (refer to section 4.4 of the PI for full details): Myocardial infarction, venous and arterial thromboembolic events, neutropenia and thrombocytopenia, infection with or without neutropenia, renal impairment, thyroid disorders, peripheral neuropathy, tumour flare reaction and tumour lysis syndrome, allergic reactions, severe skin reactions (SJS, TEN and DRESS have been reported), lactose intolerance, second primary malignancies, hepatic disorders, viral reactivation, progressive multifocal leukoencephalopathy, cataract. Clinically significant interactions: Erythropoietic agents, or other agents that may increase the risk of thrombosis, such as hormone replacement therapy, should be used with caution in multiple myeloma patients receiving lenalidomide with dexamethasone. Refer to section 4.5 of the PI for full details. Reported side effects: Some of the more frequently observed adverse reactions included neutropenia, bronchitis, diarrhoea, nasopharyngitis, muscle spasms, leucopenia, asthenia, cough, thrombocytopenia, gastroenteritis and pyrexia. Please refer to section 4.8 of the PI for other side effects seen on treatment with lenalidomide. Date of revision of abbreviated prescribing information: 23/06/2020.

Abbreviated Prescribing Information: Pomalyst® 1 mg, 2 mg, 3 mg, 4 mg hard capsules. Refer to the full Prescribing Information (PI) before prescribing. Full PI is available on request.
Name of medicine: Pomalyst® 1 mg, 2 mg, 3 mg, 4 mg hard capsules. Active ingredient: Pomalidomide. Available dosage form: Hard capsules containing pomalidomide 1 mg, 2 mg, 3 mg or 4 mg. Authorised indications: Pomalyst® in combination with bortezomib and dexamethasone is indicated in the treatment of adult patients with multiple myeloma who have received at least one prior treatment regimen including lenalidomide. Pomalyst® in combination with dexamethasone is indicated in the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior treatment regimens, including both lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy. Posology and method of administration: Dosing is continued or modified based upon clinical and laboratory findings. Pomalidomide in combination with bortezomib and dexamethasone: The recommended starting dose of Pomalyst® is 4 mg orally once daily on Days 1 to 14 of repeated 21-day cycles. Pomalidomide is administered in combination with bortezomib and dexamethasone, as shown in Table 1 of the full PI. Please refer to section 4.2 of the PI for the recommended dosing scheme for Pomalyst® in combination with bortezomib and dexamethasone. Pomalidomide in combination with dexamethasone: The recommended starting dose of Pomalyst® is 4 mg once daily taken orally on Days 1 to 21 of repeated 28-day cycles. The recommended dose of dexamethasone is 40 mg orally once daily on Days 1, 8, 15 and 22 of each 28-day treatment cycle. Treatment with pomalidomide combined with dexamethasone should be given until disease progression or until unacceptable toxicity occurs. Pomalidomide interruption or discontinuation should be considered for Grade 2-3 skin rash. Pomalidomide must be discontinued for angioedema, exfoliative or bullous rash, or if Stevens-Johnson syndrome (SJS), Toxic Epidermal Necrolysis (TEN) or Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) is suspected, and should not be resumed following discontinuation from these reactions. Special populations: Elderly (Please refer to section 4.2 of the full PI for details). Paediatric population. There is no relevant use of Pomalyst® in children aged 0-17 years for the indication of multiple myeloma. Renal impairment. No dose adjustment of pomalidomide is required for patients with renal impairment. On haemodialysis days, patients should take their pomalidomide dose following haemodialysis. Hepatic impairment. Patients with serum total bilirubin >1.5 x ULN (upper limit of normal range) were excluded from clinical studies. Hepatic impairment has a modest effect on the pharmacokinetics of pomalidomide. No adjustment of the starting dose of pomalidomide is required for patients with hepatic impairment as defined by the Child-Pugh criteria. However, patients with hepatic impairment should be carefully monitored for adverse reactions and dose reduction or interruption of pomalidomide should be used as needed. Contraindications: Pregnancy. Women of childbearing potential, unless all the conditions of the pregnancy prevention programme are met. Male patients unable to follow or comply with the required contraceptive measures. Hypersensitivity to the active substance or to any of the excipients listed in section 6.1 of the PI. Warnings: Pregnancy warning. Pomalidomide must not be taken during pregnancy, since a teratogenic effect is expected. The conditions of the Pregnancy Prevention Programme must be fulfilled for all patients unless there is reliable evidence that the patient does not have childbearing potential. Refer to Section 4.4 of the PI for a full list of the criteria for women of non-childbearing potential. Breast-feeding. It is not known if pomalidomide is excreted in human milk. Pomalidomide was detected in milk of lactating rats following administration to the mother. Counselling. For women of childbearing potential, pomalidomide is contraindicated unless all of the following are met: She understands the expected teratogenic risk to the unborn child. She understands the need for effective contraception, without interruption, at least 4 weeks before starting treatment, throughout the entire duration of treatment, and at least 4 weeks after the end of treatment. She should be capable of complying with effective contraceptive measures, and understands the need to undergo medically supervised pregnancy tests. For male patients taking pomalidomide, he understands the expected teratogenic risk if engaged in sexual activity with a pregnant woman or a woman of childbearing potential and he understands the need for the use of a condom during treatment and for 4 weeks after dose interruptions and/ or cessation of treatment. Contraception. Women of childbearing potential must use at least one effective method of contraception for at least 4 weeks before therapy, during therapy, and until at least 4 weeks after pomalidomide therapy and even in case of dose interruption unless the patient commits to absolute and continuous abstinence confirmed on a monthly basis. Please refer to section 4.4 of the PI for examples of suitable methods of contraception. Because of the increased risk of venous thromboembolism in patients with multiple myeloma taking pomalidomide and dexamethasone, combined oral contraceptive pills are not recommended. If a patient is currently using combined oral contraception the patient should switch to one of the effective methods listed in Section 4.4 of the PI. Refer to section 4.4 of the PI for full details. Pregnancy testing. According to local practice, medically supervised pregnancy tests with a minimum sensitivity of 25 mIU/mL must be performed for women of childbearing potential. Please refer to Section 4.4 of the PI for full details of pregnancy testing. Additional precautions. Patients should be instructed never to give this medicinal product to another person and to return any unused capsules to their pharmacist at the end of treatment. Patients should not donate blood, semen or sperm during treatment (including during dose interruptions) and for 4 weeks following discontinuation of pomalidomide. Other special warnings and precautions (refer to section 4.4 of the PI for full details): Haematological events, thromboembolic events, peripheral neuropathy, significant cardiac dysfunction, tumour lysis syndrome, second primary malignancies, allergic reactions and severe skin reactions, dizziness and confusion, interstitial lung disease, hepatic disorders, infections. Clinically significant interactions: Pomalidomide is not anticipated to cause clinically relevant pharmacokinetic drug-drug interactions due to P450 isoenzyme inhibition or induction or transporter inhibition when co-administered with substrates of these enzymes or transporters. Refer to section 4.5 of the PI for full details. Reported side effects: Anaemia, neutropenia, thrombocytopenia, fatigue, pyrexia, oedema peripheral, pneumonia. Prescribers should consult the full Prescribing Information in relation to other side-effects. Date of revision of abbreviated prescribing information: 23/06/2020.

References:
1. Benboubker L, et al. N Engl J Med 2014;371:906-917. 2. Facon T, et al. Blood. 2018;131:301-310. 3. Weisel K, et al. Leuk Lymph. 2017;58:153-161. 4. McCarthy PL, et al. J Clin Oncol. 2017;35:3279-3289. 5. Dimopulos MA, et al. Leukemia 2009;23:2147-2152. 6. San-Miguel JF, et al. Clin Lymphoma Myeloma Leuk 2011;11:38-43. 7. San Miguel J, et al. Lancet Oncol. 2013;14:1055-1066. 8. Revlimid® prescribing information (Hong Kong). 9. Pomalyst® prescribing information (Hong Kong).

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