HKSOM
HONG KONG SOCIETY OF MYELOMA
香港骨髓瘤學會

Hong Kong Society of Myeloma

Annual Scientific Meeting 2021

Program Book

DATE 6 November 2021 (Saturday) **TIME** 13:45 - 20:45

VENUE Salon I - V, Hyatt Regency, 18 Hanoi Road,
Tsim Shan Tsui, Kowloon, Hong Kong

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Kyprolis® (carfilzomib) for Injection

When multiple myeloma relapses in patients with at least 1 prior treatment,

LOOK TO KYPROLIS® FOR THE CLEAR WAY AHEAD

Two phase 3 studies supporting the efficacy of Kyprolis® combined with lenalidomide and dexamethasone, and Kyprolis® with dexamethasone alone.[1-5]

	ASPIRE (KRd)	ENDEAVOR (Kd)
IMPROVED MEDIAN OS	**Median OS of 48.3 months** with KRd in relapsed patients compared to 40.4 months with Rd; (HR=0.794; 95% CI: 0.667-0.945; $p=0.0045$)[1,5] (OS was a secondary endpoint in ASPIRE)	**Median OS of 47.6 months** with Kd in relapsed or refractory multiple myeloma patients compared to 40.0 months with Vd; (HR=0.791; 95% CI: 0.648-0.964; $p=0.010$)[2,5] (OS was a secondary endpoint in ENDEAVOR)
SUSTAINABLE EFFICACY	**Median PFS of 26.3 months** with KRd in relapsed patients compared to 17.6 months with Rd; (HR=0.69; 95% CI: 0.57-0.83; $p<0.0001$)[3]	**KYPROLIS® doubled the median progression-free survival** compared to bortezomib; (18.7 vs. 9.4 months; HR=0.533; 95% CI: 0.44-0.65; $p<0.0001$)[4,5]
DEEP RESPONSE	With KRd, **almost 1 out of 3 patients reached Complete Response** or better (31.8%)[3]	**KYPROLIS® doubled the rate of Complete Response** or better compared to bortezomib; (12.5% vs. 6.2%; $p=0.0005$)[5]

Kd: Kyprolis with dexamethasone; **KRd:** Kyprolis with lenalidomide and dexamethasone; **OS:** Overall survival; **PFS:** Progression-free survival; **Rd:** Lenalidomide with dexamethasone; **Vd:** Bortezomib with dexamethasone

References: 1. Siegel DS, *et al. J Clin Oncol.* 2018;36(8):728-734. 2. Dimopoulos MA, *et al. Lancet Oncol.* 2017;18(10):1327-1337. 3. Steward AK, *et al. New Engl J Med.* 2015;372:142-152. 4. Dimopoulos MA, *et al. Lancet Oncol.* 2016;17(1):27-38. 5. Kyprolis® Hong Kong Prescribing Information. December 2018.

Kyprolis® (Carfilzomib) Abbreviated Prescribing Information
Kyprolis® for injection 30 mg Kyprolis® for injection 60 mg

INDICATIONS Kyprolis in combination with either lenalidomide and dexamethasone or dexamethasone alone is indicated for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. **DOSAGE AND ADMINISTRATION** The dose is calculated using the patient's baseline body surface area (BSA). Patients with a BSA greater than 2.2 m² should receive a dose based upon a BSA of 2.2 m². Dose adjustments do not need to be made for weight changes of less than or equal to 20%. *Kyprolis in combination with lenalidomide and dexamethasone:* When combined with lenalidomide and dexamethasone, Kyprolis is administered intravenously as a 10 minute infusion, on two consecutive days, each week for three weeks (days 1, 2, 8, 9, 15, and 16), followed by a 12-day rest period (days 17 to 28). Each 28-day period is considered one treatment cycle. Kyprolis is administered at a starting dose of 20 mg/m² (maximum dose 44 mg) in cycle 1 on days 1 and 2. If tolerated, the dose should be increased on day 8 of cycle 1 to 27 mg/m² (maximum dose 60 mg). From cycle 13, the day 8 and 9 doses of Kyprolis are omitted. Treatment may be continued until disease progression or until unacceptable toxicity occurs. Treatment with Kyprolis combined with lenalidomide and dexamethasone for longer than 18 cycles should be based on an individual benefit/risk assessment, as the data on the tolerability and toxicity of carfilzomib beyond 18 cycles are limited. In combination with Kyprolis, lenalidomide is administered as 25 mg orally on days 1–21 and dexamethasone is administered as 40 mg orally or intravenously on days 1, 8, 15, and 22 of the 28 day cycles. Appropriate dose reduction for the starting dose of lenalidomide should be considered according to the recommendations in the current lenalidomide summary of product characteristics, for example for patients with baseline renal impairment. Dexamethasone should be administered 30 minutes to 4 hours before Kyprolis. *Kyprolis in combination with dexamethasone:* When combined with dexamethasone, Kyprolis is administered intravenously as a 30 minute infusion on two consecutive days, each week for three weeks (days 1, 2, 8, 9, 15, and 16) followed by a 12-day rest period (days 17 to 28). Each 28-day period is considered one treatment cycle. Kyprolis is administered at a starting dose of 20 mg/m² (maximum dose 44 mg) in cycle 1 on days 1 and 2. If tolerated, the dose should be increased on day 8 of cycle 1 to 56 mg/m² (maximum dose 123 mg). Treatment may be continued until disease progression or until unacceptable toxicity occurs. When Kyprolis is combined with dexamethasone alone, dexamethasone is administered as 20 mg orally or intravenously on days 1, 2, 8, 9, 15, 16, 22, and 23 of the 28 day cycles. Dexamethasone should be administered 30 minutes to 4 hours before Kyprolis. *Recommended dose modifications:* Dosing should be modified based on Kyprolis toxicity. See Prescribing Information for details. Special populations: *Renal impairment:* Appropriate dose reduction for the starting dose of lenalidomide in patients with baseline renal impairment should be considered according to the recommendations in the lenalidomide summary of product characteristics. No starting dose adjustment for Kyprolis is recommended in patients with baseline mild, moderate, or severe renal impairment or patients on chronic dialysis based on available pharmacokinetic data. Renal function should be assessed at treatment initiation and monitored at least monthly or in accordance with accepted clinical practice guidelines, particularly in patients with lower baseline creatinine clearance (CrCL < 30 mL/min). Appropriate dose modifications based on toxicity should be made. Since dialysis clearance of Kyprolis concentrations has not been studied, the medicinal product should be administered after the dialysis procedure. *Hepatic impairment:* The pharmacokinetics of Kyprolis has not been evaluated in patients with severe hepatic impairment. No starting dose adjustment is recommended in patients with mild or moderate hepatic impairment based on available pharmacokinetic data. Liver enzymes and bilirubin should be assessed at treatment initiation and monitored monthly during treatment with carfilzomib, regardless of baseline values, and appropriate dose modifications based on toxicity should be made. *Elderly patients:* Overall, the subject incidence of certain adverse events (including cardiac failure) in clinical trials was higher for patients who were ≥ 75 years of age compared to patients who were < 75 years of age. *Paediatric population:* The safety and efficacy of Kyprolis in paediatric patients have not been established. Method of administration: Kyprolis is to be administered by intravenous infusion. The 20/27 mg/m² dose is administered over 10 minutes. The 20/56 mg/m² dose must be administered over 30 minutes. Kyprolis must not be administered as an intravenous push or bolus. See Prescribing Information for details. **CONTRAINDICATIONS** Hypersensitivity to the active substance or to any of the excipients. Women who are breastfeeding. As Kyprolis is administered in combination with other medicinal products, refer to their summaries of product characteristics for additional contraindications. **SPECIAL WARNINGS AND PRECAUTIONS FOR USE** As Kyprolis is administered in combination with other medicinal products, the summary of product characteristics of these other medicinal products must be consulted prior to initiation of treatment with Kyprolis. As lenalidomide may be used in combination with Kyprolis, particular attention to the lenalidomide pregnancy testing and prevention requirements is needed. Cardiac disorders: New or worsening cardiac failure (e.g. congestive cardiac failure, pulmonary oedema, decreased ejection fraction), myocardial ischaemia and infarction have occurred following administration of Kyprolis. Death due to cardiac arrest has occurred within a day of Kyprolis administration and fatal outcomes have been reported with cardiac failure and myocardial infarction. While adequate hydration is required prior to dosing in cycle 1, all patients should be monitored for evidence of volume overload, especially patients at risk for cardiac failure. Stop Kyprolis for grade 3 or 4 cardiac events until recovery and consider whether to restart Kyprolis at 1 dose level reduction based on a benefit/risk assessment. The risk of cardiac failure is increased in elderly patients (≥ 75 years). The risk of cardiac failure is also increased in Asian patients. Electrocardiographic changes: There have been cases of QT interval prolongation reported in clinical studies. An effect of Kyprolis on QT interval cannot be excluded. Pulmonary toxicity: Acute respiratory distress syndrome (ARDS), acute respiratory failure, and acute diffuse infiltrative pulmonary disease such as pneumonitis and interstitial lung disease have occurred in patients receiving Kyprolis. Some of these events have been fatal. Evaluate and stop Kyprolis until resolved and consider whether to restart Kyprolis based on a benefit/risk assessment Pulmonary hypertension: Pulmonary hypertension has been reported in patients treated with Kyprolis. Some of these events have been fatal. Stop Kyprolis for pulmonary hypertension until resolved or returned to baseline and consider whether to restart Kyprolis based on a benefit/risk assessment Dyspnoea: Dyspnoea was commonly reported in patients treated with Kyprolis. Evaluate dyspnoea to exclude cardiopulmonary conditions including cardiac failure and pulmonary syndromes. Stop Kyprolis for grade 3 and 4 dyspnoea until resolved or returned to baseline and consider whether to restart Kyprolis based on a benefit/risk assessment. Hypertension: Hypertension, including hypertensive crisis and hypertensive emergency, has been observed with Kyprolis. Some of these events have been fatal. If the hypertension cannot be controlled, the Kyprolis dose should be reduced. In case of hypertensive crises, stop Kyprolis until resolved or returned to baseline and consider whether to restart Kyprolis based on a benefit/risk assessment. Acute renal failure: Cases of acute renal failure have been reported in patients who received Kyprolis. Some of these events have been fatal. Renal function should be monitored at least monthly or in accordance with accepted clinical practice guidelines, particularly in patients with lower baseline creatinine clearance. Reduce or stop dose as appropriate. Tumour lysis syndrome: Cases of tumour lysis syndrome (TLS), including with fatal outcome, have been reported in patients who received Kyprolis. Patients with a high tumour burden should be considered to be at greater risk for TLS. Ensure that patients are well hydrated before administration of Kyprolis in cycle 1, and in subsequent cycles as needed. Uric acid lowering medicinal products should be considered in patients at high risk for TLS. Evidence of TLS during treatment should be monitored for, including regular measurement of serum electrolytes, and managed promptly. Stop Kyprolis until TLS is resolved. Infusion reactions: Infusion reactions, including lifethreatening reactions, have been reported in patients who received Kyprolis. These reactions can occur immediately following or up to 24 hours after administration of Kyprolis. Dexamethasone should be administered prior to Kyprolis to reduce the incidence and severity of reactions. Haemorrhage and thrombocytopenia: Cases of haemorrhage (e.g. gastrointestinal, pulmonary and intracranial haemorrhage) have been reported in patients treated with Kyprolis, often associated with thrombocytopenia. Some of these events have been fatal. Platelet counts should be monitored frequently during treatment with Kyprolis. Reduce or stop dose as appropriate. Venous thrombosis: Cases of venous thromboembolic events, including deep vein thrombosis and pulmonary embolism with fatal outcomes, have been reported in patients who received Kyprolis. Patients with known risk factors for thromboembolism – including prior thrombosis – should be closely monitored. Thromboprophylaxis should be considered based on an individual benefit/risk assessment. Hepatic toxicity: Cases of hepatic failure, including fatal cases, have been reported. Kyprolis can cause elevations of serum transaminases. Reduce or stop dose as appropriate. Liver enzymes and bilirubin should be monitored at treatment initiation and monthly during treatment with carfilzomib, regardless of baseline values. Thrombotic microangiopathy: Cases of thrombotic microangiopathy, including thrombotic thrombocytopenic purpura and haemolytic uraemic syndrome (TTP/HUS) have been reported in patients who received Kyprolis. Some of these events have been fatal. Signs and symptoms of TTP/HUS should be monitored for. If the diagnosis is suspected, stop Kyprolis and evaluate patients for possible TTP/HUS. If the diagnosis of TTP/HUS is excluded, Kyprolis can be restarted. The safety of reinitiating Kyprolis therapy in patients previously experiencing TTP/HUS is not known. Posterior reversible encephalopathy syndrome: Cases of posterior reversible encephalopathy syndrome (PRES) have been reported in patients receiving Kyprolis. Kyprolis should be discontinued if PRES is suspected. The safety of reinitiating Kyprolis therapy in patients previously experiencing PRES is not known. Contraception: Female patients of child bearing potential (and/or their partners) must use effective contraception measures during and for one month following treatment. Male patients must use effective contraception measures during and for 3 months following treatment if their partner is pregnant or of childbearing potential and not using effective contraception. Carfilzomib may decrease the efficacy of oral contraceptives. Sodium content: This medicinal product contains 0.3 mmols (7 mg) of sodium per mL of reconstituted solution. This should be taken into consideration for patients on a controlled sodium diet. **INTERACTIONS** Carfilzomib is primarily metabolised via peptidase and epoxide hydrolase activities, and as a result, the pharmacokinetic profile of carfilzomib is unlikely to be affected by concomitant administration of cytochrome P450 inhibitors and inducers. Caution should be observed when carfilzomib is combined with substrates of Pgp (e.g. digoxin, colchicine). **FERTILITY, PREGNANCY AND LACTATION** Women of childbearing potential/Contraception in males and females: Female patients of child bearing potential treated with Kyprolis (and/or their partners) must use effective contraception measures during and for one month following treatment. Male patients must use effective contraception measures during and for 3 months following treatment if their partner is pregnant or of child bearing potential not using effective contraception. Pregnancy: There are no data from the use of carfilzomib in pregnant women. Studies in animals have shown reproductive toxicity. Kyprolis should not be used during pregnancy unless the potential benefit outweighs the potential risk to the foetus. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans is expected. Please refer to the current lenalidomide summary of product characteristics. Breastfeeding: It is unknown whether carfilzomib or its metabolites are excreted in human milk. Based on its pharmacological properties, a risk to the suckling child cannot be excluded. Consequently, as a precautionary measure, breastfeeding is contraindicated during and for at least 2 days after treatment with Kyprolis. Fertility: No fertility studies have been performed in animals. **UNDESIRABLE EFFECTS** Summary of safety profile: Serious adverse reactions that may occur during Kyprolis treatment include: cardiac failure, myocardial infarction, cardiac arrest, myocardial ischaemia, interstitial lung disease, pneumonitis, acute respiratory distress syndrome, acute respiratory failure, pulmonary hypertension, dyspnoea, hypertension including hypertensive crises, acute kidney injury, tumour lysis syndrome, infusion related reaction, gastrointestinal haemorrhage, intracranial haemorrhage, pulmonary haemorrhage, thrombocytopenia, hepatic failure, PRES, thrombotic microangiopathy and TTP/HUS. In clinical studies with Kyprolis, cardiac toxicity and dyspnoea typically occurred early in the course of Kyprolis therapy. The most common adverse reactions (occurring in > 20% of subjects) were: anaemia, fatigue, thrombocytopenia, nausea, diarrhoea, pyrexia, dyspnoea, respiratory tract infection, cough and neutropenia.

Please read the full prescribing information prior to administration and full prescribing information is available upon request. Kyprolis® is a registered trademark owned or licensed by Amgen Inc., its subsidiaries, or affiliates. Abbreviated Prescribing Information Version: HKKYPPI02

For medical inquiries or to report adverse events/product complaint, please contact 800 961 142 or email medinfo.JAPAC@amgen.com

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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#. 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[4].

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 10⁹/L, and/or platelet counts are < 75 x 10⁹/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 10⁹/L, and/or platelet counts are < 50 x 10⁹/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 10⁹/L with a platelet count ≥ 100 x 10⁹/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 10⁹/L, and/or platelet counts are < 75 x 10⁹/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 D 10 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 10⁹/L, and/or platelet counts < 75 x 10⁹/L or, dependent on bone marrow infiltration by plasma cells, platelet counts < 30 x 10⁹/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: 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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2003-HK-2100006 Mar 2021

Welcome Message

Prof. James CS Chim

Founding & Current Chairman,
Hong Kong Society of Myeloma

We would like to welcome you to the 11th Annual Scientific Meeting of the Hong Kong Society of Myeloma. In recent years, the field of myeloma is rapidly evolving. Despite the ongoing COVID epidemic, research in myeloma has not ceased, and new data is being generated and continues to refine the way forward in myeloma treatment.

Recent advances in myeloma have resulted in remarkable improvement in outcomes and quality of life. The advent of CAR-T cell, therapeutic antibodies and next generation novel agents have reshaped the treatment landscape of myeloma with ground-breaking success.

In this meeting, we are delighted to have internationally renowned myeloma experts to talk about the cutting edge advances in the management of newly diagnosed & relapsed myeloma.

Therefore, on behalf of the Society, I would like to extend to you our warmest welcome, and hope that you will enjoy these inspiring presentations.

Sincerely yours,

James Chim

IN THE TREATMENT OF RELAPSED/REFRACTORY MULTIPLE MYELOMA, NINLARO® BRINGS[1]

SUSTAINED EFFICACY^

^Tourmaline MM1 study (n=722)
Aim: Compare efficacy and tolerability IRd vs placebo-Rd in rrMM patients; Key Primary Endpoint: PFS (IRd vs placebo-Rd=20.6 months vs 14.7 months); Key Secondary Endpoint: ORR (IRd vs placebo-Rd=78.3% vs 71.5%)
I: Ixazomib; R: Lenalidomide; d: Dexamethasone; rrMM: Relapsed/Refractory Multiple Myeloma; PFS: Progression Free Survival; OS: Overall Survival; ORR: Overall Response Rate.
The rates of serious adverse events were similar in both study groups.

Abbreviated Prescribing Information [NIN0118PIL (C)HK1]
Ninlaro 2.3mg, 3mg and 4mg Capsules
Active Ingredient: Ixazomib citrate Indication: NINLARO in combination with lenalidomide and dexamethasone is indicated for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. Dose & Administration: The recommended starting dose of NINLARO is 4 mg administered orally once a week on Days 1, 8, and 15 of a 28-day treatment cycle. The recommended starting dose of lenalidomide is 25 mg administered daily on Days 1 to 21 of a 28-day treatment cycle. The recommended starting dose of dexamethasone is 40 mg administered on Days 1, 8, 15, and 22 of a 28-day treatment cycle. Treatment should be continued until disease progression or unacceptable toxicity. Ninlaro 3mg and 2.3mg are available for dose modification according to the dose modifications guidelines. NINLARO is for oral use. NINLARO should be taken at approximately the same time on days 1, 8, and 15 of each treatment cycle at least 1 hour before or at least 2 hours after food. The capsule should be swallowed whole with water. It should not be crushed, chewed, or opened. Contraindications: Hypersensitivity to ixazomib citrate. Special precautions: Thrombocytopenia has been reported with NINLARO with platelet nadirs typically occurring between Days 14-21 of each 28-day cycle and recovery to baseline by the start of the next cycle. Diarrhoea, constipation, nausea and vomiting have been reported with NINLARO, occasionally requiring use of antiemetic and antidiarrhoeal medicinal products and supportive care. The dose should be adjusted for severe (Grade 3-4) symptoms. In case of severe gastrointestinal events, monitoring of serum potassium level is recommended. Patients experiencing new or worsening peripheral neuropathy may require dose modification. Rash should be managed with supportive care or with dose modification if Grade 2 or higher. Women should avoid becoming pregnant while being treated with NINLARO. Women of childbearing potential must use highly effective contraception while taking NINLARO and for 90 days after stopping treatment. Women using hormonal contraceptives should additionally use a barrier method of contraception. Adverse Reactions: upper respiratory tract infection, thrombocytopenia, neutropenia, peripheral neuropathy, diarrhoea, nausea, vomiting, constipation, rash, peripheral oedema.
For detailed information, please consult full prescribing information.

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ixazomib capsules
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Reference: 1. Moreau P et al. N Engl J Med. 2016 Apr 28;374(17):1621-1634.
For reporting suspected side effects for Takeda products at AE.HongKong@takeda.com
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C-APROM/HK/NINL/0010(09/2021)

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Patients achieved early platelet Boost with Romiplate®1*

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- 61% of patients sustained platelet counts ≥ 50 x 10^9/L for ≥ 11 months during the treatment period[1]

Abbreviated Package Insert of ROMIPLATE Power for Solution for Injection 250mcg

Composition: Romiplostim. Indications: Adult chronic immune (idiopathic) thrombocytopenic purpura (ITP) in splenectomised patients who are refractory to other treatments (e.g. corticosteroids & immunoglobulins); 2nd-line treatment for adult non-splenectomised patients where surgery is contraindicated. **Dosage and Administration:** *SC inj* Initially 1 mcg/kg (ABW) q1w, may be increased by increments of 1 mcg/kg until achieving a PLC ≥ 50 x 10^9 /L. Max: 10 mcg/kg q1w. **Contraindications:** Hypersensitivity to romiplostim or any of the excipients or *E. coli*-derived proteins. **Precautions:** Recurrence of thrombocytopenia & bleeding after discontinuation. Increased bone marrow reticulin. Thrombotic/thromboembolic complications. Progression of existing myelodysplastic syndrome (MDS). Immunogenicity. Alterations in RBC & WBC. Renal & hepatic impairment. May impair ability to drive or operate machinery. Pregnancy & lactation. Child <18 yr. **Common adverse reactions:** Hypersensitivity reactions, Headache. **Serious adverse reactions:** reoccurrence of thrombocytopenia and bleeding after cessation of treatment, increased bone marrow reticulin, thrombotic/thromboembolic complications, progression of existing MDS to AML. **P/P:** Powd for soln for inj (vial) 250 mcg x 1's. Approved version of package insert: Sep 2019.

Please refer to the full prescribing information before prescribing. Further information is available upon request.

* Platelet response was defined as a platelet count ≥ 50 x 10^9/L. # Based on Overall Platelet Response in non-splenectomized patient

Reference: 1. Newland A, Godeau VP, Priego V, et al. Remission and platelet responses with romiplostim in primary immune thrombocytopenia: final results from a phase 2 study. *Br J Haematol. 2016;172(2):262-273.* **2.** Vishnu P, Aboulafia DM. Long-term safety and efficacy of romiplostim for treatment of immune thrombocytopenia. *J Blood Med. 2016;7:99-106.* **3.** Hong Kong Prescribing Information, Sep 2019.

THIS MATERIAL IS MEANT FOR HEALTHCARE PROFESSIONALS ONLY

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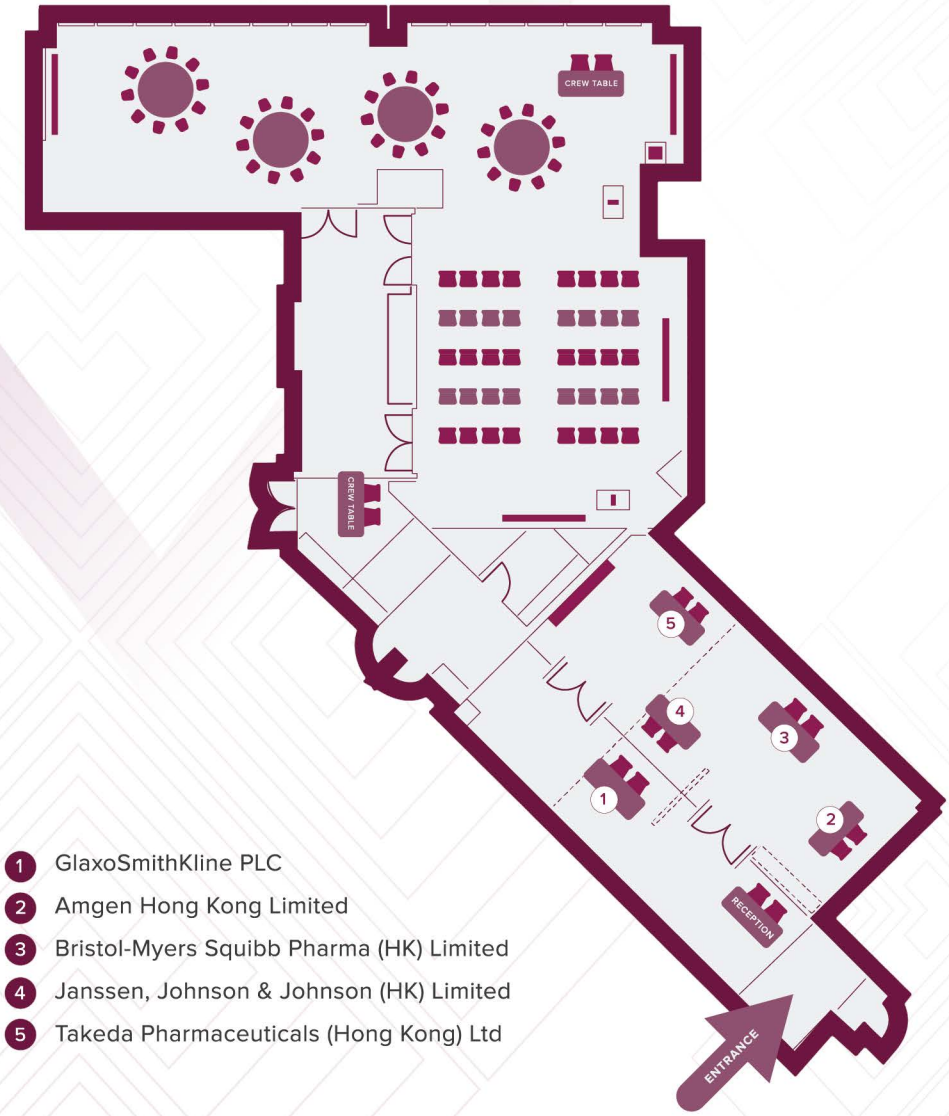
KKHK-ROM-04-FEB2021

Agenda

Time	Program
13:45 - 14:15	Registration
14:15 - 14:20	Opening Ceremony Prof. James CS Chim (Hong Kong)
14:20 - 15:00	Management of rrMM in the modern era Prof. Kwee Yong (UK) *Chaired by Prof. James CS Chim*
15:00 - 15:40	Optimising the use of IMiDs in rrMM patients Prof. Philippe Moreau (France) *Chaired by Dr. Michael Wong*
15:40 - 16:10	Tea Break
16:10 - 16:50	AL Amyloidosis : The silver lining amidst challenges Prof. Ashutosh Wechalekar (UK) *Chaired by Dr. Harold Lee*
16:50 - 17:30	Translating MM clinical trial into real world practice Prof. Heinz Ludwig (Austria) *Chaired by Dr. Herman Liu*
17:30 - 18:10	Novel approach in optimizing efficacy and convenience with carfilzomib in rrMM Dr. Keith Stewart (Canada) *Chaired by Dr. Albert Lam*
18:10 - 18:20	Certificate of Appreciation Presentation Dr. Harold Lee (Hong Kong)
18:20 - 18:30	Break
18:30 - 19:30	Evening Symposium - Sponsored by GSK Novel anti-BCMA therapy for rrMM Dr. María-Victoria Mateos (Spain) *Chaired by Prof. James CS Chim*
19:30 - 20:45	Dinner
20:45	Closing

Floor Plan

Salon I - V, Hyatt Regency, Tsim Sha Tsui, Kowloon



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Management of rrMM in the modern era

Prof. Kwee Yong
University College London, UK

Multiple myeloma (MM) is a malignant neoplasm of plasma cells in which monoclonal plasma cells proliferate in bone marrow, resulting in overabundance of monoclonal paraprotein (M protein), bone destruction, and displacement of hematopoietic cell lines. Despite the advancement in medical treatment, MM progression is common even after achievement of a complete remission, making the management of relapsed/refractory multiple myeloma (rrMM) a challenge.

This presentation will begin with a brief introduction of rrMM and the international guideline on MM management. Prof. Yong will highlight the treatment landscape of rrMM, such as the evolving role of proteasome inhibitor (PI), immunomodulatory drugs (IMiDs), anti-CD38 monoclonal antibodies (mAbs), antibody-drug conjugates (ADCs), autologous stem cell transplant (ASCT), and other novel therapies. Prof. Yong will also focus on when and how to guide treatment choice in different patient subgroups, including patients with renal impairment and high cytogenetic risk, along with recommendations, if there is any, on the specific role of anti-CD38 mAbs in these patients. Looking forward, there will be discussion on the upcoming role of minimal residual disease (MRD) negativity as a surrogate biomarker to predict treatment outcome, and as a treatment endpoint in the development of treatment strategies.

Optimizing the use of IMiDs in rrMM patients

Prof. Philippe Moreau

University Hospital of Nantes, France

Among all multiple myeloma (MM) agents, immunomodulatory drugs (IMiDs) has been the foundational treatments across the international guidelines, demonstrating a proven clinical use with significant improvement in long-term survival and quality of life. Yet, optimizing the use of IMiDs could be challenging due to various combination options available.

We are incredibly honored to have invited Prof. Moreau to give a lecture and share his invaluable opinions on this topic. Prof. Moreau, MD, is Head of the Hematology Department at the University Hospital of Nantes, France. Prof. Moreau was a member of the Organizing Committee for the 2011 International Myeloma Workshop in Paris. Prof. Moreau is currently a member of the Administration Council of the Intergroupe Francophone du Myélome (IFM), and was the chairman of the IFM from 2006 through 2009. He is a member of the steering committee of the International Myeloma Working Group.

During this lecture, Prof. Philippe Moreau will give an overview on the current development of treatment landscape and IMiD combinations, followed by an in-depth discussion on the optimization of the use of IMiDs for relapsed/refractory multiple myeloma (rrMM) patients, in terms of treatment sequencing and individualization of treatment. Prof. Moreau will also highlight the recent innovations of the 'next-gen IMiDs', i.e. CELMoD agents.

AL Amyloidosis : The silver lining amidst challenges

Prof. Ashutosh Wechalekar
University College London, UK

Systemic immunoglobulin light chain (AL) amyloidosis is a rare form of protein misfolding disorder that originates from plasma cell dyscrasia, or more rarely due to a non-plasma B-cell clone. The non-functioning and unstable immunoglobulin ALs secrete, infiltrate and deposit in peripheral organs including heart, kidney, gastrointestinal tract, liver, and nervous system, resulting in organ dysfunction. Many patients exhibit multiple organ involvement. Among these affected organs, heart involvement is the most crucial as it is the major disease driver for prognosis and mortality.

Key management goals for AL amyloidosis include not only early recognition/diagnosis, but also initiation of optimal treatment for disease control before any organ damage becomes irreversible.

In this presentation, Prof. Wechalekar will share his insights over the challenges associated with a proper diagnosis and dive deep into the latest clinical evidence that help physicians devise the most optimal treatment strategies. The significance of introducing novel therapies, e.g. anti-CD38 antibodies, such as daratumumab, in the treatment of AL amyloidosis as a frontline agent will be explored, also particularly focusing on diseases with cardiac involvement, of which prognosis tends to be dire.

Translating MM clinical trial into real world practice

Prof. Heinz Ludwig
Wilhelminen Cancer Research Institute, Austria

Patients treated in real-world clinical practice (RWCP) are usually older, having more morbidities and sometimes severe symptoms and/or rapidly progressive diseases with the need for immediate treatment initiation that precludes from enrolling them into a required lengthy screening procedure for inclusion in a clinical study.

The pivotal Tourmaline MM-1 phase 3 study randomized patients with relapsed/refractory multiple myeloma (rrMM) after 1-3 prior treatment lines to either ixazomib plus lenalidomide–dexamethasone (Rd) or placebo + Rd. Results showed in a higher rate of ≥ VGPR (48% vs.39%) and longer progression-free survival (PFS) (20.6 vs. 14.7 months) in the ixazomib-Rd (IRd) arm compared with Rd only. Treatment was well-tolerated. Subsequently, Ixazomib became available in named patient programmes stimulating the RWCP studies with IRd. Four of these studies involve 425 rrMM patients and 1-3 prior treatment lines have already been reported. The observed median PFS ranged between 21.6 and 27.6 months with IRd. One study reported overall survival (OS) data as well (median of 36.7 months). These results confirmed the high efficacy and excellent tolerability of IRd in rrMM patients in RWCP.

We are honored to have Prof. Ludwig to share essences of the study and his views on translating MM clinical trial data into real world.

Lecture 5

Novel approach in optimizing efficacy and convenience with carfilzomib in rrMM

Dr. Keith Stewart
Princess Margaret Cancer Centre, Canada

Carfilzomib is a second-generation proteasome inhibitor (PI) with selective, irreversible, robust, and well-tolerated activity in multiple myeloma, in combination with dexamethasone (Kd) or lenalidomide plus dexamethasone (KRd). However, despite the favorable benefit-risk profile of the drug, the dosing schedule (twice-weekly) of carfilzomib often leads to hesitation of clinicians when selecting treatment for patients with relapsed/refractory multiple myeloma (rrMM). Factors such as limited beddings and manpower in public hospitals, as well as patients' reluctance of revisiting the hospital for administration due to workstyle, old age, etc., have inevitably become obstacles for treatment initiation.

Recently, a phase 3 study A.R.R.O.W has demonstrated that treatment of once-weekly (70mg/m2) in rrMM patients was indeed as efficacious and safe as twice-weekly schedule (27mg/m2). These findings further demonstrated a favorable benefit-risk profile of carfilzomib, and noteworthily, supported once-weekly carfilzomib as a potent and more convenient treatment option for rrMM patients. In this presentation, Dr. Stewart will shed light on the latest emerging data of novel dosing schedule of carfilzomib, real-world case sharing, and expert opinions on the criteria of selecting patients for once-weekly or twice-weekly use of carfilzomib.

Novel anti-BCMA therapy for rrMM

Dr. María-Victoria Mateos
University Hospital of Salamanca, Spain

Given the advancements in multiple myeloma (MM) treatments, a substantial proportion of patients still have little or do not have favorable responses to the current therapies. Moreover, some of the treatments are not uniformly tolerated in all patients, driving scientists to seek breakthroughs in developing novel mechanisms of action that offer durable responses and better tolerated treatments for relapsed/refractory multiple myeloma (rrMM).

B-cell maturation antigen (BCMA) is a cell-surface receptor, which is expressed on MM cells, but virtually absent on naïve and memory B cells, making it an ideal therapeutic target for treating MM patients. Belantamab mafodotin is a first-in-class anti-BCMA immunoconjugate with an afucosylated, humanized immunoglobulin G (IgG1) anti-BCMA monoclonal antibody. It binds to BCMA and kills MM cells via a multimodal mechanism, demonstrating its efficacy as a monotherapy for MM treatment in adult patients, who have received at least four prior therapies.

In this lecture, Dr. Mateos will highlight essences of the multimodal mechanism of belantamab mafodotin, and disseminate the related clinical data presented in the pivotal data DREAMM-2. She will also share her invaluable personal experience in adverse event management, along with case study of using belantamab mafodotin in heavily pre-treated MM patients.

Acknowledgment

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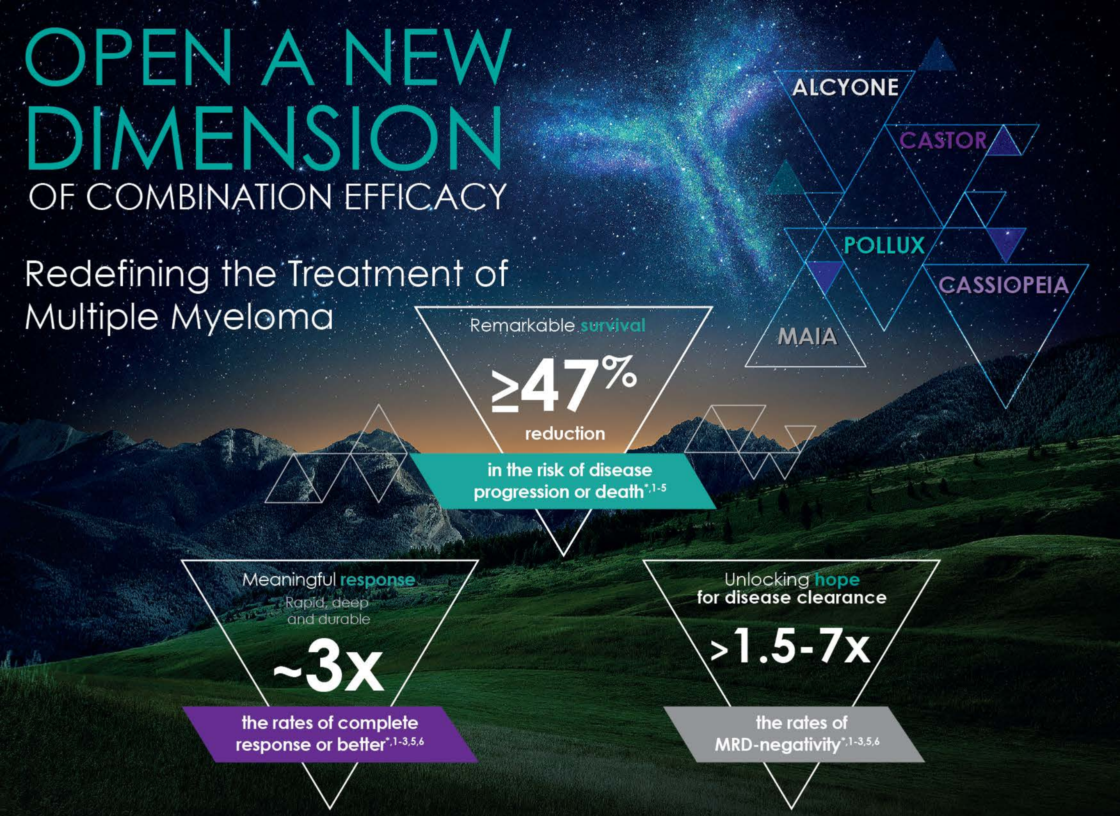

- AE profile consistent with regimen components, without new safety signals identified [7,8]
- Low rates of discontinuation due to AEs, and manageable IRRs [7,8]

DARZALEX™ (daratumumab) in combination with lenalidomide + dexamethasone, or with bortezomib, melphalan and prednisone, is indicated for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.
DARZALEX™ in combination with bortezomib, thalidomide and dexamethasone, is indicated for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant.
DARZALEX™ in combination with lenalidomide + dexamethasone, or bortezomib + dexamethasone, is indicated for the treatment of adult patients with multiple myeloma who have received at least one prior therapy[9].
See **DARZALEX™** prescribing information for full indication, including its use as a monotherapy.

* DARZALEX™ + lenalidomide/dexamethasone vs. + lenalidomide/dexamethasone (for relapse MM); DARZALEX™ + bortezomib/dexamethasone vs. bortezomib/dexamethasone; DARZALEX™ + bortezomib/melphalan/prednisone vs. bortezomib/melphalan/prednisone. DARZALEX™ + lenalidomide/dexamethasone vs. + lenalidomide/dexamethasone (for newly diagnosed MM); DARZALEX™ + bortezomib/thalidomide/dexamethasone vs. bortezomib/thalidomide/dexamethasone.

AE = adverse event. IRR = infusion-related reaction. MM = multiple myeloma. MRD = minimal residual disease.

References:

1. Mateos MV, et al. Poster presented at the 61st annual meeting of the American Society of Hematology (ASH). Orlando, December 7-10 2019. 2. Bahlis NJ, et al. Poster presented at the 61st annual meeting of the American Society of Hematology (ASH). Orlando, December 7-10 2019. 3. Mateos MV, et al. Lancet 2020;11:132-141. 4. Facon T, et al. Lancet Oncol. 2021;S1470-2045(21)00466-6. 5. Moreau P, et al. Lancet 2019;394(10192):29-38. 6. Facon T, et al. N Engl J Med 2019;380:2104-2115. 7. Dimopoulos MA, et al. N Engl J Med 2016;375:1319-1331. 8. Palumbo A, et al. N Engl J Med 2016;375:754-766. 9. DARZALEX™ HK Prescribing Information P06.

Darzalex™ Concentrate for Solution for Infusion 100mg/5mL, 400mg/20mL
ABBREVIATED PRESCRIBING INFORMATION
ACTIVE INGREDIENT(S): daratumumab
INDICATION(S): DARZALEX is indicated: • in combination with lenalidomide and dexamethasone or with bortezomib, melphalan and prednisone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant. • in combination with bortezomib, thalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant. • in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. • as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a proteasome inhibitor and an immunomodulatory agent and who have demonstrated disease progression on the last therapy. DOSAGE & ADMINISTRATION: Intravenous (IV) infusion only following dilution with sodium chloride 9 mg/mL (0.9%) solution for injection. DARZALEX dosing schedule - In combination with lenalidomide (4-week cycle regimen) and for monotherapy: 16 mg/kg body weight given weekly from weeks 1 to weeks 8, then every 2 weeks from weeks 9 to 24 and every 4 weeks from week 25 onwards until disease progression. In combination with bortezomib, melphalan and prednisone (6-week cycle dosing regimen): 16 mg/kg body weight, given weekly from weeks 1 to week 6, and then every 3 weeks for week 7 to 54 and every 4 weeks from week 55 onwards until disease progression. Bortezomib is given twice weekly at Weeks 1, 2, 4 and 5 for the first 6-week cycle, followed by once weekly at Weeks 1, 2, 4 and 5 for eight more 6-week cycles. In combination with bortezomib, thalidomide and dexamethasone (4-week cycle regimens) for treatment of newly diagnosed patients eligible for autologous stem cell transplant (ASCT): 16 mg/kg body weight given weekly for induction from weeks 1 – 8, followed by every 2 weeks from weeks 9 – 16, and stop for high dose chemotherapy and ASCT. For consolidation, every 2 weeks from weeks 1 to 8. In combination with bortezomib (3-week cycle regimen): 16 mg/kg body weight, given once a week for the first 9 weeks. From week 10 to 24, DARZALEX is given every 3 weeks, and then every 4 weeks from week 25 onwards until disease progression. Pre- and post-infusion medicinal products should be administered to reduce the risk of infusion-related reactions. To facilitate administration, the first prescribed 16 mg/kg dose at Week 1 may be split over two consecutive days i.e. 8 mg/kg on Day 1 and Day 2 respectively. CONTRAINDICATIONS: Known hypersensitivity to the active substance or to any of the excipients in the DARZALEX formulation. SPECIAL WARNINGS & PRECAUTIONS: Infusion-related reactions (IRRs): DARZALEX can cause serious infusion related reactions (IRRs), including anaphylactic reactions. Monitor all patients throughout the infusion for IRRs. Monitor post-infusion until symptoms resolve for patients experience any Grade IRRs. Patients should be pre-medicated with antihistamines, antipyretics and corticosteroids to reduce the risk of IRRs prior treatment. Reduce infusion rate when re-starting infusion for patients with Grade 1,2 or 3 IRRs. If anaphylactic reaction or life-threatening (Grade 4) infusion reaction occurs, initiate appropriate emergency resuscitation immediately and discontinue DARZALEX therapy immediately and permanently. Neutropenia/Thrombocytopenia: DARZALEX may increase neutropenia and thrombocytopenia induced by background therapy. Monitor complete blood cell counts periodically during treatment and monitor patients with neutropenia for signs of infection. Interference with indirect antiglobulin test (indirect Coombs test): Daratumumab binds to CD38 found at low levels on red blood cells and may result in a positive indirect Coombs test. Patients should be typed and screened prior to starting daratumumab treatment. In event of a planned transfusion blood transfusion centres should be notified of this interference with indirect antiglobulin tests. Interference with determination of complete response: Daratumumab is a human IgG kappa monoclonal antibody that can be detected on both, the serum protein electrophoresis and immunofixation assays used for clinical monitoring of endogenous M-protein. This interference can impact the determination of complete response and of disease progression in some patients with IgG kappa myeloma protein. Hepatitis B virus (HBV) reactivation: Hepatitis B virus reactivation, in some cases fatal, has been reported in patients treated with DARZALEX. HBV screening should be performed in all patients before initiation of treatment. For patients with evidence of positive HBV serology, monitor signs of HBV reactivation during, and for at least six months following the end of treatment. In patients who develop reactivation of HBV while on DARZALEX, suspend treatment with DARZALEX and institute appropriate treatment. Excipients: Each 5 mL and 20 mL vial of DARZALEX contains 0.4 mmol and 1.6 mmol (9.3 mg and 37.3 mg) sodium, respectively. This corresponds to 0.46% and 1.86% of the WHO recommended maximum daily intake of 2 g sodium for an adult, respectively. SIDE EFFECTS: Most frequent adverse reactions: IRR, fatigue, nausea, diarrhoea, constipation, pyrexia, dyspnoea, cough, neutropenia, thrombocytopenia, anaemia, oedema peripheral, asthenia, peripheral sensory neuropathy and upper respiratory tract infection. Serious adverse reactions: sepsis, pneumonia, bronchitis, upper respiratory tract infection, pulmonary oedema, influenza, pyrexia, dehydration, diarrhoea and atrial fibrillation. Refer to the full prescribing information for other side effects. PREGNANCY & LACTATION: Women of child-bearing potential should use effective contraception during, and for 3 months after cessation of daratumumab treatment. Daratumumab should not be used during pregnancy unless the benefit of treatment to the woman is considered to outweigh the potential risks to the fetus. The effect of daratumumab on newborns/infants is unknown. A decision should be made whether to discontinue breast-feeding or to discontinue DARZALEX therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman. INTERACTIONS: Due to the high affinity to a unique epitope on CD38, daratumumab is not anticipated to alter drug-metabolising enzymes. Interference with indirect antiglobulin test (indirect Coombs test): Daratumumab interference mitigation methods include treating reagent RBCs with dithiothreitol to disrupt daratumumab binding or other locally validated methods or consider phenotyping/genotyping. Interference with serum protein electrophoresis and immunofixation tests: consider using validated daratumumab-specific IFE assay to distinguish daratumumab from any remaining endogenous M protein in the patient's serum for suspected daratumumab interference.
PLEASE REFER TO FULL PRESCRIBING INFORMATION BEFORE PRESCRIBING.
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For appropriate patients faced with relapsed/refractory multiple myeloma

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Target BCMA for RRMM

BLENREP is the first and only BCMA-targeted antibody-drug conjugate (ADC) monotherapy.[1] So you can offer your RRMM patients a clear option.

INDICATION

BLENREP is indicated as monotherapy for the treatment of multiple myeloma in adult patients, who have received at least four prior therapies and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy.

Important Safety Information for Blenrep (Belantamab mafodotin)

- The most commonly reported adverse reactions were keratopathy including microcyst-like epithelial changes in corneal epithelium with or without changes in visual acuity, blurred vision, and dry eye.
- Patients should be advised to use caution when driving or operating machinery as Blenrep may affect their vision.
- Patients should have an ophthalmic examination performed by an eye care professional at baseline, before the subsequent 3 treatment cycles, and as clinically indicated whilst on Blenrep treatment
- Physicians should advise patients to administer preservative-free artificial tears at least 4 times a day beginning on the first day of infusion and continuing until completion of treatment

BLENREP
belantamab
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Abbreviated Prescribing Information

NAME OF THE MEDICINAL PRODUCT Blenrep **QUALITATIVE AND QUANTITIVATIVE COMPOSITION** One vial of powder contains 100 mg of belantamab mafodotin. After reconstitution, the solution contains 50mg belantamab mafodotin per mL. **INDICATIONS** Blenrep is indicated as monotherapy for the treatment of multiple myeloma in adult patients, who have received at least four prior therapies and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy. **POSOLOGY AND METHOD OF ADMINISTRATION** The recommended dose is 2.5 mg/kg of Blenrep administered as an intravenous infusion once every 3 weeks. It is recommended that treatment should be continued until disease progression or unacceptable toxicity. Method of Administration Blenrep must be reconstituted and diluted by a healthcare professional prior to administration as an intravenous infusion. Blenrep should be infused over a minimum of 30 minutes. Recommended Supportive Care Patients should have an ophthalmic examination (including visual acuity and slit lamp examination) performed by an eye care professional at baseline, before the subsequent 3 treatment cycles, and as clinically indicated whilst on treatment. Physicians should advise patients to administer preservative-free artificial tears at least 4 times a day beginning on the first day of infusion and continuing until completion of treatment as this may reduce corneal symptoms.

Dose Modifications

Dose modifications for corneal adverse reactions

Severity	Eye examination findings	Recommended dose modifications
Mild	*Corneal examination finding(s)* Mild superficial keratopathy *Change in BCVA* Decline from baseline of 1 line on Snellen Visual Acuity	Continue treatment at current dose.
Moderate	*Corneal examination finding(s)* Moderate superficial keratopathy *Change in BCVA* Decline from baseline of 2 or 3 lines (and Snellen Visual Acuity not worse than 20/200)	Withhold treatment until improvement in examination findings and BCVA to mild severity or better. Consider resuming treatment at a reduced dose of 1.9 mg/kg.
Severe	*Corneal examination finding(s)* Severe superficial keratopathy Corneal epithelial defect *Change in BCVA* Decline from baseline of more than 3 lines	Withhold until improvement in examination findings and BCVA to mild severity or better. For worsening symptoms that are unresponsive to appropriate management, consider discontinuation.

Dose modifications for other adverse reactions

Adverse reaction	Severity	Recommended dose modifications
Thrombocytopenia	Grade 2-3: Platelet count 25,000 to less than 75,000/microlitres	Consider withholding Blenrep and/or reducing the dose of Blenrep to 1.9 mg/kg.
	Grade 4: Platelet count less than 25,000/microlitres	Withhold Blenrep until platelet count improves to Grade 3 or better. Consider resuming at a reduced dose of 1.9 mg/kg.
Infusion-related reactions	Grade 2 (moderate)	Interrupt infusion and provide supportive treatment. Once symptoms resolve, resume at lower infusion rate by at least 50%.
Other Adverse Reactions	Grade 3 or 4 (severe)	Interrupt infusion and provide supportive treatment. Once symptoms resolve, resume at lower infusion rate reduced by at least 50%. If anaphylactic or life-threatening infusion reaction, permanently discontinue the infusion and institute appropriate emergency care.
	Grade 3	Withhold Blenrep until improvement to Grade 1 or better. Consider resuming at a reduced dose.
	Grade 4	Consider permanent discontinuation of Blenrep. If continuing treatment, withhold until improvement to Grade 1 or better and resume at reduced dose.

WARNINGS AND PRECAUTIONS Corneal adverse reactions Corneal adverse reactions have been reported with the use of Blenrep. The most commonly reported adverse reactions were keratopathy or microcyst-like epithelial changes in corneal epithelium with or without changes in visual acuity, blurred vision, and dry eye symptoms. Patients with a history of dry eyes were more prone to develop changes in the corneal epithelium. Changes in visual acuity may be associated with difficulty in driving or operating machinery. Ophthalmic examinations, including assessment of visual acuity and slit lamp examination, should be performed at baseline, before the subsequent 3 treatment cycles and during treatment as clinically indicated. Patients should be advised to administer apreservative-free artificial tears at least 4 times a day during treatment. Patients should avoid using contact lenses until the end of treatment. Patients experiencing keratopathy with or without changes in visual acuity may require a dose modification or treatment discontinuation based on severity of findings. Cases of corneal ulcer have been reported. These should be managed promptly and as clinically indicated by an eye care professional. Treatmen twith Blenrep should be interrupted until the corneal ulcer has healed. Thrombocytopenia Thrombocytopenic events were frequently reported. Thrombocytopenia may lead to serious bleeding events, including gastrointestinal and intracranial bleeding. Complete blood counts should be obtained at baseline and monitored during treatment, as clinically indicated. Patients experiencing Grade 3 or 4 thrombocytopenia or those on concomitant anticoagulant treatments may require more frequent monitoring and should be managed with a dose delay or dose reduction. Supportive therapy should be provided according to standard medical practice. Infusion-Related Reactions Most IRRs were Grade 1-2 and resolved within the same day. If a grade 2 or higher infusion- related reaction occurs during administration, reduce the infusion rate or stop the infusion depending on the severity of the symptoms. Institute appropriate medical treatment and restart infusion at a slower rate, if the patient's condition is stable. If Grade 2 or higher IRR occurs, administer premedication for subsequent infusions. **INTERACTIONS** No formal drug interaction studies have been performed with Blenrep. **FERTILITY, PREGNANCY AND LACTATION** The pregnancy status of child-bearing women should be verified prior to initiating therapy with Blenrep. Women of child-bearing potential should use effective contraception during treatment with Blenrep and for 4 months after the last dose. Men with female partners of child-bearing potential should use effective contraception during treatment with Blenrep and for 6 months after the last dose. Pregnancy There are no data from the use of Blenrep in pregnant women. Blenrep should not be used during pregnancy unless the benefit to the mother outweighs the potential risks to the foetus. If a pregnant woman needs to be treated she should be clearly advised on the potential risk to the foetus. Breast-feeding It is not known whether Blenrep is excreted into human milk. Women should be advised to discontinue breast-feeding prior to initiating treatment with Blenrep and for 3 months after the last dose. Fertility Based on findings in animals and the mechanism of action, Blenrep may impair fertility in females and males of reproductive potential. **ADVERSE REACTIONS** The frequency of adverse reactions is defined using the following convention: very common (≥1/10), common (≥1/100 to <1/10) and uncommon (≥ 1/1000 to <1/100). Infections & infestations: Very common: Pneumonia; Common: Upper respiratory tract infection Blood and lymphatic system disorders: Very common: Thrombocytopenia, anaemia, lymphopenia, leukopenia, neutropenia Eye disorders: Very common: Keratopathy, blurred vision events, dry eye events; Common: Photophobia, eye irritation; Uncommon: ulcerative keratitis, infective keratitis Gastrointestinal disorders: Very common: Nausea, diarrhea; Common: Vomiting General disorders and administration site conditions: Very common: Pyrexia, fatigue Investigations: Very common: Increased aspartate aminotransferase, increased gamma glutamyltransferase; Common: Increased creatine phosphokinase Injury, poisoning and procedural complications: Very common: Infusion-related reactions **OVERDOSE** There is no known specific antidote for Blenrep overdose. In the event of an overdose, the patient should be monitored for any signs or symptoms of adverse effects and appropriate supportive treatment should be instituted immediately.

Abbreviated Prescribing Information based on Blenrep Prescribing Information (HK082021(GDS02/EMA20210729)).

Please read the full prescribing information prior to administration. Full prescribing information is available on request from GlaxoSmithKline Ltd, 23/F, Tower 6, The Gateway, 9 Canton Road, Tsimshatsui, Kowloon, Hong Kong or Level 20, AIA Tower, Nos 251A - 301 Avenida Comercial De Macau, Macau

For adverse events reporting, please call GlaxoSmithKline Limited at (852) 3189 8989 (Hong Kong) or (853) 2871 5569 (Macau) or email to HK Adverse Event mailbox: HKAdverseEvent@gsk.com

Reference: 1. BLENREP (belantamab mafodotin) Summary oaf Product Characteristics.

The material is for the reference and use by healthcare professionals only. For adverse event reporting, please call GlaxoSmithKline Limited at (852) 3189 8989 (Hong Kong). Full Prescribing Information is available upon request. Please read the full prescribing information prior to administration, available from GlaxoSmithKline Limited. Trade marks are owned by or licensed to the GSK group of companies.

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