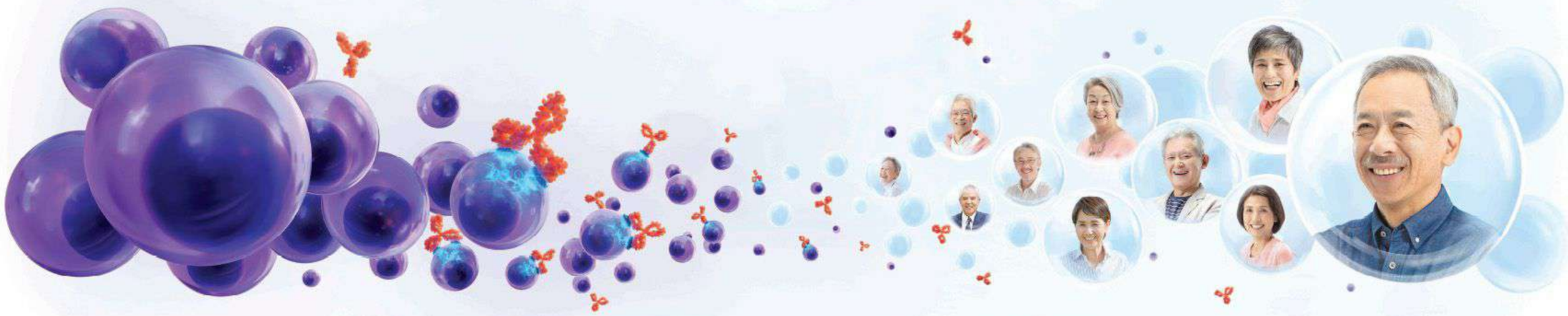
IN THE TREATMENT OF **RELAPSED REFRACTORY MULTIPLE MYELOMA**

SARCLISA® (isatuximab)

ACHIEVE **GREATER OUTCOMES** FOR **YOUR PATIENTS**



IKEMA[2,4]: SARCLISA + Kd vs Kd (N=302)

mPFS 35.7 mo*
vs 19.2 mo with Kd alone

HR=0.58
(95.4% CI: 0.42-0.79)

Superior PFS[1]

ICARIA[3]: SARCLISA + Pd vs Pd (N=307)

mPFS 11.53 mo
vs 6.47 mo with Pd alone

HR=0.596
(95% CI: 0.44-0.81; *P*=0.001)

IKEMA trial: SARCLISA + Kd[1,2]

IKEMA (EFC15246) was a multicentre, multinational, randomised, open-label, 2-arm, phase 3 study that evaluated the efficacy and safety of SARCLISA in 302 patients with relapsed and/or refractory multiple myeloma who had received 1 to 3 prior lines of therapy. Patients received either SARCLISA 10 mg/kg administered as an IV infusion in combination with Kd (n=179) or Kd alone (n=123), administered in 28-day cycles until disease progression or unacceptable toxicity. PFS was the primary endpoint; secondary endpoints included ORR, CR, ≥VGPR, MRD-, and OS. Median follow-up for the first interim analysis was 20.7 months.

ICARIA trial: SARCLISA + Pd[1,3]

ICARIA (EFC14335) was a multicentre, multinational, randomised, open-label, 2-arm, phase 3 study that evaluated the efficacy and safety of SARCLISA in 307 patients with relapsed and refractory multiple myeloma who had received at least 2 prior lines of therapy, including lenalidomide and a PI. Patients received either SARCLISA 10 mg/kg administered as an IV infusion in combination with Pd (n=154) or Pd alone (n=153), administered in 28-day cycles until disease progression or unacceptable toxicity. PFS was the primary endpoint; ORR was one of the secondary endpoints. Median follow-up for the first interim analysis was 11.6 months.

Most common adverse reactions[1,2,4]

- In ICARIA, the most frequent adverse reactions (≥20%) were neutropenia (47%), infusion reactions (38%), pneumonia (31%), upper respiratory tract infection (28%), diarrhoea (26%), and bronchitis (24%)
- In IKEMA, the most frequent adverse reactions (≥20%) were infusion reactions (46%), hypertension (37%), diarrhoea (36%), upper respiratory tract infection (36%), pneumonia (29%), fatigue (28%), dyspnoea (28%), insomnia (24%), bronchitis (23%), and back pain (22%).

SARCLISA is indicated:

- In combination with pomalidomide and dexamethasone, for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on the last therapy
- In combination with carfilzomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior therapy

*Assessment by masked independent response committee (IRC)

References: 1. Sarclisa Hong Kong prescribing information based on EU SmPC 29 July 2021. 2. Moreau P, et al. Lancet 2021; 397: 2361–71. 3. Attal M, et al. Lancet. 2019;394(10214):2096-2107. 4. Moreau P, et al. Presented at ESMO Virtual Plenaries, 2022 and 8th COMy World Congress. 20th May, 2022.

Presentation: SARCLISA 20 mg/mL concentrate for solution for infusion. One ml of concentrate for solution for infusion contains 20 mg of isatuximab. Each vial contains 100 mg of isatuximab in 5 mL of concentrate (100 mg/5mL). Each vial contains 500 mg of isatuximab in 25 mL of concentrate (500 mg/25mL). Indications: I. In combination with pomalidomide and dexamethasone, for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on the last therapy. II. In combination with carfilzomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. Dosage & Administration: Intravenous infusion. Each treatment cycle consists of a 28-day period. Treatment is repeated until disease progression or unacceptable toxicity.

Cycles	Dosing schedule
Cycle 1	Days 1, 8, 15, and 22 (weekly)
Cycle 2 and beyond	Days 1, 15 (every 2 weeks)

Premedication should be used prior to SARCLISA infusion with the following medicinal products: I. a. Dexamethasone 40 mg oral or intravenous (or 20 mg oral or intravenous for patients≧75 years of age): when administered in combination with isatuximab and pomalidomide. b. Dexamethasone 20 mg (intravenous on the days of isatuximab and/or Carfilzomib infusions, and oral on the other days): when administered in combination with isatuximab and carfilzomib. II. Acetaminophen 650 mg to 1000 mg oral (or equivalent). III. Diphenhydramine 25 mg to 50 mg intravenous or oral (or equivalent [e.g., cetirizine, promethazine, dexchlorpheniramine]). The intravenous route is preferred for at least the first 4 infusions. The above recommended dose of dexamethasone corresponds to the total dose to be administered only once before the infusion. The recommended premedication agents should be administered 15-60 minutes prior to starting a SARCLISA infusion. Contraindications: Hypersensitivity to the active substance or to any of its excipients. Precautions: Vital signs should be frequently monitored during the entire SARCLISA infusion. When required, interrupt SARCLISA infusion and provide appropriate medical and supportive measures. In case symptoms do not improve to grade≦1 after interruption of SARCLISA infusion, persist or worsen despite appropriate medicinal products, require hospitalization or are life-threatening, permanently discontinue SARCLISA and institute appropriate management. Complete blood cell counts should be monitored periodically during treatment. Patients with neutropenia should be monitored for signs of infection. No dose reductions of SARCLISA are recommended. SARCLISA dose delays and the use of colony-stimulating factors (e.g. G-CSF) should be considered to mitigate the risk of neutropenia. Patients receiving SARCLISA should be closely monitored for signs of infection and appropriate standard therapy instituted. Antibiotics and antiviral prophylaxis can be considered during treatment. Physicians should carefully evaluate patients before and during treatment as per IMWG guidelines for occurrence of SPM and initiate treatment as indicated. To avoid potential problems with RBC transfusion, patients being treated with SARCLISA should have blood type and screen tests performed prior to the first infusion. Phenotyping may be considered prior to starting SARCLISA treatment as per local practice. If treatment with SARCLISA has already started, the blood bank should be informed. Patients should be monitored for theoretical risk of haemolysis. If an emergency transfusion is required, non-cross-matched ABO/Rh-compatible RBCs can be given as per local blood bank practices. Drug Interactions: Isatuximab has no impact on the pharmacokinetics of pomalidomide or carfilzomib, or vice versa. Pregnancy and lactation: There are no available data on isatuximab use in pregnant women. Animal reproduction toxicity studies have not been conducted with isatuximab. Immunoglobulin G1 monoclonal antibodies are known to cross the placenta after the first trimester of pregnancy. The use of isatuximab in pregnant women is not recommended. It is unknown whether isatuximab is excreted in human milk. Human IgGs are known to be excreted in breast milk during the first few days after birth, which is decreasing to low concentrations soon afterwards; however, a risk to the breast-fed child cannot be excluded during this short period just after birth. For this specific period, a decision must be made whether to discontinue breast-feeding or to discontinue/abstain from isatuximab therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman. Afterwards, isatuximab could be used during breast-feeding if clinically needed. Undesirable effects: isatuximab in combination with pomalidomide and dexamethasone: Most common adverse reactions reported- pneumonia, upper respiratory tract infection, bronchitis, neutropenia, febrile neutropenia, dyspnoea, diarrhoea, nausea, vomiting, infusion reaction. isatuximab in combination with carfilzomib and dexamethasone: Most common adverse reaction reported- pneumonia, upper respiratory tract infection, bronchitis, hypertension, dyspnoea, cough, diarrhoea, vomiting, fatigue, infusion reaction. For other undesirable effects, please refer to the full prescribing information. Preparation: The preparation of the infusion solution must be done under aseptic conditions. Legal Classification: Part 1, First & Third Schedules Poison Full prescribing information is available upon request.

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