SARCLISA Regimens Have **Proven Results in Lenalidomide-Refractory Myeloma**[1,2]

SARCLISA has been studied in 2 phase 3 trials that included lenalidomide-refractory patients[1,2]

Key lenalidomide-free regimens approved and guideline recommended for early use[1-8]	Median prior LoT	Refractory to lenalidomide
SARCLISA trials		
ICARIA-MM: *IsaPd vs Pd*	**3**	**93%**
IKEMA: *IsaKd vs Kd*	**2**	**33%**
Trials with other regimens		
APOLLO: *DPd vs Pd*	2	80%
CANDOR: *DKd vs Kd*	2	33%
CASTOR: *DVd vs Vd*	2	28%
OPTIMISMM: *PVd vs Vd*	2	70%
ENDEAVOR: *Kd vs Vd*	2	25%

Although use of lenalidomide in 1L therapy is increasingly common based on guideline recommendations, other key RRMM trials excluded lenalidomide-refractory patients, including POLLUX (DRd vs Rd; median prior LoT: 1), ELOQUENT-2 (ERd vs Rd; median prior LoT: 2), ASPIRE (KRd vs Rd; median prior LoT: 2), and TOURMALINE (IRd vs Rd; median prior LoT: 2).[9-13]

Guidelines recommend **anti-CD38 mAbs in combination with Kd or Pd** for patients with lenalidomide-refractory multiple myeloma at first relapse[8,9,14]

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

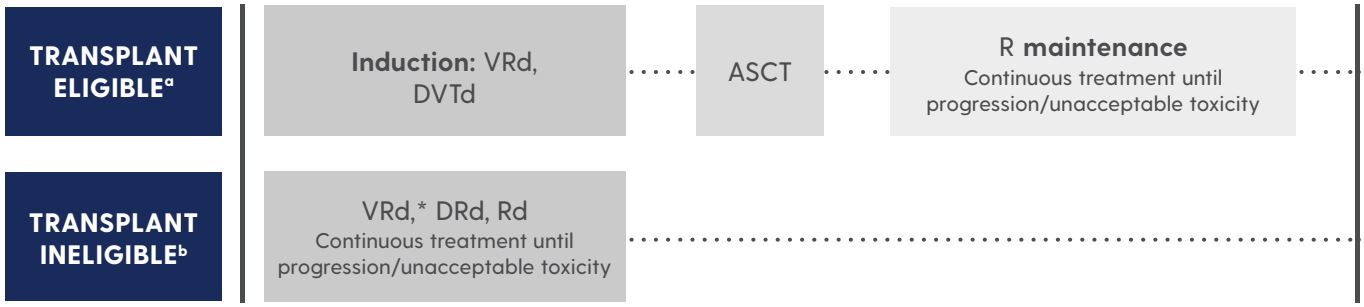
1L=first line; DKd=daratumumab, carfilzomib, dexamethasone; DPd=daratumumab, pomalidomide, dexamethasone; DRd=lenalidomide, dexamethasone, daratumumab; DVd=daratumumab, bortezomib, dexamethasone; ERd=elotuzumab, lenalidomide, dexamethasone; IRd=ixazomib, lenalidomide, dexamethasone; IsaKd=isatuximab, carfilzomib, dexamethasone; IsaPd=isatuximab, pomalidomide, dexamethasone; Kd=carfilzomib and dexamethasone; KRd=carfilzomib, lenalidomide, dexamethasone; LoT=line of therapy; mAb=monoclonal antibody; Pd=pomalidomide and dexamethasone; PVd=pomalidomide, bortezomib, dexamethasone; Rd=lenalidomide and dexamethasone; RRMM=relapsed and/or refractory multiple myeloma; Vd=bortezomib and dexamethasone.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

▼ SARCLISA® (isatuximab)

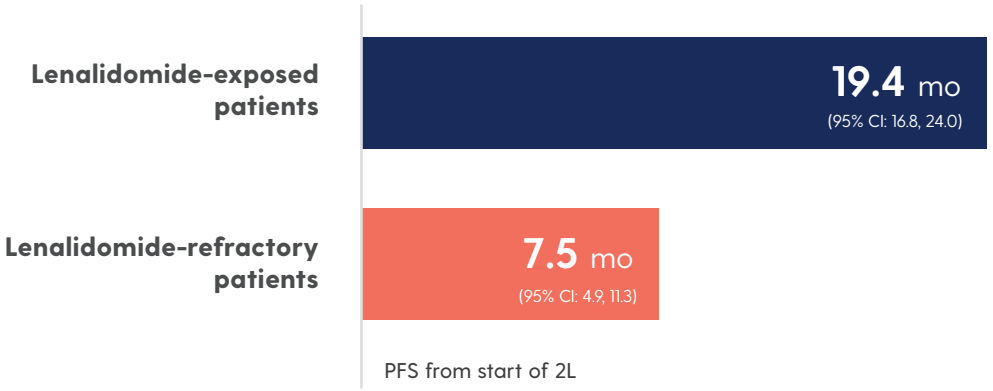
In MM, **Lenalidomide-Refractory Disease Has Been Associated With Poor Outcomes** and May Limit Treatment Options[15,16]

Frontline treatment with lenalidomide-based regimens until progression is recommended in clinical guidelines and is increasingly common[9]



*V dropped after cycle 8.[17]

Shorter PFS for lenalidomide-refractory[†] patients at first relapse[15]



With increasing use of lenalidomide in frontline, **lenalidomide-free regimens are needed** that can improve outcomes in patients with lenalidomide-refractory myeloma **as early as first relapse**[15,16]

[†]Per IMWG criteria, refractoriness is defined as no response to therapy or disease progression within <60 days of the last dose.[8]
[a]Regimens not containing lenalidomide also recommended for induction include: DVTd, VCd, VTd.[9]
[b]Regimens not containing lenalidomide also recommended include: DVMP, VMP.[9]

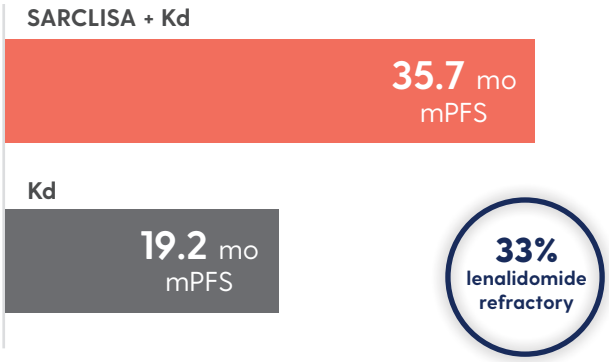
2L=second line; ASCT=autologous stem cell transplant; DVMP=daratumumab, bortezomib, melphalan, prednisone; DVTd=daratumumab, bortezomib, thalidomide, dexamethasone; IMWG=International Myeloma Working Group; MM=multiple myeloma; PFS=progression-free survival; R=lenalidomide; Rd=lenalidomide and dexamethasone; V=bortezomib; VCd=bortezomib, cyclophosphamide, dexamethasone; VMP=bortezomib, melphalan, prednisone; VRd=bortezomib, lenalidomide, dexamethasone; VTd=bortezomib, thalidomide, dexamethasone.

SARCLISA® (isatuximab)

SARCLISA Demonstrated Superior PFS
When Added to Kd or Pd[18]

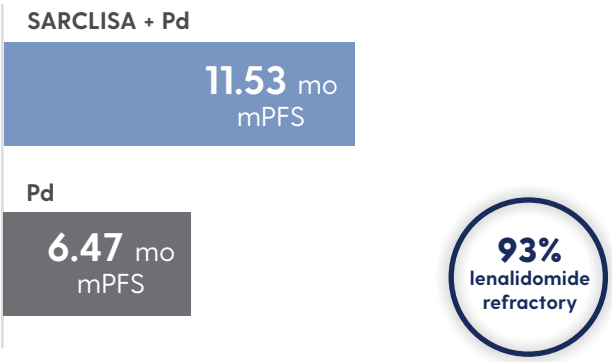
IKEMA: Unprecedented mPFS of 3 years with SARCLISA + Kd

in a pivotal trial that includes lenalidomide-refractory patients[2,4,18-38]



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

ICARIA-MM: The addition of SARCLISA to Pd extended mPFS to nearly 1 year[1,18]



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

- Results for SARCLISA + Kd are from an updated analysis done at a median follow-up of 44 months[2]
- At an interim analysis of 21 months, mPFS with SARCLISA + Kd was NR vs 19.15 months with Kd (HR=0.531 [99% CI: 0.318, 0.889; *P*=0.0013])[18]

SARCLISA improved PFS in lenalidomide-refractory patients, consistent with ITT results[2,18,39]*

Relative Risk Reduction†

SARCLISA + Kd (n=57) vs Kd (n=42)

ITT HR: 0.58

41%

HR=0.59 (95% CI: 0.35, 0.97)
Median follow-up: 44 months

SARCLISA + Pd (n=144) vs Pd (n=140)

ITT HR: 0.596

41%

HR=0.59 (95% CI: 0.43, 0.82)
Median follow-up: 11.6 months

With lenalidomide increasingly prescribed in first-line treatment and commonly given until progression, **SARCLISA is an effective and guideline-recommended, lenalidomide-free option in RRMM**[9,15,16]

*Results are from prespecified subgroup analyses.
†Reduction in risk of death or progression.

ITT=intent to treat; mPFS=median progression-free survival; NR=not reached.

SARCLISA® (isatuximab)

Safety Experience for IKEMA and ICARIA-MM

Discontinuation rates

- In IKEMA, discontinuation rates due to adverse reactions were 12.4% with SARCLISA + Kd vs 18.0% with Kd[2]
- In ICARIA-MM, discontinuation rates due to adverse reactions were 7.2% with SARCLISA + Pd vs 12.8% with Pd[1]

Most common adverse reactions

- 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%)[18]
- In ICARIA-MM, the most common adverse reactions (≥20%) were neutropenia (47%), infusion reactions (38%), pneumonia (31%), upper respiratory tract infection (28%), diarrhoea (26%), and bronchitis (24%)[18]

Haematology laboratory abnormalities

- In IKEMA, Grade 3 or Grade 4 anaemia, neutropenia, and thrombocytopenia occurred in 24%, 20%, and 30% of patients treated with SARCLISA + Kd, respectively[40]
- In ICARIA-MM, Grade 3 or Grade 4 anaemia, neutropenia, and thrombocytopenia occurred in 32%, 85%, and 31% of patients treated with SARCLISA + Pd, respectively[1]

Study designs

IKEMA: a randomised, open-label, phase 3 study evaluating the efficacy and safety of SARCLISA + Kd vs Kd in 302 patients with relapsed and/or refractory multiple myeloma who had received 1 to 3 prior lines of therapy. PFS was the primary endpoint; secondary endpoints included ORR, ≥VGPR, CR, MRD-, and OS.[18,41]

ICARIA-MM: a randomised, open-label, phase 3 study evaluating the efficacy and safety of SARCLISA + Pd vs Pd in 307 patients with relapsed and refractory multiple myeloma who had received at least 2 prior lines of therapy, including lenalidomide and a proteasome inhibitor. PFS was the primary endpoint; secondary endpoints included ORR and OS.[1,18]

Please see the Abbreviated Prescribing Information on the following pages.

CR=complete response; MRD-=minimal residual disease negative/negativity; ORR=overall response rate; OS=overall survival; VGPR=very good partial response.

SARCLISA® (isatuximab)

SARCLISA® (isatuximab) – Abbreviated Prescribing Information

Name and Presentation: SARCLISA 20 mg/mL concentrate for solution for infusion. Each vial contains 100 mg of isatuximab in 5 mL of concentrate (100 mg/5 mL) or 500 mg of isatuximab in 25 mL of concentrate (500 mg/25 mL). Isatuximab is an immunoglobulin G1 (IgG1) monoclonal antibody (mAb).

Therapeutic indications: In combination with pomalidomide and dexamethasone, for the treatment of adult patients with relapsed and refractory multiple myeloma (MM) who have received at least two prior therapies including lenalidomide and a proteasome inhibitor (PI) 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.

Dosage and administration: SARCLISA should be administered by a healthcare professional, in an environment where resuscitation facilities are available. Premedication should be used 15-60 minutes prior to SARCLISA infusion with the following medicinal products to reduce the risk and severity of infusion reactions: Dexamethasone 40 mg (when administered in combination with isatuximab and pomalidomide) or 20 mg (when administered in combination with isatuximab and carfilzomib) oral or intravenous, 20 mg for patients ≥75 years of age, Acetaminophen, Diphenhydramine. The recommended dose of SARCLISA is 10 mg/kg body weight administered as an intravenous infusion in combination with pomalidomide and dexamethasone or in combination with carfilzomib and dexamethasone (isatuximab regimen). Dosing schedule: cycle 1: days 1, 8, 15 and 22 (weekly), cycle 2 and beyond: days 1, 15 (every 2 weeks). Each treatment cycle consists of a 28-day period.

Method of administration: SARCLISA is for intravenous use. For details on preparation and infusion rate see full SmPC.

Contraindications: Hypersensitivity to the active substance or to any of the excipients. See full SmPC for full list of excipients.

Warnings and precautions: Infusion reactions, mostly mild or moderate, were observed in 38.2% of patients treated with SARCLISA in ICARIA, and in 45.8% in IKEMA but resolved on the same day in 98% of infusions. Vital signs should be frequently monitored during the entire infusion and when required infusion should be interrupted or permanently discontinued in case symptoms that do not improve to grade ≤1 after infusion interruption. Serious infusion reactions including severe anaphylactic reactions have also been observed after SARCLISA administration. Most of the grade 3-4 neutropenia have been reported as laboratory abnormalities. Neutropenic complications have been observed in 1/3 of patients treated with SARCLISA. A higher incidence of infections including grade ≥3 infections occurred with SARCLISA. Antibacterial and antiviral prophylaxis (such as herpes zoster prophylaxis) can be considered during treatment. Patients receiving SARCLISA should be closely monitored for signs of infection. Physicians should carefully evaluate patients before and during treatment as per International Myeloma Working Group (IMWG) guidelines for occurrence of second primary malignancies (SPM) and treatment should be initiated as indicated. Patients should be monitored closely and appropriate precautions taken for tumor lysis syndrome. Isatuximab binds to CD38 on red blood cells (RBCs) and may result in a false positive indirect antiglobulin test (indirect Coombs test). There is currently no available information with regards to how long the interference may persist. Based on the half-life of isatuximab, it may persist for approximately 6 months after the last infusion of SARCLISA. Patient should have blood type and screen tests performed prior to the first infusion of Isatuximab and should be monitored for theoretical risk of haemolysis. For details in tests interference see full SmPC.

Drug interactions: Isatuximab has no impact on the pharmacokinetics of pomalidomide and vice versa. Isatuximab may interfere with serological testing and with Serum Protein Electrophoresis and Immunofixation assays. In patients with persistent very good partial response, where isatuximab interference is suspected, consider using a validated isatuximab-specific IFE assay to distinguish isatuximab from any remaining endogenous M-protein in the patient's serum, to facilitate determination of complete response.

Fertility, pregnancy and lactation: Women of childbearing potential treated with isatuximab should use effective contraception during treatment and for 5 months after cessation of treatment. The use of isatuximab in pregnant women is not recommended since there are no available data.

SARCLISA® (isatuximab)

SARCLISA® (isatuximab) – Abbreviated Prescribing Information (cont'd)

Undesirable effects: Observed in ICARIA: *Infections/infestations:* very common: pneumonia, upper respiratory tract infection, bronchitis: common: Herpes zoster. *Neoplasms benign, malignant and unspecified:* common: skin cancer, solid tumour (non-skin cancer): uncommon: haematology malignancy. Blood/lymphatic system disorders: very common: neutropenia, febrile neutropenia. *Metabolism and nutrition disorders:* common: decreased appetite. *Cardiac disorders:* common: atrial fibrillation. *Respiratory, thoracic and mediastinal disorders:* very common: dyspnoea. *Gastrointestinal disorders:* very common: diarrhoea, nausea, vomiting. *Investigations:* common: weight decreased. *Injury, poisoning and procedural complications:* very common: infusion reaction. *Immune system disorders:* uncommon: anaphylactic reaction. Observed in IKEMA: *Infections/infestations:* very common: pneumonia, upper respiratory tract infection, bronchitis: common: Herpes Zoster. *Vascular disorder:* very common: hypertension. *Neoplasms benign, malignant and unspecified:* common: Skin cancers and solid tumors other than skin cancers. *Blood/lymphatic system disorders:* common: neutropenia. *Respiratory, thoracic and mediastinal disorders:* very common: dyspnoea and cough. *Gastrointestinal disorders:* very common: diarrhoea and vomiting. *General disorders and administration site conditions:* very common: Fatigue. *Injury, poisoning and procedural complications:* very common: infusion reaction. *Immune system disorders:* uncommon: anaphylactic reaction.

Pharmacotherapeutic group: Antineoplastic agents, monoclonal antibodies, ATC code: L01FC02.

List of excipients: Sucrose, Histidine hydrochloride monohydrate, Histidine, Polysorbate 80 and Water for injections.

Legal classification: Prescription Only Medicine.

Marketing authorization holder: Sanofi Winthrop Industrie, 82, avenue Raspail, 94250 Gentilly, France.

Date of last revised: April 2023.

Abbreviated Prescribing Information based on the EU SmPC as of March 2023.

Before prescribing always refer to your full local prescribing information as this information may vary from country to country

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