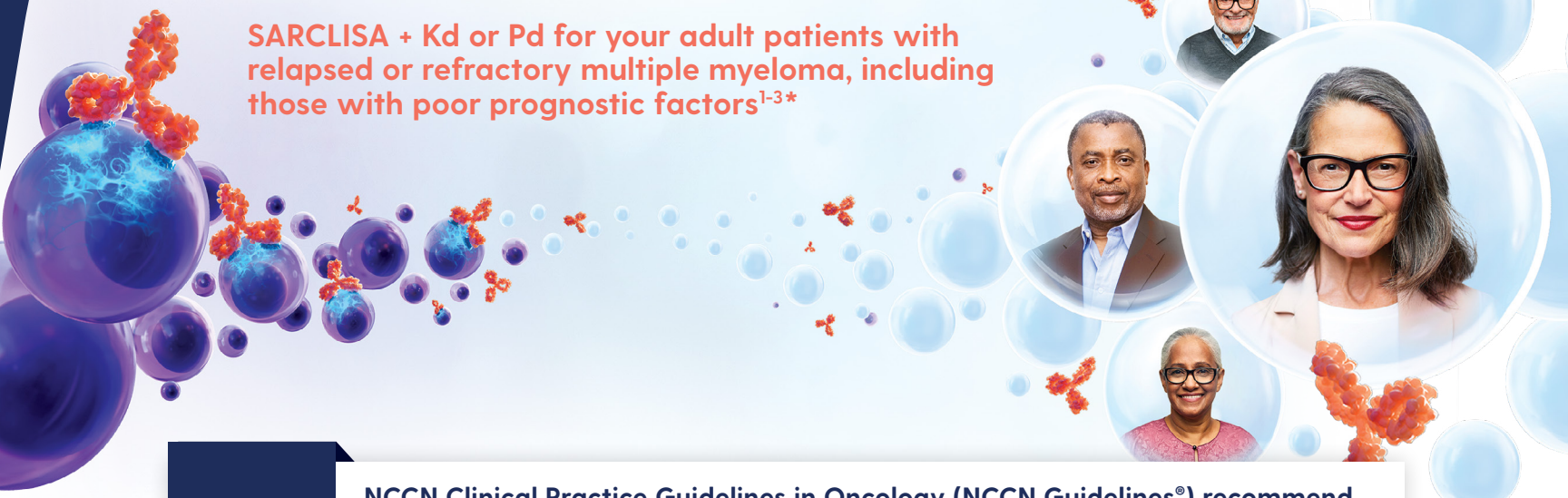
TREATING WITH SARCLISA + Kd OR Pd
AS EARLY AS FIRST RELAPSE

SARCLISA + Kd or Pd for your adult patients with relapsed or refractory multiple myeloma, including those with poor prognostic factors[1-3]*



NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) recommend isatuximab-irfc (SARCLISA) for previously treated multiple myeloma[4]

- In combination with pomalidomide and dexamethasone (**Preferred, Category 1**)
- In combination with carfilzomib and dexamethasone

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*Poor prognostic factors may include renal insufficiency, older age, high cytogenetic risk, and refractoriness to prior therapies.[5,6]
Kd=carfilzomib and dexamethasone; NCCN=National Comprehensive Cancer Network; Pd=pomalidomide and dexamethasone.

Indication

SARCLISA (isatuximab-irfc) is indicated:

- In combination with pomalidomide and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least 2 prior therapies including lenalidomide and a proteasome inhibitor
- In combination with carfilzomib and dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received 1 to 3 prior lines of therapy

Important Safety Information

CONTRAINDICATIONS

SARCLISA is contraindicated in patients with severe hypersensitivity to isatuximab-irfc or to any of its excipients.

WARNINGS AND PRECAUTIONS

Infusion-Related Reactions

Serious infusion-related reactions (IRRs), including life-threatening anaphylactic reactions, have occurred with SARCLISA treatment. Severe signs and symptoms include cardiac arrest, hypertension, hypotension, bronchospasm, dyspnea, angioedema, and swelling.

Please see Important Safety Information throughout, and accompanying full Prescribing Information.

SARCLISA®
(isatuximab-irfc)
Injection for IV use | 500 mg/25 mL, 100 mg/5 mL

IKEMA Trial: **SARCLISA + Carfilzomib and Dexamethasone (Kd)**

Evaluated in 302 patients in a phase 3, multicenter, multinational, randomized, open-label study[1,2]

Patients with relapsed or refractory multiple myeloma who had received 1 to 3 prior lines of therapy (N=302)

Randomized 3:2

- SARCLISA[a] + Kd[b] (n=179)
- Kd[b] (n=123)

PRIMARY ENDPOINT: PFS*

Key secondary endpoints: ORR, ≥VGPR, CR, MRD negativity, OS

Treatment was administered in 28-day cycles until disease progression or unacceptable toxicity.

[a]SARCLISA 10 mg/kg was administered as an IV infusion weekly in the first cycle and every 2 weeks thereafter.

[b]Carfilzomib was administered as an IV infusion during cycle 1 at a dose of 20 mg/m^2 on days 1 and 2, and at 56 mg/m^2 on days 8, 9, 15, and 16; during subsequent cycles, it was administered at 56 mg/m^2 on days 1, 2, 8, 9, 15, and 16. Dexamethasone (IV on the days of SARCLISA and/or carfilzomib infusions, and orally on the other days) 20 mg was given on days 1, 2, 8, 9, 15, 16, 22, and 23 of each 28-day cycle.

Patients with poor prognostic factors at baseline[+] were included in IKEMA[1,2]

49% *Older age (≥65 years)*	**20%** *Impaired renal function[‡]*
24% *High cytogenetic risk[§]*	**33%** *Refractory to lenalidomide*

Overall, demographic and disease characteristics at baseline were similar between the 2 treatment groups. The median number of prior lines of therapy was 2 (range, 1 to 4),[¶] with 44% of patients who received 1 prior line of therapy.

*PFS results were assessed by an IRC, based on central laboratory data for M-protein, and central radiologic imaging review using the IMWG criteria. An interim analysis was conducted when 65% of the 159 PFS events (ie, 103 events) were observed.[1,2]

[+]Poor prognostic factors may include renal insufficiency, older age, high cytogenetic risk, and refractoriness to prior therapies.[5,6]

[‡]Impaired renal function is defined as eGFR <60 mL/min/1.73 m^2.[1]

[§]High-risk cytogenetic status is defined as the presence of del(17p) and/or t(4;14) and/or t(14;16). Chromosomal abnormality was considered positive if present in at least 30% of analyzed plasma cells, except for del(17p), where the threshold is at least 50%.[1]

[¶]Inclusion criteria for the IKEMA study specified 1 to 3 prior lines of therapy; however, a small number of patients included in the study had received >3 prior lines of therapy (n=5/302, 1.7%).[2]

Important Safety Information (cont'd)

Infusion-Related Reactions (cont'd)

Based on ICARIA-MM, IRRs occurred in 38% of patients treated with SARCLISA, pomalidomide, and dexamethasone (Isa-Pd). All IRRs started during the first SARCLISA infusion and resolved on the same day in 98% of the cases.

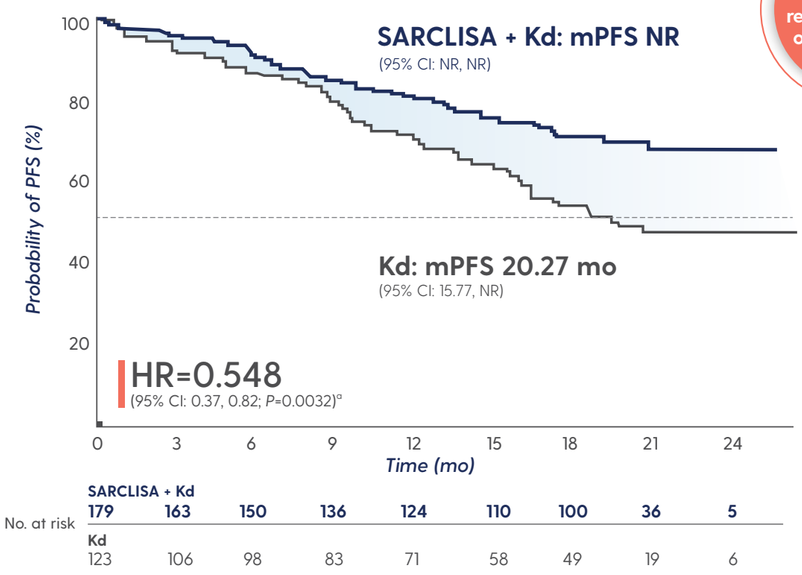
In IKEMA, infusion-related reactions occurred in 46% of patients treated with SARCLISA, carfilzomib, and dexamethasone (Isa-Kd). In the Isa-Kd arm, the infusion-related reactions occurred on the infusion day in 99% of episodes. In patients treated with Isa-Kd, 95% of those experiencing an infusion-related reaction experienced it during the first cycle of treatment. All infusion-related reactions resolved: within the same day in 74% of episodes, and the day after in 24% of episodes.

IKEMA: SARCLISA + Kd

SARCLISA + Kd Demonstrated Superior PFS vs Kd Alone

Median PFS with SARCLISA + Kd is not yet reached (NR)[1]

45% reduction in risk of progression or death



PFS results are based on a prespecified interim analysis, with a median follow-up time of 20.7 months. PFS results were assessed by an IRC, based on central laboratory data for M-protein, and central radiologic imaging review using the IMWG criteria.

[a]Stratified by the number of previous lines of therapy (1 vs >1) and R-ISS stage (I or II vs III vs not classified) according to IRT.

The median duration of treatment in the SARCLISA + Kd group was 80 weeks vs 61 weeks for the Kd group[1]

***74%* OF PATIENTS IN THE SARCLISA + Kd ARM HAD NOT PROGRESSED**
vs 59% in the Kd arm at the interim analysis cut-off date[2]

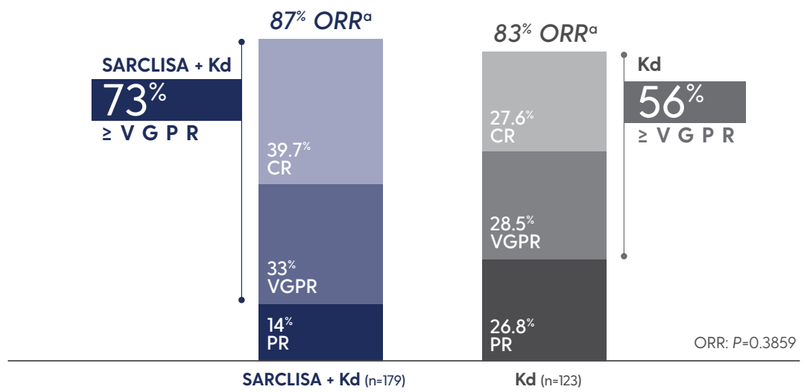
CR=complete response; eGFR=estimated glomerular filtration rate; IMWG=International Myeloma Working Group; IRC=independent response committee; IRT=interactive response technology; IV=intravenous; mPFS=median progression-free survival; M-protein=monoclonal protein; MRD=minimal (or measured) residual disease; ORR=overall response rate; OS=overall survival; PFS=progression-free survival; R-ISS=Revised International Staging System; VGPR=very good partial response.

Please see Important Safety Information throughout, and accompanying full Prescribing Information.

SARCLISA® (isatuximab-irfc)
Injection for IV use | 500 mg/25 mL, 100 mg/5 mL

Patients in the **IKEMA Trial Achieved Deep Responses***

Response rates across treatment arms[1]



[a]sCR, CR, VGPR, and PR were evaluated by the IRC using the IMWG response criteria. Results are based on a prespecified interim analysis with a median follow-up time of 20.7 months.[1]

As ORR did not reach statistical significance, CR, VGPR, and PR were not tested for significance[2]

- ORR: SARCLISA + Kd, 87% (95% CI: 0.81, 0.91); Kd, 83% (95% CI: 0.75, 0.89). 95% CI estimated using the Clopper-Pearson method[1]
- The median time to first response among responders was 1.08 months in the SARCLISA + Kd arm and 1.12 months in the Kd arm[2]

*A response of ≥VGPR.
PR=partial response; sCR=stringent complete response.

Important Safety Information (cont'd)

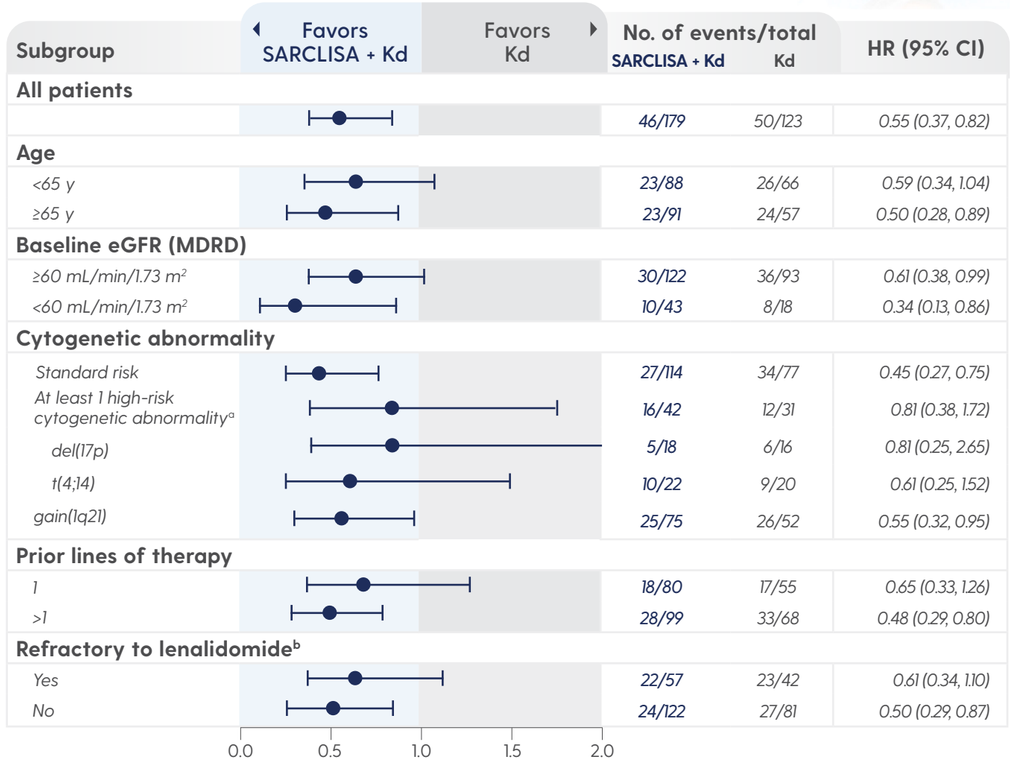
Infusion-Related Reactions (cont'd)

The most common symptoms (≥5%) of an infusion-related reaction in ICARIA-MM and IKEMA (N=329) included dyspnea, cough, nasal congestion, and nausea. Anaphylactic reactions occurred in less than 1% of patients. To decrease the risk and severity of IRRs, premedicate patients prior to SARCLISA infusion with acetaminophen, H_2 antagonists, diphenhydramine or equivalent, and dexamethasone.

Monitor vital signs frequently during the entire SARCLISA infusion. For patients with grade ≥2 reactions, interrupt SARCLISA infusion and provide appropriate medical management. For patients with grade 2 or grade 3 reactions, if symptoms improve to grade ≤1, restart SARCLISA infusion at half of the initial infusion rate, with supportive care as needed, and closely monitor patients. If symptoms do not recur after 30 minutes, the infusion rate may be increased to the initial rate, and then increased incrementally. In case symptoms do not improve to grade ≤1 after interruption of SARCLISA infusion, persist or worsen despite appropriate medications, or require hospitalization, permanently discontinue SARCLISA and institute appropriate management. Permanently discontinue SARCLISA if an anaphylactic reaction or life-threatening (grade 4) IRR occurs and institute appropriate management.

IKEMA: SARCLISA + Kd

Consistent PFS Results Across Subgroups, Including Those With Poor Prognostic Factors at Baseline[2+]



[a]High-risk cytogenetic status was defined as the presence of del(17p) and/or t(4;14) and/or t(14;16). Chromosomal abnormality was considered positive if present in at least 30% of analyzed plasma cells, except for del(17p), where the threshold was at least 50%. Gain(1q21), present in 42% of patients, was also analyzed and was considered positive if there were at least 3 copies in at least 30% of analyzed plasma cells.[1,2]
[b]Lenalidomide-refractory subgroups were not prespecified.[2]

Study limitations

Prespecified subgroup analysis; subgroups were not powered to show differences between treatment arms.

*Poor prognostic factors may include renal insufficiency, older age, high cytogenetic risk, and refractoriness to prior therapies.[5,6]
MDRD=modification of diet in renal disease.

Please see Important Safety Information throughout, and accompanying full Prescribing Information.

SARCLISA® (isatuximab-irfc)
Injection for IV use | 500 mg/25 mL, 100 mg/5 mL

IKEMA: SARCLISA + Kd

Meet Charles: An RRMM Patient With Renal Insufficiency After Relapsing Early on First-line Lenalidomide Maintenance

Current patient information

55 years of age

Cytogenetic risk
Standard

ECOG PS 0

Renal function (eGFR)
44 mL/min/1.73 m²

Diagnosis

Diagnosed ~3 years ago after acute onset of renal insufficiency and hypercalcemia

1st line

VRd induction → ASCT → lenalidomide maintenance (CR for 27 months posttransplant; recovery of renal function)

1st relapse

Relapsed with hypercalcemia, anemia, and recurring renal insufficiency

2nd-line treatment considerations for Charles

- High symptom burden at early relapse on lenalidomide maintenance
- Impaired renal function
- Refractory to lenalidomide
- Candidate for a triplet regimen that includes a multimodal anti-CD38 mAb and a novel PI

CONSIDER SARCLISA + Kd AS EARLY AS FIRST RELAPSE
for patients with impaired renal function and patients refractory to lenalidomide[1]

This is a hypothetical case study and should not substitute a healthcare provider's decision.
ASCT=autologous stem cell transplant; ECOG PS=Eastern Cooperative Oncology Group performance status; mAb=monoclonal antibody; PI=proteasome inhibitor; RRMM=relapsed or refractory multiple myeloma; VRd=bortezomib, lenalidomide, dexamethasone.

Important Safety Information (cont'd)

Neutropenia

SARCLISA may cause neutropenia.

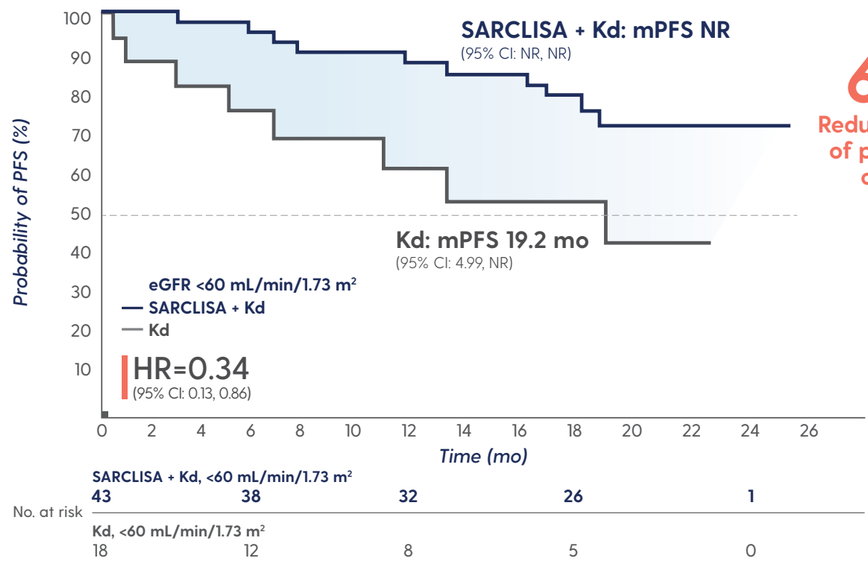
In patients treated with Isa-Pd, neutropenia occurred in 96% of patients and grade 3-4 neutropenia occurred in 85% of patients. Neutropenic complications occurred in 30% of patients, including febrile neutropenia (12%) and neutropenic infections (25%), defined as infection with concurrent grade ≥3 neutropenia. The most frequent neutropenic infections included infections of the upper respiratory tract (10%), lower respiratory tract (9%), and urinary tract (3%).

IKEMA: SARCLISA + Kd

PFS Results in Patients With Renal Impairment and Patients Refractory to Lenalidomide

In IKEMA, 20% of patients had impaired renal function and 33% were refractory to lenalidomide[1,2]

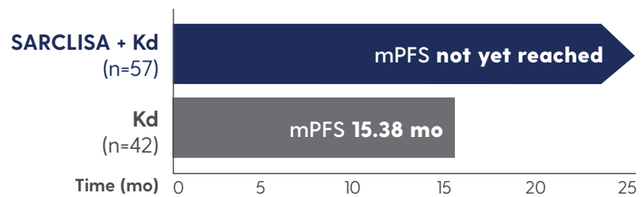
PFS in patients with renal impairment[2]



66% ↓
Reduction in risk of progression or death

Median follow-up time of 20.7 months. PFS assessed by IRC. Events occurring more than 8 weeks after the last valid disease assessment are censored.

PFS in patients refractory to lenalidomide[2]



39% ↓
Reduction in the risk of disease progression
HR=0.61 (95% CI: 0.34, 1.10)

Study limitations

Prespecified subgroup analysis; subgroups were not powered to show differences between treatment arms. Lenalidomide-refractory subgroups were not prespecified.

Please see Important Safety Information throughout, and accompanying full Prescribing Information.

SARCLISA®
(isatuximab-irfc)
Injection for IV use | 500 mg/25 mL, 100 mg/5 mL

IKEMA: SARCLISA + Kd

Meet Alice: An RRMM Patient With High Cytogenetic Risk and Rapid Disease Progression on First-line Maintenance Therapy

Current patient information

68 years of age

Cytogenetic risk
High
t(4;14) and gain(1q21)

ECOG PS 1

Older age

Diagnosis

Diagnosed 19 months ago after persistent worsening bone pain prompted MRI that identified humoral lesion

1st line

VRd induction → ASCT → bortezomib and lenalidomide maintenance (VGPR for 13 months posttransplant)

1st relapse

Rapid increase in M-spike and abrupt onset of bone pain with PET scan showing FDG-avid disease in the axial and appendicular skeleton

2nd-line treatment considerations for Alice

- Rapid, aggressive disease progression
- High cytogenetic risk
- Presence of gain(1q21)
- Double refractory to lenalidomide and bortezomib
- Candidate for a triplet combination that includes a multimodal anti-CD38 mAb and a novel PI

CONSIDER SARCLISA + Kd AS EARLY AS FIRST RELAPSE
for patients with high cytogenetic risk and patients with rapid disease progression[1]

This is a hypothetical case study and should not substitute a healthcare provider's decision.
FDG=fluorodeoxyglucose; MRI=magnetic resonance imaging; PET=positron emission tomography.

Important Safety Information (cont'd)

Neutropenia (cont'd)

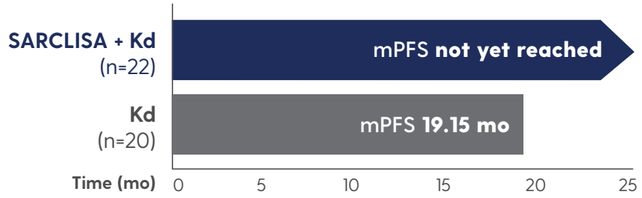
In patients treated with Isa-Kd, neutropenia occurred in 55% of patients, with grade 3-4 neutropenia in 19% of patients (grade 3 in 18% and grade 4 in 1.7%). Neutropenic complications occurred in 2.8% of patients, including febrile neutropenia (1.1%) and neutropenic infections (1.7%).

IKEMA: SARCLISA + Kd

PFS Results in Patients With Cytogenetic Abnormalities and Older Age

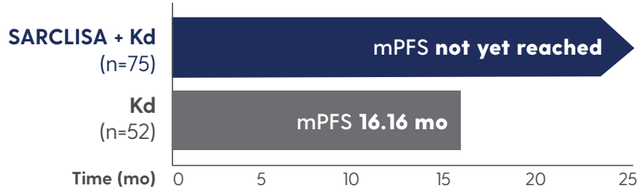
In IKEMA, 14% of patients were positive for t(4;14), 42% were positive for gain(1q21), and 49% were of older age[2]*

PFS in patients with presence of t(4;14)



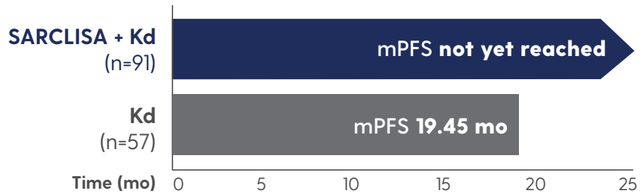
39%↓
Reduction in the risk of disease progression
HR=0.61 (95% CI: 0.25, 1.52)

PFS in patients with presence of gain(1q21)



45%↓
Reduction in the risk of disease progression
HR=0.55 (95% CI: 0.32, 0.95)

PFS in older patients (aged ≥65 years)



50%↓
Reduction in the risk of disease progression
HR=0.50 (95% CI: 0.28, 0.89)

Median follow-up time of 20.7 months.[1]

Study limitations

Prespecified subgroup analysis; subgroups were not powered to show differences between treatment arms.

*High-risk cytogenetic status was defined as the presence of del(17p) and/or t(4;14) and/or t(14;16). Chromosomal abnormality was considered positive if present in at least 30% of analyzed plasma cells, except for del(17p), where the threshold is at least 50%. Gain(1q21), present in 42% of patients, was also analyzed and was considered positive if there were at least 3 copies in at least 30% of analyzed plasma cells.[1,2]

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(isatuximab-irfc)
Injection for IV use | 500 mg/25 mL, 100 mg/5 mL

ICARIA-MM Trial: **SARCLISA + Pomalidomide and Dexamethasone (Pd)**

Evaluated in 307 patients in a phase 3, multicenter, multinational, randomized, open-label study[1]

Patients with relapsed and/or refractory multiple myeloma who received at least 2 prior therapies, including lenalidomide and a PI (N=307)

Randomized 1:1

- SARCLISA[a] + Pd[b] (n=154)
- Pd[b] (n=153)

PRIMARY ENDPOINT: PFS*

Key secondary endpoints: ORR,[+] OS

Treatment was administered in 28-day cycles until disease progression or unacceptable toxicity.

[a]SARCLISA 10 mg/kg was administered as an IV infusion weekly in the first cycle and every 2 weeks thereafter.

[b]Pomalidomide 4 mg was taken orally once daily from day 1 to day 21 of each 28-day cycle. Low-dose dexamethasone (orally or IV) 40 mg (20 mg for patients ≥75 years of age) was given on days 1, 8, 15, and 22 for each 28-day cycle.

Patients with poor prognostic factors at baseline[‡] were included in ICARIA-MM[1,3]

Baseline characteristics

- **20%** *Elderly (≥75 years)*
- **36%** *Impaired renal function[§]*
- **20%** *High cytogenetic risk[¶]*
- **93%** *Refractory to lenalidomide*

Overall, demographic and disease characteristics at baseline were similar between the 2 treatment groups. **The median number of prior lines of therapy was 3 (range, 2 to 11).**

*PFS results were assessed by an IRC, based on central laboratory data for M-protein, and central radiologic imaging review using the IMWG criteria. Median time to follow-up was 11.6 months.[1]
[+]sCR, CR, VGPR, and PR were evaluated by the IRC using the IMWG response criteria.[1]
[‡]Poor prognostic factors may include renal insufficiency, older age, high cytogenetic risk, and refractoriness to prior therapies.[5,6]
[§]eGFR <60 mL/min/1.73 m^2.[1]
[¶]Of the patients who had high-risk chromosomal abnormalities at study entry, del(17p), t(4;14), and t(14;16) were present in 12.1%, 8.5%, and 1.6% of patients, respectively.[2]

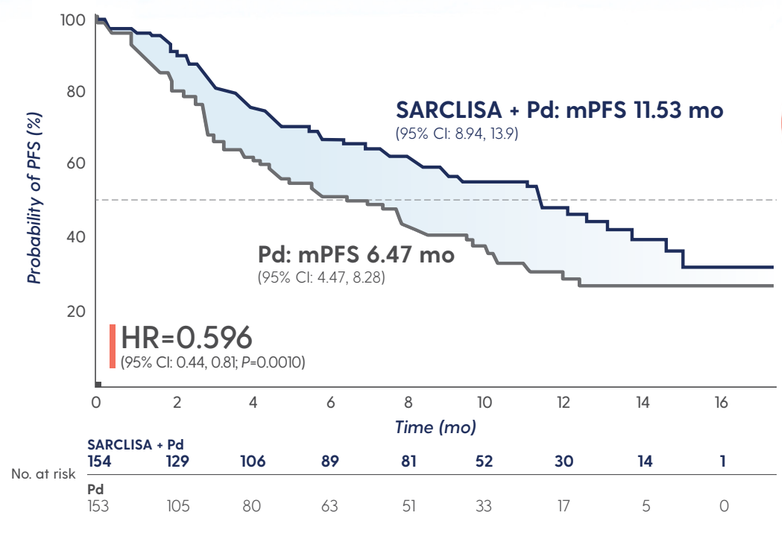
Important Safety Information (cont'd)

Neutropenia (cont'd)

Monitor complete blood cell counts periodically during treatment. Consider the use of antibiotics and antiviral prophylaxis during treatment. Monitor patients with neutropenia for signs of infection. In case of grade 4 neutropenia, delay SARCLISA dose until neutrophil count recovery to at least 1.0 x 10^9/L, and provide supportive care with growth factors, according to institutional guidelines. No dose reductions of SARCLISA are recommended.

SARCLISA + Pd **Extended Median PFS to ~1 Year**

Superior PFS with SARCLISA + Pd vs Pd alone[1]



>5 month increase in median PFS

At a median follow-up time of 11.6 months, 43 patients (27.9%) receiving SARCLISA + Pd and 56 patients (36.6%) receiving Pd had died. Median OS was not reached for either treatment group at interim analysis. The OS results at interim analysis did not reach statistical significance.

The median duration of treatment was 41 weeks for the SARCLISA + Pd group vs 24 weeks for the Pd group

GREATER THAN 40% ***REDUCTION IN THE RISK OF PROGRESSION OR DEATH in patients receiving SARCLISA + Pd***[1]

Important Safety Information (cont'd)

Second Primary Malignancies

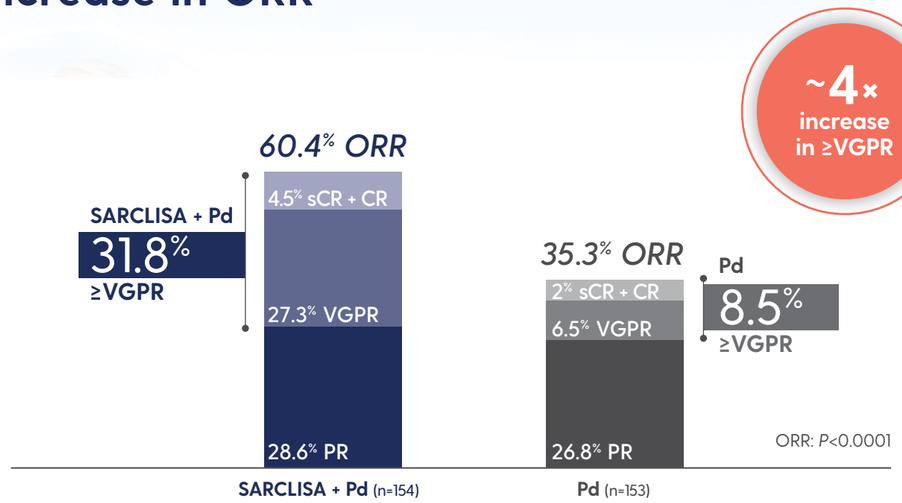
The incidence of second primary malignancies is increased in patients treated with SARCLISA-containing regimens. The overall incidence of second primary malignancies in all the SARCLISA-exposed patients was 3.6%.

In ICARIA-MM, second primary malignancies occurred in 3.9% of patients in the Isa-Pd arm and in 0.7% of patients in the Pd arm.

Please see Important Safety Information throughout, and accompanying full Prescribing Information.

SARCLISA® (isatuximab-irfc)
Injection for IV use | 500 mg/25 mL, 100 mg/5 mL

SARCLISA + Pd Showed a **Significant Increase in ORR**[1]



ORR: SARCLISA + Pd (95% CI: 0.52, 0.68), Pd (95% CI: 0.28, 0.43). 95% CI estimated using the Clopper-Pearson method.

MEDIAN TIME TO FIRST RESPONSE WAS 35 DAYS
with SARCLISA + Pd vs 58 days with Pd alone among responders[1]

Important Safety Information (cont'd)

Second Primary Malignancies (cont'd)

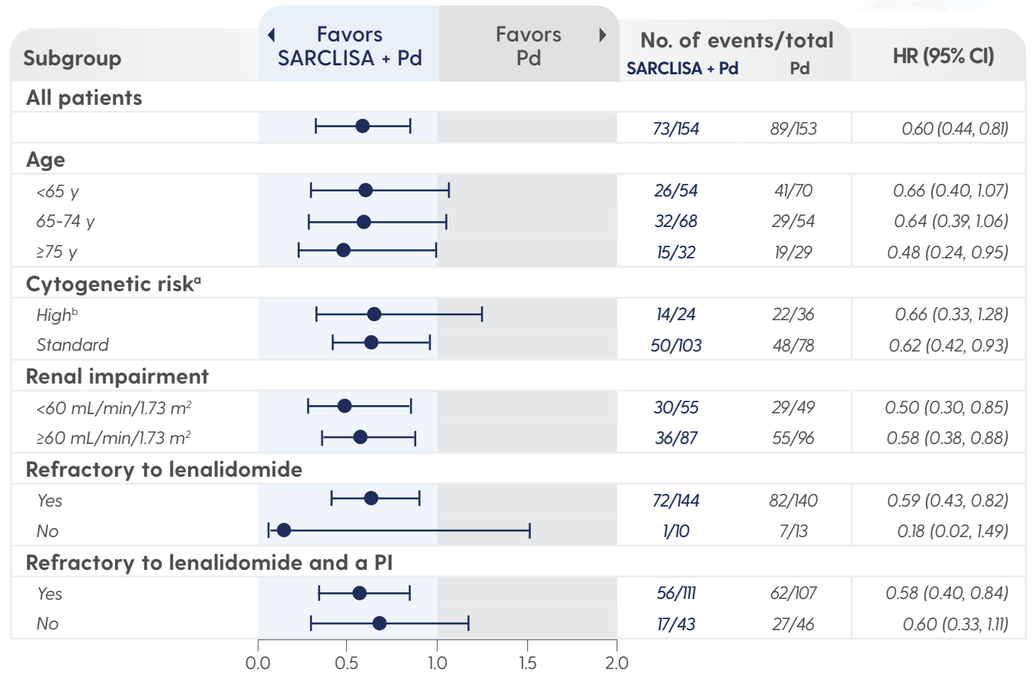
In IKEMA, second primary malignancies occurred in 7% of patients in the Isa-Kd arm and in 4.9% of patients in the Kd arm.

The most common (≥1%) second primary malignancies in ICARIA-MM and IKEMA (N=329) included skin cancers (4% with SARCLISA-containing regimens and 1.5% with comparative regimens) and solid tumors other than skin cancer (1.8% with SARCLISA-containing regimens and 1.5% with comparative regimens). All patients with skin cancer continued treatment after resection of the skin cancer.

Monitor patients for the development of second primary malignancies.

Please see Important Safety Information throughout, and accompanying full Prescribing Information.

Consistent PFS Results Across Subgroups, Including Those With Poor Prognostic Factors at Baseline[2,3]*



[a]Cytogenetic risk information was missing for 18% of patients in the SARCLISA + Pd arm and 26% of patients in the Pd arm.[3]
[b]Of the patients who had high-risk chromosomal abnormalities at study entry, del(17p), t(4;14), and t(14;16) were present in 12%, 8%, and 2% of patients, respectively.[1]

Study limitations

Prespecified subgroup analysis; subgroups were not powered to show differences between treatment arms.

*Poor prognostic factors may include renal insufficiency, older age, high cytogenetic risk, and refractoriness to prior therapies.[5,6]

Important Safety Information (cont'd)

Laboratory Test Interference

Interference with Serological Testing (Indirect Antiglobulin Test)

SARCLISA binds to CD38 on red blood cells (RBCs) and may result in a false-positive indirect antiglobulin test (indirect Coombs test). The indirect antiglobulin test was positive during Isa-Pd treatment in 68% of the tested patients, and during Isa-Kd treatment in 63% of patients. In patients with a positive indirect antiglobulin test, blood transfusions were administered without evidence of hemolysis. ABO/RhD typing was not affected by SARCLISA treatment.

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(isatuximab-irfc)
Injection for IV use | 500 mg/25 mL, 100 mg/5 mL

Meet Laura: An RRMM Patient With High Cytogenetic Risk, Cardiovascular Comorbidities, and Disease Progression on First-line Maintenance Therapy

Current patient information

68 years of age

Cytogenetic risk
High
t(4;14)

ECOG PS 0

Cardiovascular comorbidities
ECG shows EF 45%, uncontrolled hypertension

Older age

Diagnosis

Diagnosed 3 years ago after work-up for fatigue revealed anemia

1st line

VRd induction → ASCT → bortezomib and lenalidomide maintenance (CR for 30 months posttransplant)

1st relapse

Peripheral neuropathy; relapsed with new lesion in humerus found on MRI

2nd-line treatment considerations for Laura

- High cytogenetic risk
- Cardiovascular comorbidities
- Double refractory to lenalidomide and bortezomib
- Candidate for a triplet combination that includes a multimodal anti-CD38 mAb and a third-generation IMiD®

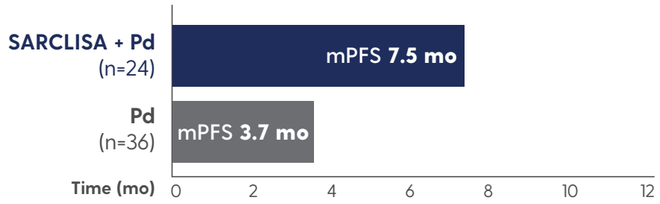
CONSIDER SARCLISA + Pd AS EARLY AS FIRST RELAPSE
for patients with high cytogenetic risk and patients with cardiovascular comorbidities[1]

This is a hypothetical case study and should not substitute a healthcare provider's decision.
ECG=echocardiogram; EF=ejection fraction; HF=heart failure; IMiD=immunomodulatory drug.

PFS Results in Patients With High Cytogenetic Risk and Patients Refractory to Lenalidomide

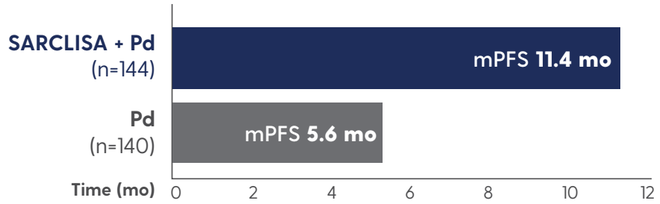
In ICARIA-MM, 20% of patients had high cytogenetic risk and 93% were refractory to lenalidomide*[1]

PFS in patients with high cytogenetic risk[2,3]



34% ↓
Reduction in the risk of disease progression
HR=0.66 (95% CI: 0.33, 1.28)

PFS in patients refractory to lenalidomide[2,3]



41% ↓
Reduction in the risk of disease progression
HR=0.59 (95% CI: 0.43, 0.82)

Study limitations

Prespecified subgroup analysis; subgroups were not powered to show differences between treatment arms.

*Cytogenetics by central lab; cutoff 50% for del(17p), 30% for t(4;14) and t(14;16).[3]

Important Safety Information (cont'd)

Laboratory Test Interference (cont'd)

Before the first SARCLISA infusion, conduct blood type and screen tests on SARCLISA-treated patients. Consider phenotyping prior to starting SARCLISA treatment. If treatment with SARCLISA has already started, inform the blood bank that the patient is receiving SARCLISA and that SARCLISA interference with blood compatibility testing can be resolved using dithiothreitol-treated RBCs. If an emergency transfusion is required, non–cross-matched ABO/RhD-compatible RBCs can be given as per local blood bank practices.

Please see Important Safety Information throughout, and accompanying full Prescribing Information.

SARCLISA®
(isatuximab-irfc)
Injection for IV use | 500 mg/25 mL, 100 mg/5 mL

ICARIA-MM: SARCLISA + Pd

Meet Ben: An Elderly RRMM Patient With Worsening Renal Insufficiency and Disease Progression on First-line Maintenance Therapy

Current patient information

78 years of age

Cytogenetic risk
Standard

ECOG PS 1

Elderly

Renal function (eGFR)
48 mL/min/1.73 m^2

Diagnosis

Diagnosed ~3.5 years ago after presenting with anemia, moderate renal insufficiency, mild hypercalcemia, and severe osteoporosis; transplant ineligible

1st line

VRd induction → lenalidomide maintenance (VGPR for 36 months); developed persistent peripheral neuropathy during induction

1st relapse

Relapse confirmed after consecutive labs showed increase of M-protein and light chains, recurrence of hypercalcemia, and reappearance of renal insufficiency

2nd-line treatment considerations for Ben

- Elderly
- Impaired renal function
- Refractory to lenalidomide
- Developed neuropathy from prior bortezomib treatment
- Candidate for a triplet combination that includes a multimodal anti-CD38 mAb and a third-generation IMiD

CONSIDER SARCLISA + Pd AS EARLY AS FIRST RELAPSE
for elderly patients and patients with impaired renal function[1]

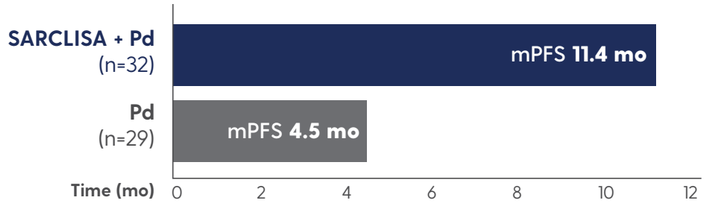
This is a hypothetical case study and should not substitute a healthcare provider's decision.

ICARIA: SARCLISA + Pd

PFS Results in Elderly Patients and Patients With Impaired Renal Function

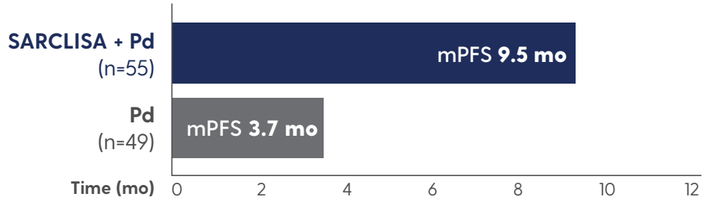
In ICARIA-MM, 20% of patients were elderly (≥75 years) and 36% had impaired renal function[3]*

PFS in elderly patients (aged ≥75 years)[2,3]



52%↓
Reduction in the risk of disease progression
HR=0.48 (95% CI: 0.24, 0.95)

PFS in patients with renal impairment[2,3]



50%↓
Reduction in the risk of disease progression
HR=0.50 (95% CI: 0.30, 0.85)

Study limitations

Prespecified subgroup analysis; subgroups were not powered to show differences between treatment arms.

*eGFR <60 mL/min/1.73 m^2.[1]

Important Safety Information (cont'd)

Laboratory Test Interference (cont'd)

Interference with Serum Protein Electrophoresis and Immunofixation Tests

SARCLISA is an IgG kappa monoclonal antibody that can be incidentally detected on both serum protein electrophoresis and immunofixation assays used for the clinical monitoring of endogenous M-protein. This interference can impact the accuracy of the determination of complete response in some patients with IgG kappa myeloma protein.

Please see Important Safety Information throughout, and accompanying full Prescribing Information.

SARCLISA®
(isatuximab-irfc)
Injection for IV use | 500 mg/25 mL, 100 mg/5 mL

Adverse Reactions for SARCLISA + Kd

Adverse reactions (≥10%) in patients receiving SARCLISA + Kd with a difference between arms of ≥5% compared with Kd alone[1]

Adverse reactions	SARCLISA + Kd (n=177)			Kd (n=122)		
	All grades	Grade 3	Grade 4	All grades	Grade 3	Grade 4
General disorders and administration site conditions						
IRR[a]	46%	0.6%	0%	3.3%	0%	0%
Infections						
Upper respiratory tract infection[b]	67%	9%	0%	57%	7%	0%
Pneumonia[c]	36%	19%	3.4%	30%	15%	2.5%
Bronchitis[d]	24%	2.3%	0%	13%	0.8%	0%
Vascular disorders						
Hypertension[e]	37%	20%	0.6%	32%	18%	1.6%
Respiratory, thoracic, and mediastinal disorders						
Dyspnea[f]	29%	5%	0%	24%	0.8%	0%
Cough[g]	23%	0%	0%	15%	0%	0%
Gastrointestinal disorders						
Diarrhea	36%	2.8%	0%	29%	2.5%	0%
Vomiting	15%	1.1%	0%	9%	0.8%	0%
General disorders and administration site conditions						
Fatigue[h]	42%	5%	0%	32%	3.3%	0%

[a]IRR includes IRR, cytokine release syndrome, and hypersensitivity.
[b]Upper respiratory tract infection includes acute sinusitis, chronic sinusitis, H1N1 influenza, H3N2 influenza, influenza, laryngitis, laryngitis viral, nasal herpes, nasopharyngitis, pharyngitis, pharyngotonsillitis, respiratory syncytial virus infection, rhinitis, sinusitis, sinusitis bacterial, tonsillitis, tracheitis, upper respiratory tract infection, viral rhinitis, respiratory tract infection, respiratory tract infection viral, influenza-like illness, parainfluenzae virus infection, respiratory tract infection bacterial, and viral upper respiratory tract infection.
[c]Pneumonia includes atypical pneumonia, lower respiratory tract infection, lower respiratory tract infection viral, *Pneumocystis jirovecii* pneumonia, pneumonia, pneumonia influenzal, pneumonia legionella, pneumonia pneumococcal, pneumonia respiratory syncytial viral, pneumonia streptococcal, pneumonia viral, pulmonary sepsis, and pulmonary tuberculosis.
[d]Bronchitis includes bronchitis, bronchitis viral, respiratory syncytial virus bronchitis, bronchitis chronic, and tracheobronchitis.
[e]Hypertension includes hypertension, blood pressure increased, and hypertensive crisis.
[f]Dyspnea includes dyspnea and dyspnea exertional.
[g]Cough includes cough, productive cough, and allergic cough.
[h]Fatigue includes fatigue and asthenia.

Serious adverse reactions

- Serious adverse reactions occurred in 59% of patients receiving SARCLISA + Kd[1]
  - The most frequent serious adverse reactions in >5% of patients who received SARCLISA + Kd were pneumonia (25%) and upper respiratory tract infections (9%)
- Fatal adverse reactions occurred in 3.4% of patients receiving SARCLISA + Kd (those occurring in >1% of patients were pneumonia in 1.7% and cardiac failure in 1.1% of patients) vs 3.3% in the Kd arm[1,2]

IRR=infusion-related reaction.

Please see Important Safety Information throughout, and accompanying full Prescribing Information.

IKEMA: SARCLISA + Kd

Additional Safety Experience for SARCLISA + Kd

Hematology laboratory abnormalities in patients receiving SARCLISA + Kd vs Kd alone[1]

Laboratory parameter	SARCLISA + Kd (n=177)			Kd (n=122)		
	All grades	Grade 3	Grade 4	All grades	Grade 3	Grade 4
Hemoglobin decreased	99%	22%	0%	99%	20%	0%
Lymphocytes decreased	94%	52%	17%	95%	43%	14%
Platelets decreased	94%	19%	11%	88%	16%	8%
Neutrophils decreased	55%	18%	1.7%	43%	7%	0.8%

The denominator used to calculate the percentage was based on the safety population.

Complete blood cell counts should be monitored periodically during treatment. Patients with neutropenia should be monitored for signs of infection. In case of infection, appropriate standard therapy should be instituted. Antibiotics and antiviral prophylaxis can be considered during treatment.

Cardiac failure[1]*+

- In IKEMA, cardiac failure was reported in 7.3% of patients in the SARCLISA + Kd group (grade ≥3, 4%) and in 6.6% of patients in the Kd group (grade ≥3, 4.1%)
- Serious cardiac failure was observed in 4% of patients in the SARCLISA + Kd group and in 3.3% of patients in the Kd group

Permanent treatment discontinuation due to adverse reactions (grades 1 to 4)[1,2]

SARCLISA + Kd	Kd
8%	14%

- The most frequent adverse reactions requiring permanent discontinuation were infections (2.8%, SARCLISA + Kd; 4.9%, Kd)
- Dosage interruptions due to an adverse reaction occurred in 33% of patients who received SARCLISA. The most frequent adverse reaction requiring dosage interruption was IRR (30%)

THE ADDITION OF SARCLISA TO Kd
did not increase treatment discontinuations due to adverse reactions vs Kd alone[1,2]

*Cardiac failure included cardiac failure, cardiac failure congestive, cardiac failure acute, cardiac failure chronic, left ventricular failure, and pulmonary edema.[1]
+See the current Prescribing Information for carfilzomib for more information.

SARCLISA® (isatuximab-irfc)
Injection for IV use | 500 mg/25 mL, 100 mg/5 mL

Adverse Reactions for SARCLISA + Pd

Adverse reactions (≥10%) in patients receiving SARCLISA + Pd with a difference between arms of ≥5% compared with Pd alone[1]

Adverse reactions	SARCLISA + Pd (n=152)			Pd (n=149)		
	All grades	Grade 3	Grade 4	All grades	Grade 3	Grade 4
General disorders and administration site conditions						
IRR[a]	38%	1.3%	1.3%	0%	0%	0%
Infections						
Upper respiratory tract infection[b]	57%	9%	0%	42%	3.4%	0%
Pneumonia[c]	31%	22%	3.3%	23%	16%	2.7%
Blood and lymphatic system disorders						
Febrile neutropenia	12%	11%	1.3%	2%	1.3%	0.7%
Respiratory, thoracic, and mediastinal disorders						
Dyspnea[d]	17%	5%	0%	12%	1.3%	0%
Gastrointestinal disorders						
Diarrhea	26%	2%	0%	19%	0.7%	0%
Nausea	15%	0%	0%	9%	0%	0%
Vomiting	12%	1.3%	0%	3.4%	0%	0%

[a]IRR includes IRR, cytokine release syndrome, and drug hypersensitivity.
[b]Upper respiratory tract infection includes bronchiolitis, bronchitis, bronchitis viral, chronic sinusitis, fungal pharyngitis, influenza-like illness, laryngitis, nasopharyngitis, parainfluenzae virus infection, pharyngitis, respiratory tract infection, respiratory tract infection viral, rhinitis, sinusitis, tracheitis, upper respiratory tract infection, and upper respiratory tract infection bacterial.
[c]Pneumonia includes atypical pneumonia, bronchopulmonary aspergillosis, pneumonia, pneumonia haemophilus, pneumonia influenzal, pneumonia pneumococcal, pneumonia streptococcal, pneumonia viral, candida pneumonia, pneumonia bacterial, haemophilus infection, lung infection, pneumonia fungal, and *Pneumocystis jirovecii* pneumonia.
[d]Dyspnea includes dyspnea, dyspnea exertional, and dyspnea at rest.

Serious adverse reactions

- Serious adverse reactions occurred in 62% of patients receiving SARCLISA + Pd[1]
  - Serious adverse reactions in >5% of patients who received SARCLISA + Pd included pneumonia (26%), upper respiratory tract infection (7%), and febrile neutropenia (7%)
- Fatal adverse reactions occurred in 11% of patients in the SARCLISA + Pd arm (those that occurred in >1% of patients were pneumonia and other infections [3%]) vs 11% in the Pd arm[1,2]

Please see Important Safety Information throughout, and accompanying full Prescribing Information.

ICARIA-MM: SARCLISA + Pd

Additional Safety Experience for SARCLISA + Pd

Hematology laboratory abnormalities in patients receiving SARCLISA + Pd vs Pd alone[1]

Laboratory parameter	SARCLISA + Pd (n=152)			Pd (n=149)		
	All grades	Grade 3	Grade 4	All grades	Grade 3	Grade 4
Hemoglobin decreased	99%	32%	0%	97%	28%	0%
Neutrophils decreased	96%	24%	61%	92%	38%	31%
Lymphocytes decreased	92%	42%	13%	92%	35%	8%
Platelets decreased	84%	14%	16%	79%	9%	15%

The denominator used to calculate the percentages was based on the safety population.

Complete blood cell counts should be monitored periodically during treatment. Patients with neutropenia should be monitored for signs of infection. In case of infection, appropriate standard therapy should be instituted. Antibiotics and antiviral prophylaxis can be considered during treatment.

The median duration of treatment was 41 weeks for the SARCLISA + Pd group vs 24 weeks for the Pd group.

Permanent treatment discontinuation due to adverse reactions (grades 1 to 4)[1,2]

SARCLISA + Pd	Pd
7%	12%

- Dosage interruptions due to an adverse reaction occurred in 31% of patients who received SARCLISA + Pd
  - Discontinuations from treatment due to infection were reported in 2.6% of patients receiving SARCLISA + Pd vs 5.4% of patients receiving Pd alone
  - The most frequent adverse reaction requiring dosage interruption was IRR (28%)

THE ADDITION OF SARCLISA TO Pd did not increase treatment discontinuations due to adverse reactions vs Pd alone[1,2]

SARCLISA®
(isatuximab-irfc)
Injection for IV use | 500 mg/25 mL, 100 mg/5 mL

SARCLISA Is a **Multimodal Anti-CD38 mAb**

Targeted binding to a specific epitope induces distinct antitumor activity[1,3,8]

Directly destroys

myeloma cells through apoptosis without the need for crosslinking

Triggers cancer cell death

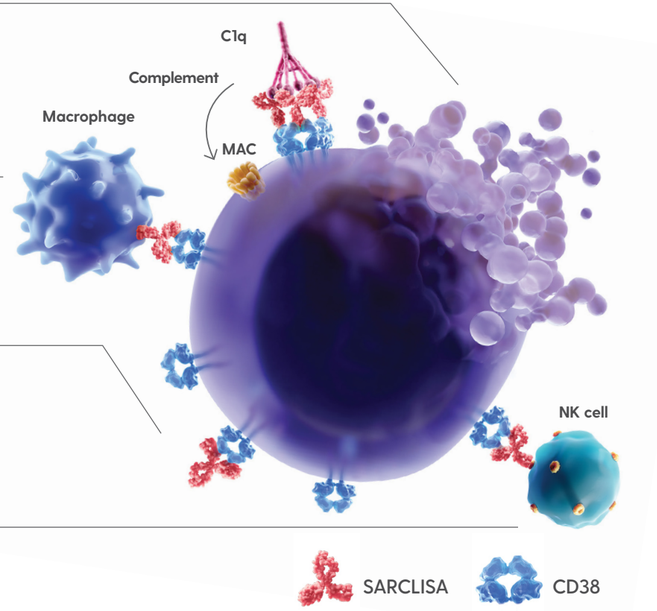
through tumor cell targeting, including ADCC, ADCP, and CDC

Inhibits CD38

enzymatic activity through suppression of the CD38 ectoenzyme

Enhances immune cell function

through NK cell activation and a decrease in immunosuppressors



ADCC=antibody-dependent cell-mediated cytotoxicity; ADCP=antibody-dependent cellular phagocytosis; C1q=complement component 1q; CDC=complement-dependent cytotoxicity; MAC=membrane attack complex; NK=natural killer.

References: 1. SARCLISA [prescribing information]. Bridgewater, NJ: sanofi-aventis U.S. LLC. **2.** Data on file. sanofi-aventis U.S. LLC. **3.** Attal M, Richardson PG, Rajkumar SV, et al; on behalf of the ICARIA-MM study group. Isatuximab plus pomalidomide and low-dose dexamethasone versus pomalidomide and low-dose dexamethasone in patients with relapsed and refractory multiple myeloma (ICARIA-MM): a randomised, multicentre, open-label, phase 3 study. *Lancet*. 2019;394(10214):2096-2107. **4.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Multiple Myeloma V.7.2021. © National Comprehensive Cancer Network, Inc. 2021. All rights reserved. Accessed May 5, 2021. To view the most recent and complete version of the guideline, go online to NCCN.org. **5.** Jhaveri M, Romanus D, Raju A, et al. Real-world prescribing patterns in U.S. multiple myeloma (MM) patients refractory to lenalidomide in the front line. Poster presented at: 21st Congress of the European Hematology Association; June 9-12, 2016; Copenhagen, Denmark. **6.** Hájek R, Jarkovsky J, Maisnar V, et al. Real-world outcomes of multiple myeloma: retrospective analysis of the Czech Registry of Monoclonal Gammopathies. *Clin Lymphoma Myeloma Leuk*. 2018;18(6):e219-e240. doi:10.1016/j.clml.2018.04.003. **7.** Capra M, Martin T, Moreau P, et al. Isatuximab plus carfilzomib and dexamethasone versus carfilzomib and dexamethasone in relapsed multiple myeloma patients with renal impairment: IKEMA subgroup analysis. Poster presented at: 62nd American Society of Hematology Virtual Scientific Meeting; December 5-8, 2020. Poster 3241. **8.** Martin TG, Corzo K, Chiron M, et al. Therapeutic opportunities with pharmacological inhibition of CD38 with isatuximab. *Cells*. 2019;8(12):1522. doi:10.3390/cells8121522.

Important Safety Information (cont'd)

Embryo-Fetal Toxicity

Based on the mechanism of action, SARCLISA can cause fetal harm when administered to a pregnant woman. SARCLISA may cause fetal immune cell depletion and decreased bone density. Advise pregnant women of the potential risk to a fetus. Advise females with reproductive potential to use an effective method of contraception during treatment with SARCLISA and for at least 5 months after the last dose. The combination of SARCLISA with pomalidomide is contraindicated in pregnant women because pomalidomide may cause birth defects and death of the unborn child. Refer to the pomalidomide prescribing information on use during pregnancy.

Please see Important Safety Information throughout, and accompanying full Prescribing Information.

SARCLISA®
(isatuximab-irfc)
Injection for IV use | 500 mg/25 mL, 100 mg/5 mL

Indication

SARCLISA (isatuximab-irfc) is indicated:

- In combination with pomalidomide and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least 2 prior therapies including lenalidomide and a proteasome inhibitor
- In combination with carfilzomib and dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received 1 to 3 prior lines of therapy

Important Safety Information

CONTRAINDICATIONS

SARCLISA is contraindicated in patients with severe hypersensitivity to isatuximab-irfc or to any of its excipients.

WARNINGS AND PRECAUTIONS

Infusion-Related Reactions

Serious infusion-related reactions (IRRs), including life-threatening anaphylactic reactions, have occurred with SARCLISA treatment. Severe signs and symptoms include cardiac arrest, hypertension, hypotension, bronchospasm, dyspnea, angioedema, and swelling.

Based on ICARIA-MM, IRRs occurred in 38% of patients treated with SARCLISA, pomalidomide, and dexamethasone (Isa-Pd). All IRRs started during the first SARCLISA infusion and resolved on the same day in 98% of the cases.

In IKEMA, infusion-related reactions occurred in 46% of patients treated with SARCLISA, carfilzomib, and dexamethasone (Isa-Kd). In the Isa-Kd arm, the infusion-related reactions occurred on the infusion day in 99% of episodes. In patients treated with Isa-Kd, 95% of those experiencing an infusion-related reaction experienced it during the first cycle of treatment. All infusion-related reactions resolved: within the same day in 74% of episodes, and the day after in 24% of episodes.

The most common symptoms (≥5%) of an infusion-related reaction in ICARIA-MM and IKEMA (N=329) included dyspnea, cough, nasal congestion, and nausea. Anaphylactic reactions occurred in less than 1% of patients. To decrease the risk and severity of IRRs, premedicate patients prior to SARCLISA infusion with acetaminophen, H_2 antagonists, diphenhydramine or equivalent, and dexamethasone.

Monitor vital signs frequently during the entire SARCLISA infusion. For patients with grade ≥2 reactions, interrupt SARCLISA infusion and provide appropriate medical management. For patients with grade 2 or grade 3 reactions, if symptoms improve to grade ≤1, restart SARCLISA infusion at half of the initial infusion rate, with supportive care as needed, and closely monitor patients. If symptoms do not recur after 30 minutes, the infusion rate may be increased to the initial rate, and then increased incrementally. In case symptoms do not improve to grade ≤1 after interruption of SARCLISA infusion, persist or worsen despite appropriate medications, or require hospitalization, permanently discontinue SARCLISA and institute appropriate management. Permanently discontinue SARCLISA if an anaphylactic reaction or life-threatening (grade 4) IRR occurs and institute appropriate management.

Neutropenia

SARCLISA may cause neutropenia.

In patients treated with Isa-Pd, neutropenia occurred in 96% of patients and grade 3-4 neutropenia occurred in 85% of patients. Neutropenic complications occurred in 30% of patients, including febrile neutropenia (12%) and neutropenic infections (25%), defined as infection with concurrent grade ≥3 neutropenia. The most frequent neutropenic infections included infections of the upper respiratory tract (10%), lower respiratory tract (9%), and urinary tract (3%).

In patients treated with Isa-Kd, neutropenia occurred in 55% of patients, with grade 3-4 neutropenia in 19% of patients (grade 3 in 18% and grade 4 in 1.7%). Neutropenic complications occurred in 2.8% of patients, including febrile neutropenia (1.1%) and neutropenic infections (1.7%).

Monitor complete blood cell counts periodically during treatment. Consider the use of antibiotics and antiviral prophylaxis during treatment. Monitor patients with neutropenia for signs of infection. In case of grade 4 neutropenia, delay SARCLISA dose until neutrophil count recovery to at least 1.0 x 10^9/L, and provide supportive care with growth factors, according to institutional guidelines. No dose reductions of SARCLISA are recommended.

Second Primary Malignancies

The incidence of second primary malignancies is increased in patients treated with SARCLISA-containing regimens. The overall incidence of second primary malignancies in all the SARCLISA-exposed patients was 3.6%.

In ICARIA-MM, second primary malignancies occurred in 3.9% of patients in the Isa-Pd arm and in 0.7% of patients in the Pd arm.

In IKEMA, second primary malignancies occurred in 7% of patients in the Isa-Kd arm and in 4.9% of patients in the Kd arm.

The most common (≥1%) second primary malignancies in ICARIA-MM and IKEMA (N=329) included skin cancers (4% with SARCLISA-containing regimens and 1.5% with comparative regimens) and solid tumors other than skin cancer (1.8% with SARCLISA-containing regimens and 1.5% with comparative regimens). All patients with skin cancer continued treatment after resection of the skin cancer.

Monitor patients for the development of second primary malignancies.

Laboratory Test Interference

Interference with Serological Testing (Indirect Antiglobulin Test)

SARCLISA binds to CD38 on red blood cells (RBCs) and may result in a false-positive indirect antiglobulin test (indirect Coombs test). The indirect antiglobulin test was positive during Isa-Pd treatment in 68% of the tested patients, and during Isa-Kd treatment in 63% of patients. In patients with a positive indirect antiglobulin test, blood transfusions were administered without evidence of hemolysis. ABO/RhD typing was not affected by SARCLISA treatment.

Before the first SARCLISA infusion, conduct blood type and screen tests on SARCLISA-treated patients. Consider phenotyping prior to starting SARCLISA treatment. If treatment with SARCLISA has already started, inform the blood bank that the patient is receiving SARCLISA and that SARCLISA interference with blood compatibility testing can be resolved using dithiothreitol-treated RBCs. If an emergency transfusion is required, non–cross-matched ABO/RhD-compatible RBCs can be given as per local blood bank practices.

Interference with Serum Protein Electrophoresis and Immunofixation Tests

SARCLISA is an IgG kappa monoclonal antibody that can be incidentally detected on both serum protein electrophoresis and immunofixation assays used for the clinical monitoring of endogenous M-protein. This interference can impact the accuracy of the determination of complete response in some patients with IgG kappa myeloma protein.

Embryo-Fetal Toxicity

Based on the mechanism of action, SARCLISA can cause fetal harm when administered to a pregnant woman. SARCLISA may cause fetal immune cell depletion and decreased bone density. Advise pregnant women of the potential risk to a fetus. Advise females with reproductive potential to use an effective method of contraception during treatment with SARCLISA and for at least 5 months after the last dose. The combination of SARCLISA with pomalidomide is contraindicated in pregnant women because pomalidomide may cause birth defects and death of the unborn child. Refer to the pomalidomide prescribing information on use during pregnancy.

ADVERSE REACTIONS

In combination with pomalidomide and dexamethasone: The most common adverse reactions (≥20%) were upper respiratory tract infection, infusion-related reactions, pneumonia, and diarrhea. The most common hematology laboratory abnormalities (≥80%) were decreased hemoglobin, decreased neutrophils, decreased lymphocytes, and decreased platelets.

In combination with carfilzomib and dexamethasone: The most common adverse reactions (≥20%) were upper respiratory tract infection, infusion-related reactions, fatigue, hypertension, diarrhea, pneumonia, dyspnea, insomnia, bronchitis, cough, and back pain. The most common hematology laboratory abnormalities (≥80%) were decreased hemoglobin, decreased lymphocytes, and decreased platelets.

Serious adverse reactions occurred in 62% of patients receiving Isa-Pd. Serious adverse reactions in >5% of patients who received Isa-Pd included pneumonia (26%), upper respiratory tract infections (7%), and febrile neutropenia (7%). Fatal adverse reactions occurred in 11% of patients (those that occurred in more than 1% of patients were pneumonia and other infections [3%]).

Serious adverse reactions occurred in 59% of patients receiving Isa-Kd. The most frequent serious adverse reactions in >5% of patients who received Isa-Kd were pneumonia (25%) and upper respiratory tract infections (9%). Adverse reactions with a fatal outcome during treatment were reported in 3.4% of patients in the Isa-Kd group (those occurring in more than 1% of patients were pneumonia occurring in 1.7% and cardiac failure in 1.1% of patients).

USE IN SPECIAL POPULATIONS

Because of the potential for serious adverse reactions in the breastfed child from isatuximab-irfc administered in combination with Pd, advise lactating women not to breastfeed during treatment with SARCLISA.

Please see accompanying full Prescribing Information.

SARCLISA®
(isatuximab-irfc)
Injection for IV use | 500 mg/25 mL, 100 mg/5 mL

For your adult patients with relapsed or refractory multiple myeloma

***Consider SARCLISA + Kd or Pd as early as first relapse**, including for patients with poor prognostic factors*

*SARCLISA + Kd or Pd demonstrated improved PFS vs Kd or Pd alone and consistent PFS results across prespecified subgroups[1-3]**

SARCLISA + Kd
IKEMA

mPFS: Not yet reached (NR) with SARCLISA + Kd (n=179) vs 20.27 months with Kd alone (n=123), **HR=0.548** (95% CI: 0.37, 0.82; *P*=0.0032)[1]

SARCLISA + Pd
ICARIA-MM

mPFS: 11.53 months with SARCLISA + Pd (n=154) vs 6.47 months with Pd alone (n=153), **HR=0.596** (95% CI: 0.44, 0.81; *P*=0.0010)[1]

- SARCLISA demonstrated consistent PFS results across prespecified subgroups when added to Kd or Pd in the IKEMA and ICARIA-MM trials, respectively, including in patients with poor prognostic factors such as[2,3]:

Advanced age | **Renal impairment** | **High cytogenetic risk** | **Lenalidomide refractoriness**

  - Subgroup analyses were not powered to show statistical significance. Lenalidomide-refractory subgroups were not prespecified in the IKEMA trial
- Patients who permanently discontinued treatment due to adverse reactions: SARCLISA + Kd, 8%; SARCLISA + Pd, 7%[1]

Indication

SARCLISA (isatuximab-irfc) is indicated:

- In combination with pomalidomide and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least 2 prior therapies including lenalidomide and a proteasome inhibitor
- In combination with carfilzomib and dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received 1 to 3 prior lines of therapy

Important Safety Information

CONTRAINDICATIONS

SARCLISA is contraindicated in patients with severe hypersensitivity to isatuximab-irfc or to any of its excipients.

WARNINGS AND PRECAUTIONS

Infusion-Related Reactions

Serious infusion-related reactions (IRRs), including life-threatening anaphylactic reactions, have occurred with SARCLISA treatment. Severe signs and symptoms include cardiac arrest, hypertension, hypotension, bronchospasm, dyspnea, angioedema, and swelling.

Please see Important Safety Information throughout, and accompanying full Prescribing Information.

SANOFI GENZYME

MAT-US-2102022-v1.0-06/2021

SARCLISA®
(isatuximab-irfc)
Injection for IV use | 500 mg/25 mL, 100 mg/5 mL