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

A GUIDE FOR NURSES

Information about SARCLISA, including
clinical trial information and dosing instructions

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 two prior therapies including lenalidomide and a proteasome inhibitor.

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

Infusion-related reactions (IRRs) have been observed in 39% of patients treated with SARCLISA. All IRRs started during the first SARCLISA infusion and resolved on the same day in 98% of the cases. The most common symptoms of an IRR included dyspnea, cough, chills, and nausea. The most common severe signs and symptoms included hypertension and dyspnea.

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

SARCLISA Is the First Anti-CD38 Antibody Studied in a Phase 3 Trial in Combination With Pd vs Pd Alone

ICARIA-MM: A multicenter, open-label, randomized, phase 3 study[1]

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

Randomized 1:1

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

[a]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.

- SARCLISA 10 mg/kg was administered as an IV infusion weekly in the first cycle and every 2 weeks thereafter
- Treatment administered in 28-day cycles until disease progression or unacceptable toxicity

Primary endpoint: PFS*
Key secondary endpoints: ORR,† OS

*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.

†sCR, CR, VGPR, and PR were evaluated by the IRC using the IMWG response criteria.

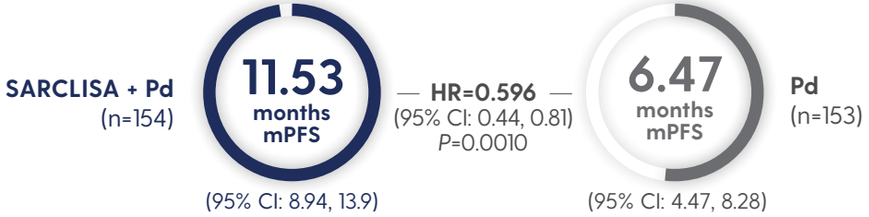
CR=complete response; IMWG=International Myeloma Working Group; IRC=independent response committee; IV=intravenous; M-protein=myeloma protein; ORR=overall response rate; OS=overall survival; Pd=pomalidomide and dexamethasone; PFS=progression-free survival; PI=proteasome inhibitor; PR=partial response; sCR=stringent complete response; VGPR=very good partial response.

Important Safety Information (cont'd)

Infusion-Related Reactions (cont'd)
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 1 or 2 reactions, interrupt SARCLISA infusion and provide appropriate medical support. If symptoms improve, restart SARCLISA infusion at half of the initial rate, with supportive care as needed, and closely monitor patients.

SARCLISA + Pd Demonstrated Superior Efficacy vs Pd Alone

Median PFS of ~1 year with SARCLISA + Pd[1]



The median duration of treatment was 41 weeks with SARCLISA + Pd vs 24 weeks with Pd.[1]

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.[1]

A significant increase in responses shown with SARCLISA + Pd[1‡]

SARCLISA + Pd (n=154)		**Pd** (n=153)
60.4% ORR	***P*<0.0001**	**35.3%** ORR
31.8% ≥VGPR	**~4× increase**	**8.5%** ≥VGPR
35 days	**Median time to first response among responders**	**58** days

The median duration of response among responders was 13.3 months (95% CI: 10.6, NR) with SARCLISA + Pd vs 11.1 months (95% CI: 8.5, NR) with Pd alone.[1]

‡ORR included sCR, CR, VGPR, and PR. ORR: SARCLISA + Pd (95% CI: 52.2%, 68.2%), Pd (95% CI: 27.8%, 43.4%).

mPFS=median progression-free survival; NR=not reached.

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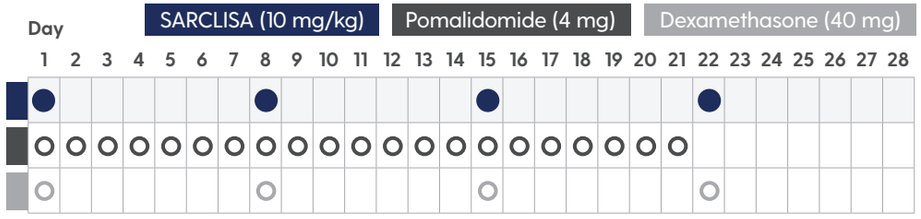
Recommended Dose and Schedule

- 10 mg/kg actual body weight administered as an IV infusion in combination with Pd[1]
- 250-mL fixed infusion volume[1]
- Premedication should be administered 15 to 60 minutes prior to infusion of SARCLISA[1]
- Treatment is repeated until disease progression or unacceptable toxicity[1]

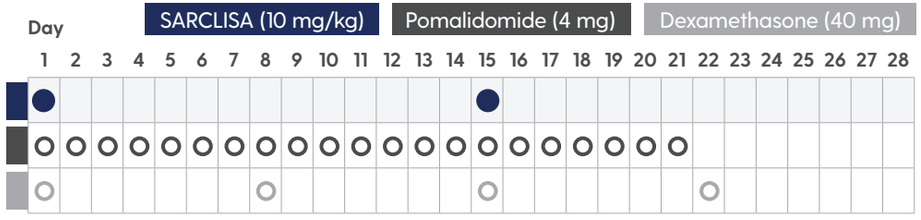
Weekly dosing for first cycle, followed by every other week for subsequent cycles[1]

SARCLISA + Pd dosing schedule[1]

Cycle 1



Cycle 2 and beyond



In the clinical trial, 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.[1]

- Each treatment cycle consists of a 28-day period[1]
- If a planned dose of SARCLISA is missed, administer the dose as soon as possible and adjust the treatment schedule accordingly, maintaining the treatment interval[1]

See page 13 for information about dose modifications.

Premedication

Administer the following premedications prior to SARCLISA infusion to reduce the risk and severity of IRRs.[1]

Dexamethasone	40 mg orally or IV (or 20 mg orally or IV for patients ≥75 years of age)
Acetaminophen	650 mg to 1000 mg orally (or equivalent)
H_2 antagonists	Institution-preferred agent
Diphenhydramine	25 mg to 50 mg orally or IV (or equivalent) **The IV route is preferred for at least the first 4 infusions**

The above recommended dose of dexamethasone (orally or IV) corresponds to the total dose to be administered only once before infusion as part of the premedication and of the backbone treatment, before SARCLISA and pomalidomide administration.[1]

Administer the recommended premedication agents 15 to 60 minutes prior to starting a SARCLISA infusion.[1]

No post-treatment medications are required for SARCLISA

IRR=infusion-related reaction.

Important Safety Information (cont'd)

Infusion-Related Reactions (cont'd)

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 or recur after interruption, permanently discontinue SARCLISA and institute appropriate management. Permanently discontinue SARCLISA if a grade 3 or higher IRR occurs and institute appropriate emergency medical management.

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Preparation and Administration

Prepare the solution for infusion using an aseptic technique[1]

Calculate the dose (mg) of required SARCLISA based on actual patient weight (measured prior to each cycle to have the administered dose adjusted accordingly)

- More than one SARCLISA vial may be necessary to obtain the required dose for the patient

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit

Remove the volume of diluent from the 250-mL sodium chloride injection, USP, or 5% dextrose injection, USP, diluent bag that is equal to the required volume of SARCLISA injection

Withdraw the necessary volume of SARCLISA injection and dilute by adding to the infusion bag of 0.9% sodium chloride injection, USP, or 5% dextrose injection, USP, to achieve the appropriate SARCLISA concentration for infusion

The infusion bag must be made of polyolefins (PO), polyethylene (PE), polypropylene (PP), polyvinyl chloride (PVC) with di-(2-ethylhexyl) phthalate (DEHP), or ethyl vinyl acetate (EVA)

Gently homogenize the diluted solution by inverting the bag. Do not shake

Important Safety Information (cont'd)

Neutropenia

SARCLISA may cause neutropenia. Neutropenia (reported as laboratory abnormality) occurred in 96% of patients and grade 3-4 neutropenia occurred in 85% of patients treated with SARCLISA, pomalidomide, and dexamethasone (Isa-Pd). Febrile neutropenia occurred in 12% of patients and neutropenic infections, defined as infection with concurrent grade ≥3 neutropenia, occurred in 25% of patients treated with Isa-Pd. The most frequent neutropenic infections included those of upper respiratory tract (10%), lower respiratory tract (9%), and urinary tract (3%).

Preparation and Administration (cont'd)

Example dose calculations[1]

Dose × patient weight	Required dose	Withdrawal amount (20 mg/mL)
10 mg/kg × 60 kg	**600 mg** 	**30 mL**
10 mg/kg × 80 kg	**800 mg** 	**40 mL**
10 mg/kg × 100 kg	**1000 mg** 	**50 mL**

Administering SARCLISA

- Administer the infusion solution by IV infusion using an IV tubing infusion set (in PE, PVC with or without DEHP, polybutadiene [PBD], or polyurethane [PU]) with a 0.22-micron in-line filter (polyethersulfone [PES], polysulfone, or nylon)[1]
- The infusion solution should be administered for a period of time that will depend on the infusion rate (see table on page 8)[1]
- Use prepared SARCLISA infusion solution within 48 hours when stored refrigerated at 36°F to 46°F (2°C to 8°C), followed by 8 hours (including the infusion time) at room temperature[1]
- Do not administer SARCLISA infusion solution concomitantly in the same IV line with other agents[1]

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Infusion Rates of SARCLISA Administration

Incremental escalation of the infusion rate should be considered only in the absence of IRRs.[1] Refer to page 13 for dose modifications.

	Dilution volume	Initial rate	Absence of IRR	Rate increment	Maximum rate	Total time (if no rate adjustments)
First infusion	250 mL	25 mL/h	For 60 min	25 mL/h every 30 min	150 mL/h	**3 h 20 min**
Second infusion	250 mL	50 mL/h	For 30 min	50 mL/h for 30 min, then increase by 100 mL/h every 30 min	200 mL/h	**1 h 53 min**
Subsequent infusions	250 mL	200 mL/h	–	–	200 mL/h	**75 min**

SARCLISA should be administered by a healthcare professional, with immediate access to emergency equipment and appropriate medical support to manage IRRs if they occur.

75-minute infusion time starting after the second infusion in the absence of IRRs[1]

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 × 10^9/L, and provide supportive care with growth factors, according to institutional guidelines. No dose reductions of SARCLISA are recommended.

Second Primary Malignancies
Second primary malignancies were reported in 3.9% of patients in the SARCLISA, pomalidomide, and dexamethasone (Isa-Pd) arm and in 0.7% of patients in the pomalidomide and dexamethasone (Pd) arm, and consisted of skin squamous cell carcinoma (2.6% of patients in the Isa-Pd arm and in 0.7% of patients in the Pd arm), breast angiosarcoma (0.7% of patients in the Isa-Pd arm), and myelodysplastic syndrome (0.7% of patients in the Isa-Pd arm). With the exception of the patient with myelodysplastic syndrome, patients were able to continue SARCLISA treatment. Monitor patients for the development of second primary malignancies.

Infusion Times With Rate Increments

SARCLISA week 1 infusion, single dose			250-mL dilution volume	
Start	**End**	**Rate (mL/h)**	**mL infused**	**Total infused**
0:00	0:30	25	12.5	12.5
0:30	1:00	25	12.5	25
1:00	1:30	50	25	50
1:30	2:00	75	37.5	87.5
2:00	2:30	100	50	137.5
2:30	3:00	125	62.5	200
3:00	3:20	150	50	250
Total time	**3:20**			

SARCLISA week 2 infusion, single dose			250-mL dilution volume	
Start	**End**	**Rate (mL/h)**	**mL infused**	**Total infused**
0:00	0:30	50	25	25
0:30	1:00	100	50	75
1:00	1:52:30	200	175	250
Total time	**1:52:30**			

SARCLISA week 3 infusion, single dose			250-mL dilution volume	
Start	**End**	**Rate (mL/h)**	**mL infused**	**Total infused**
0:00	1:15	200	250	250
Total time	**1:15**			

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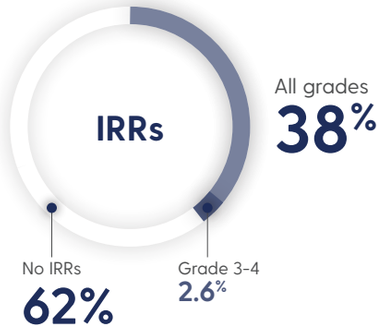
Adverse Reactions for SARCLISA + Pd

IRRs[1]

Onset of IRRs was typically within 24 hours from the start of the infusion. IRRs were reported in 38% of patients treated with SARCLISA.

- 1st All patients who experienced IRRs experienced them during the first infusion of SARCLISA. IRRs resolved on the same day in 98% of cases
  - 2% of patients also experienced IRRs at their second infusion, and 1.3% experienced IRRs at their fourth infusion
- Signs and symptoms of grade 3 or higher IRRs included dyspnea, hypertension, and bronchospasm



- The incidence of infusion interruptions because of IRRs was 29.6%. The median time to infusion interruption was 55 minutes
- SARCLISA alone was discontinued in 3% of patients due to IRRs

Managing IRRs[1]

- Monitor vital signs frequently during the entire SARCLISA infusion
- For patients with grade 1 or 2 reactions, interrupt SARCLISA infusion and provide appropriate medical support
  - If symptoms improve, 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, as shown on page 9
  - If symptoms do not improve or recur after interruption, permanently discontinue SARCLISA and institute appropriate management
- If a grade 3 or higher IRR occurs, permanently discontinue SARCLISA therapy and institute appropriate medical management

Adverse Reactions for SARCLISA + Pd (cont'd)

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

	SARCLISA + Pd (n=152)			Pd (n=149)		
Adverse reaction	**All grades**	**Grade 3**	**Grade 4**	**All grades**	**Grade 3**	**Grade 4**
IRRs	38%	1.3%	1.3%	0%	0%	0%
Infections						
Pneumonia[a]	31%	22%	3.3%	23%	16%	2.7%
Upper respiratory tract infection[b]	57%	9%	0%	42%	3.4%	0%
Blood and lymphatic system disorders						
Febrile neutropenia	12%	11%	1.3%	2%	1.3%	0.7%
Respiratory, thoracic, and mediastinal disorders						
Dyspnea[c]	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]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.
[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]Dyspnea includes dyspnea, dyspnea exertional, and dyspnea at rest.

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Adverse Reactions for SARCLISA + Pd (cont'd)

Treatment-emergent 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
Anemia	99%	32%	0%	97%	28%	0%
Neutropenia	96%	24%	61%	92%	38%	31%
Lymphopenia	92%	42%	13%	92%	35%	8%
Thrombocytopenia	84%	14%	16%	79%	9%	15%

Serious and fatal adverse reactions[1]

- Serious adverse reactions occurred in 62% of patients receiving SARCLISA + Pd
  - 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 (those that occurred in more than 1% of patients were pneumonia and other infections [3%])

Discontinuation rates[1]

- Dosage interruptions due to an adverse reaction occurred in 31% of patients who received SARCLISA + Pd. The most frequent adverse reaction requiring dosage interruption was IRR (28%)
- 7% of patients receiving SARCLISA + Pd permanently discontinued treatment due to adverse reactions

Adverse Reactions for SARCLISA + Pd (cont'd)

Infections[1]

- The incidence of grade 3 or higher infections was 43% in the SARCLISA + Pd group
- Pneumonia was the most commonly reported severe infection, with grade 3 reported in 22% of patients in the SARCLISA + Pd group compared with 16% in the Pd group, and grade 4 in 3.3% of patients in the SARCLISA + Pd group compared with 2.7% in the Pd group
- Discontinuations from treatment due to infection were reported in 2.6% of patients in the SARCLISA + Pd group compared with 5.4% in the Pd group
- Fatal infections were reported in 3.3% of patients in the SARCLISA + Pd group compared with 4% in the Pd group

Neutropenia[1]

- 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
- If grade 4 neutropenia occurs, consider dose delays until neutrophil count recovery to at least 1.0 × 10^9/L, and provide supportive care with growth factors, according to institutional guidelines

Dose modifications[1]

No dose reduction of SARCLISA is recommended. Dose delay may be required to allow recovery of blood counts in the event of hematological toxicity. For information concerning drugs given in combination with SARCLISA, see the manufacturer's Prescribing Information.

For other medicinal products that are administered with SARCLISA, refer to the respective current Prescribing Information.

No dose reduction of SARCLISA is recommended[1]

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Storage and Handling

SARCLISA injection is a clear to slightly opalescent, colorless to slightly yellow solution, essentially free of visible particulates, supplied as follows[1]:

- One 100 mg/5 mL single-dose vial in a carton: NDC 0024-0654-01
- One 500 mg/25 mL single-dose vial in a carton: NDC 0024-0656-01

Storage requirements[1]

- Store SARCLISA in a refrigerator at 36°F to 46°F (2°C to 8°C) in the original carton to protect from light
- Do not freeze
- Do not shake

Handling and disposal[1]

Discard unused portion of solution. All materials that have been utilized for dilution and administration should be disposed of according to standard procedures.

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). In ICARIA-multiple myeloma (MM), the indirect antiglobulin test was positive during SARCLISA treatment in 67.7% of the tested 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.

Important Safety Information (cont'd)

Laboratory Test Interference (cont'd)

Interference with Serological Testing (Indirect Antiglobulin Test) (cont'd)

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 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

The most common adverse reactions (≥20%) were neutropenia (laboratory abnormality, 96% Isa-Pd vs 92% Pd), infusion-related reactions (38% Isa-Pd vs 0% Pd), pneumonia (31% Isa-Pd vs 23% Pd), upper respiratory tract infection (57% Isa-Pd vs 42% Pd), and diarrhea (26% with Isa-Pd vs 19% Pd). Serious adverse reactions occurred in 62% of patients receiving SARCLISA. 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%]).

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.

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Key Benefits of SARCLISA Dosing and Administration

75-minute infusion time starting after the second infusion in the absence of IRRs[1]
- All patients who experienced IRRs experienced them during the first infusion of SARCLISA. IRRs resolved on the same day in 98% of cases

Weight-based dosing with 250-mL fixed-volume dilution[1]
- Vials available in convenient 100 mg/5 mL and 500 mg/25 mL sizes

No postinfusion medications required[1]
- Premedication is administered prior to infusion to reduce the risk and severity of IRRs

CareASSIST by Sanofi Genzyme for SARCLISA:
Resources and support for your eligible patients

Call **1-833-WE+CARE** (1-833-930-2273), Mon – Fri, 9 AM – 8 PM ET, or visit **SanofiCareAssist.com/hcp/sarclisa** to learn more.

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 two prior therapies including lenalidomide and a proteasome inhibitor.

Select 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

Infusion-related reactions (IRRs) have been observed in 39% of patients treated with SARCLISA. All IRRs started during the first SARCLISA infusion and resolved on the same day in 98% of the cases. The most common symptoms of an IRR included dyspnea, cough, chills, and nausea. The most common severe signs and symptoms included hypertension and dyspnea.

Please see full Prescribing Information.

Reference: 1. SARCLISA [prescribing information]. Bridgewater, NJ: sanofi-aventis U.S. LLC.

SANOFI GENZYME

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