NOW APPROVED: A NEW CD38-DIRECTED THERAPY[1]

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

NCCN Guidelines® Category 1 recommendation for isatuximab-irfc (SARCLISA)

Isatuximab-irfc (SARCLISA), in combination with pomalidomide and dexamethasone, is recommended by the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) as a Category 1 option for previously treated multiple myeloma.[2]

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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 full Prescribing Information.

Important Safety Information (cont'd)

WARNINGS AND PRECAUTIONS

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. 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.

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%).

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.

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. 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.

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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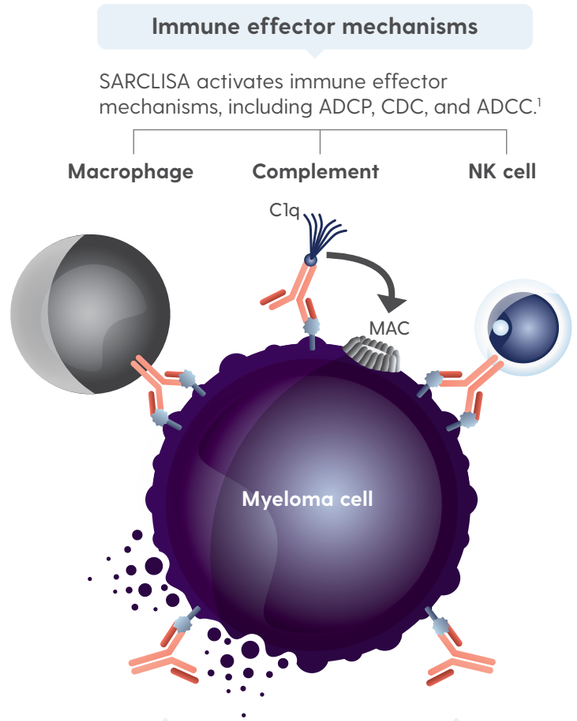
SARCLISA: A CD38-directed cytolytic antibody

Selective binding triggers multiple mechanisms, leading to the death of CD38-expressing tumor cells[1]



The combination of SARCLISA and pomalidomide enhanced ADCC activity and direct tumor cell killing compared to SARCLISA alone in vitro.[1]

Image is not to scale.

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

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The first phase 3 trial evaluating a CD38-directed monoclonal antibody + Pd vs Pd alone

A multicenter, open-label, randomized, phase 3 study in patients with relapsed refractory multiple myeloma[1]

Patients with relapsed refractory multiple myeloma who received at least 2 prior therapies, including lenalidomide and a PI

Randomized 1:1 (N=307)

SARCLISA + Pd (n=154)

Pd (n=153)

- 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

- 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]

IV=intravenous; ORR=overall response rate; OS=overall survival; Pd=pomalidomide and dexamethasone; PFS=progression-free survival; PI=proteasome inhibitor.

Important Safety Information

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. 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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Baseline characteristics

Baseline characteristics (N=307)[1]

Median patient age	67 y (range 36-86)
≥75 y	20%
History of COPD or asthma at study entry	10%
Renal impairment (creatinine clearance <60 mL/min/1.73 m²)	34%
ISS stage at study entry	
Stage I	37%
Stage II	36%
Stage III	25%
Patients with high-risk chromosomal abnormalities at study entry	20%
del(17p)	12%
t(4;14)	8%
t(14;16)	2%
Median number of prior lines of therapy	3 (range 2-11)
Received prior PI	100%
Received prior lenalidomide	100%
Received prior stem cell transplantation	56%
Refractory to lenalidomide	93%
Refractory to a PI	76%
Refractory to both an immunomodulator and a PI	73%

In the trial population[1]

93% of patients were refractory to lenalidomide

20% of patients had high-risk chromosomal abnormalities at study entry

34% of patients had renal impairment

10% of patients had a history of COPD or asthma at study entry

COPD=chronic obstructive pulmonary disease; ISS=International Staging System.

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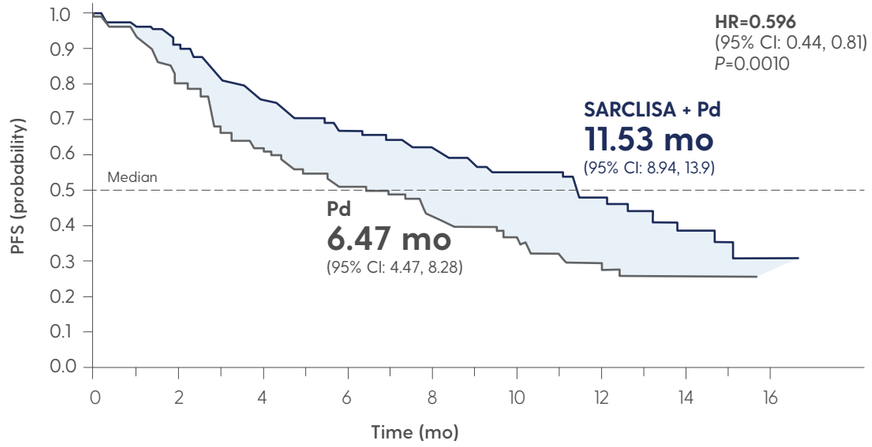
Significant increase in median PFS demonstrated with SARCLISA + Pd vs Pd alone

PFS (primary endpoint)[1]



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 follow-up was 11.6 months.[1]

40% **reduction in the risk of disease progression or death** in patients treated with SARCLISA + Pd[1]

IMWG=International Myeloma Working Group; IRC=independent response committee.

Important Safety Information (cont'd)

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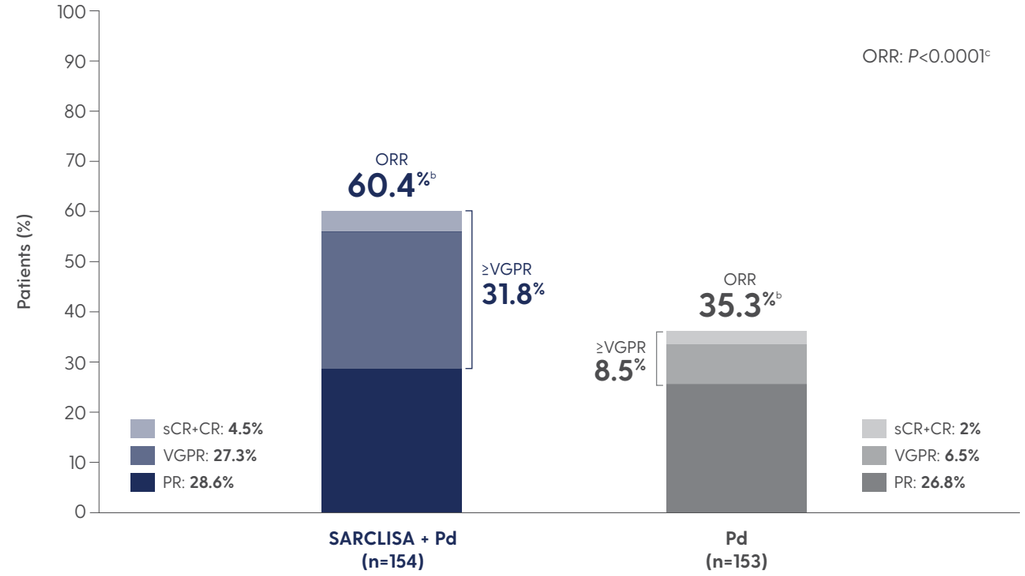
SARCLISA + Pd improved ORR and ≥VGPR vs Pd alone

ORR (secondary endpoint)[1,a]



[a]sCR, CR, VGPR, and PR were evaluated by the IRC using the IMWG response criteria.
[b]SARCLISA + Pd (95% CI: 52.2%, 68.2%), Pd (95% CI: 27.8%, 43.4%). 95% CI estimated using the Clopper-Pearson method.
[c]Stratified by age (<75 years vs ≥75 years) and number of previous lines of therapy (2 or 3 vs >3) according to interactive response technology.

- The median duration of treatment was 41 weeks for the SARCLISA + Pd group compared with 24 weeks for the Pd group[1]
- Median OS was not reached for either treatment group at interim analysis[1]

Median time to first response was 35 days in the SARCLISA + Pd arm vs 58 days in the Pd arm[1]

NCCN Guidelines Category 1 recommendation for isatuximab-irfc (SARCLISA)

Isatuximab-irfc (SARCLISA), in combination with pomalidomide and dexamethasone, is recommended by the NCCN Guidelines as a Category 1 option for previously treated multiple myeloma.[2]

CR=complete response; PR=partial response; sCR=stringent complete response; VGPR=very good partial response.

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Safety profile

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

Adverse reaction	SARCLISA + Pd (n=152), %			Pd (n=149), %		
	All grades	Grade 3	Grade 4	All grades	Grade 3	Grade 4
Infusion-related reactions	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	–	19	0.7	–
Nausea	15	0	–	9	0	–
Vomiting	12	1.3	–	3.4	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.

7% of patients who received SARCLISA discontinued treatment due to an adverse reaction (grades 1-4)[1]

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

Safety profile (cont'd)

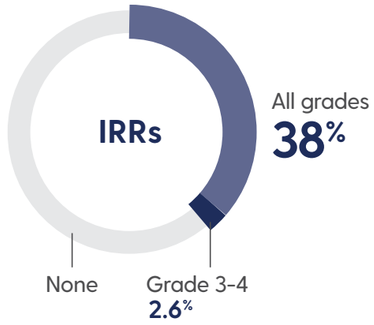
Treatment-emergent hematology laboratory abnormalities in patients receiving SARCLISA + Pd vs Pd alone[1]

Laboratory parameter	SARCLISA + Pd (n=152), n (%)			Pd (n=149), n (%)		
	All grades	Grade 3	Grade 4	All grades	Grade 3	Grade 4
Anemia	151 (99)	48 (32)	0	145 (97)	41 (28)	0
Neutropenia	146 (96)	37 (24)	92 (61)	137 (92)	57 (38)	46 (31)
Lymphopenia	140 (92)	64 (42)	19 (13)	137 (92)	52 (35)	12 (8)
Thrombocytopenia	127 (84)	22 (14)	25 (16)	118 (79)	14 (9)	22 (15)

Infusion-related reactions[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.

- 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



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 and in 4% in the Pd group

IRR=infusion-related reaction.

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Recommended dose and schedule

Administer preinfusion medications. The recommended dose of SARCLISA is 10 mg/kg actual body weight administered as an intravenous (IV) infusion in combination with pomalidomide and dexamethasone (Pd).[1]

- SARCLISA is given as a 250-mL fixed-volume infusion[1]
- No dose reduction of SARCLISA is recommended[1]

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

- 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]
- Treatment is repeated until disease progression or unacceptable toxicity[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]

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. 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.

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Administration and infusion rates

Preparation and administration[1]

- 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 solution should be administered for a period of time that will depend on the infusion rate. 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
- Do not administer SARCLISA infusion solution concomitantly in the same IV line with other agents

Infusion rates of SARCLISA administration[1]

Incremental escalation of the infusion rate should be considered only in the absence of IRRs.

	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**

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

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Premedication and dose modifications

Premedication[1]

Administer the following premedications prior to SARCLISA infusion to reduce the risk and severity of IRRs:

- 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
- 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.

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

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 manufacturer's Prescribing Information.

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

No post-treatment medications are required for SARCLISA

Important Safety Information (cont'd)

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.

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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CareASSIST by Sanofi Genzyme for SARCLISA

Resources and support for your eligible patients

Access and Reimbursement
Assistance navigating the insurance process, including benefits investigations, claims assistance, and information about prior authorizations and appeals.

Financial Assistance
CareASSIST offers programs and services that can help eligible patients with the cost of SARCLISA.

Resource Support
Information on independent support services for patients and caregivers, as well as product ordering and replacement information.

If your patients have commercial insurance, they may qualify for **the CareASSIST Copay Program***

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.

*Restrictions may apply. Please visit SanofiCareAssist.com/hcp/sarclisa for full program details.

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Introducing SARCLISA: A new CD38-directed monoclonal antibody

SARCLISA was approved based on a phase 3 trial in combination with Pd vs Pd alone[1]

Significant increase in median PFS[1]

SARCLISA + Pd
11.53 months

vs

Pd alone
6.47 months

HR=0.596; *P*=0.0010

Improved response rates[1]

SARCLISA + Pd
60.4% ORR

vs

Pd alone
35.3% ORR

SARCLISA + Pd
31.8% ≥VGPR

vs

Pd alone
8.5% ≥VGPR

ORR: *P*<0.0001

- 7% of patients who received SARCLISA discontinued treatment due to an adverse reaction (grades 1-4)[1]

Infusion time decreases after the first infusion[1]

Infusion time decreases to 75 minutes starting after the second infusion in the absence of IRRs.

Most common adverse reactions (≥20%)

Neutropenia (laboratory abnormality, 96% with SARCLISA + Pd vs 92% with Pd), upper respiratory tract infection (57% with SARCLISA + Pd vs 42% with Pd), IRRs (38% with SARCLISA + Pd vs 0% with Pd), pneumonia (31% with SARCLISA + Pd vs 23% with Pd), and diarrhea (26% with SARCLISA + Pd vs 19% with Pd)[1]

Indication

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References: 1. SARCLISA [prescribing information]. Bridgewater, NJ: sanofi-aventis U.S. LLC.
2. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Multiple Myeloma V.3.2020. © National Comprehensive Cancer Network, Inc. 2020. All rights reserved. Accessed March 20, 2020. To view the most recent and complete version of the guideline, go online to NCCN.org.

SANOFI GENZYME

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