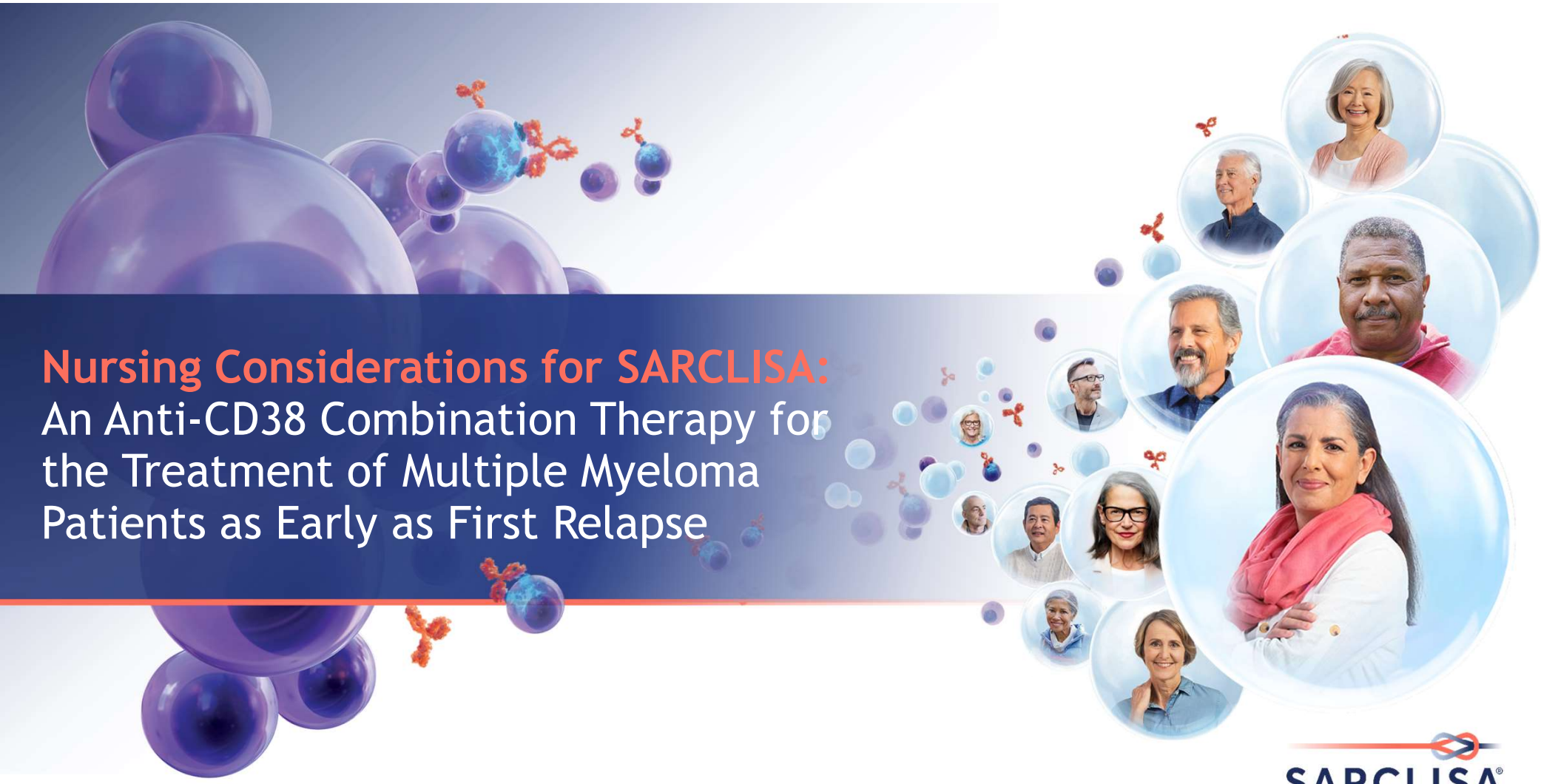
Nursing Considerations for SARCLISA:
An Anti-CD38 Combination Therapy for the Treatment of Multiple Myeloma Patients as Early as First Relapse



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MAT-US-2020341-V3.0-8/2021

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

Important Disclosures

- This program is sponsored by Sanofi Genzyme
- The content contained in this presentation was developed by Sanofi Genzyme
- No continuing medical education (CME) credits are available
- The speaker is a paid consultant for Sanofi Genzyme

Presentation Overview

Learn about the indications, dosage and administration, safety profile, and additional important safety information for SARCLISA in patients with Relapsed or Refractory Multiple Myeloma (RRMM)

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

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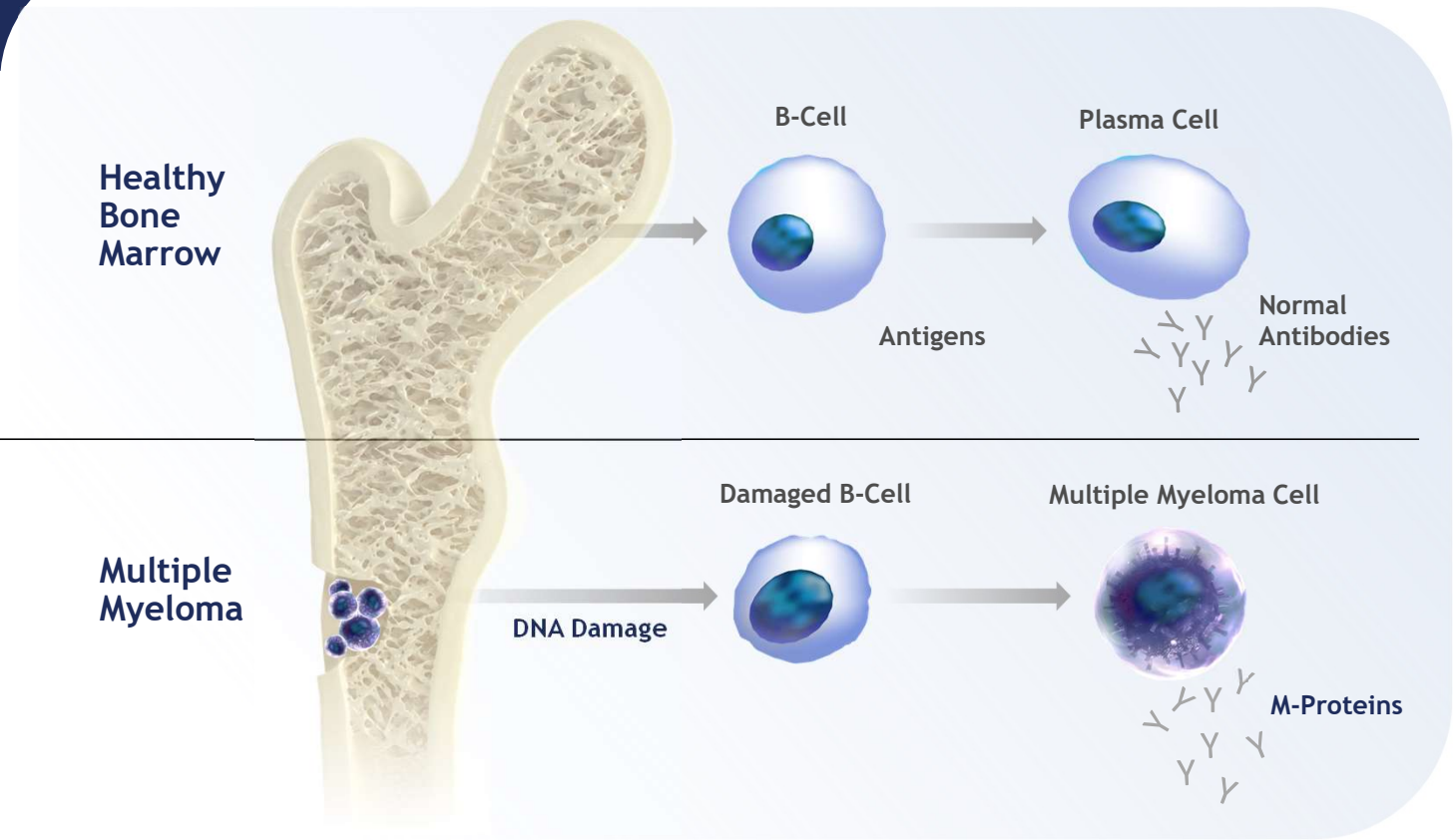
Multiple Myeloma Is an Incurable Clonal Plasma Cell Malignancy[1]



- Multiple myeloma is characterized by **secretion of monoclonal immunoglobulin protein** (M-protein), which is produced by abnormal plasma cells[2]
- The clinical manifestations of disease are driven by **monoclonal protein, malignant cells, or cytokines** secreted from malignant cells and include signs of end-organ damage[2]

References: 1. Remes K, et al. *PLoS One*. 2018;13(12):e0208507; **2.** Kumar SK, et al. *Nat Rev Dis Primers*. 2017;3:17046.

Diagnosis of Multiple Myeloma Stems From a Combination of End-Organ Damage and Biomarkers of Active Disease

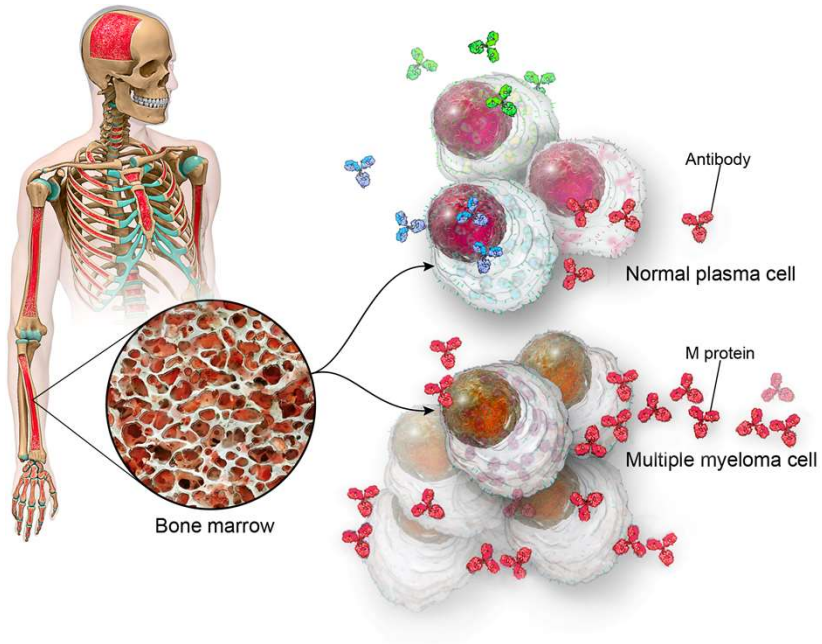
Diagnosis of Multiple Myeloma requires any <u>one or more</u> of the following criteria below*

Biomarker of malignancy (SLiM Criteria)

- **S** ≥**S**ixty-percent (60%) clonal BM plasma cells
- **Li** Serum free **Li**ght chain ratio involved:uninvolved ≥100
- **M** >1 focal lesion (≥5 mm each) detected by **M**RI studies

CRAB criteria refers to evidence of end-organ damage

- **C** **C**alcium elevation (>11 mg/dL or >1 mg/dL higher than ULN)
- **R** **R**enal insufficiency (CrCl <40 mL/min or serum creatinine >2 mg/dL)
- **A** **A**nemia (Hb <10 g/dL or > 2 g/dL below the LLN)
- **B** **B**one disease (≥1 lytic lesions on skeletal radiography, CT or PET/CT)



*In addition to Clonal bone marrow plasma cells >10% or biopsy-proven bony or extramedullary plasmacytoma.
BM, bone marrow; CrCl, creatinine clearance; CT, computed tomography; LLN, lower limit of normal; MRI, magnetic resonance imaging; PET, positron emission tomography; ULN, upper limit of normal.
Reference: Rajkumar SV. *Am Soc Clin Oncol Educ Book*. 2016;35:e418-e423.

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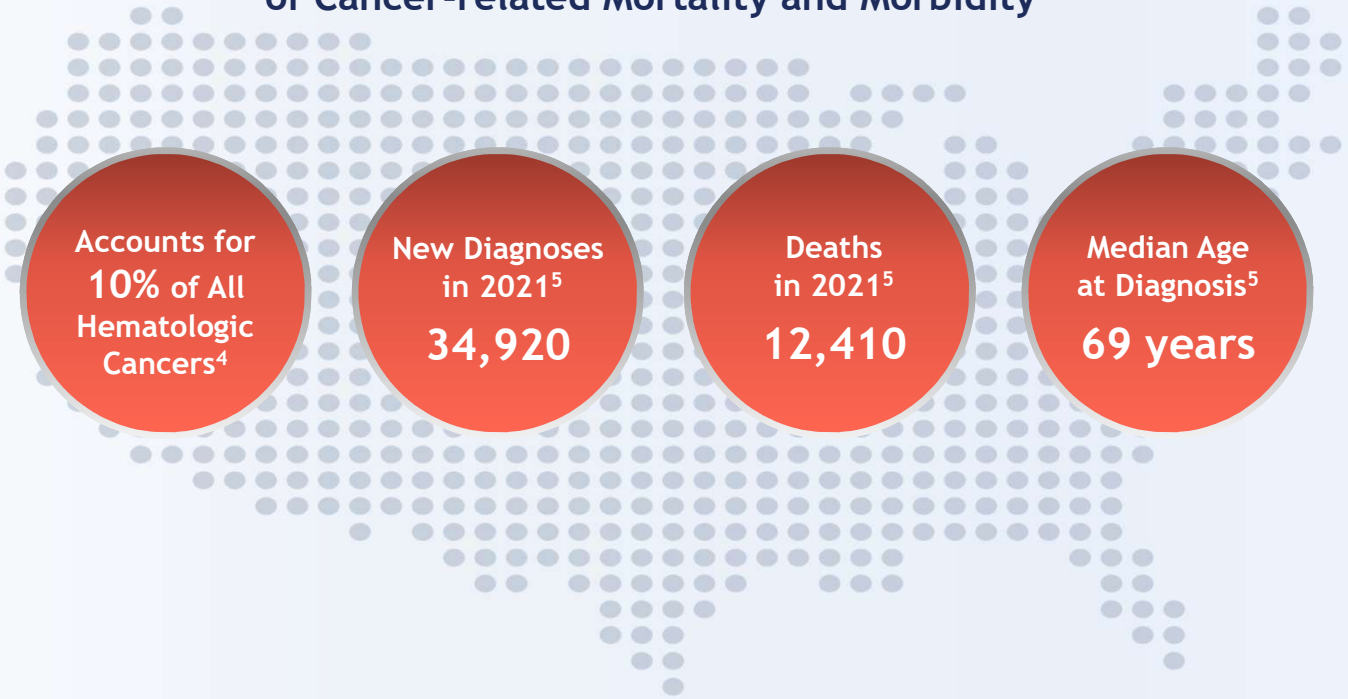
Multiple Myeloma Is the Second Most Common Hematologic Malignancy[1]*

Multiple Myeloma Represents a Significant Cause of Cancer-related Mortality and Morbidity[2-5]*

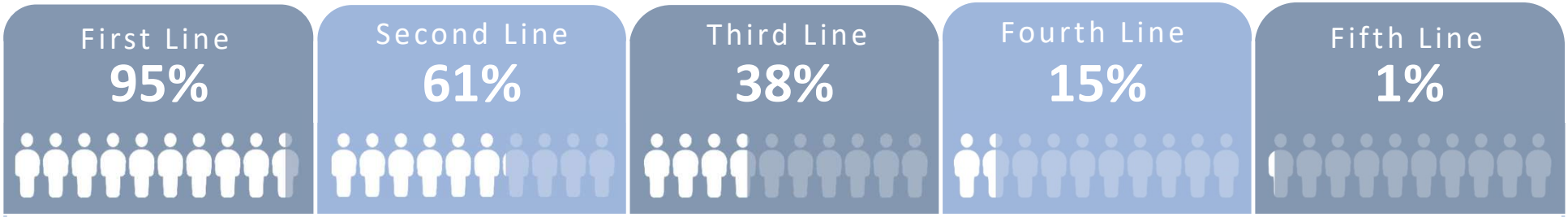


*These statistics were derived from SEER Cancer database, April 2021.

References: **1**. Kazandjian D. *Semin Oncol*. 2016;43(6):676-681; **2**. Terpos E, et al. *Haematologica*. 2015;100(10):1254-1266; **3**. Kvam AK, Waage A. *Haematologica*. 2015;100(6):704-705; **4**. Rajkumar SV. *Am J Hematol*. 2016;91(7):719-734; **5**. National Cancer Institute (NCI). Cancer stat facts: myeloma. https://seer.cancer.gov/statfacts/html/mulmy.html. Accessed April 15, 2021.

It Is Imperative to Choose the Appropriate Treatment for Each Patient at First Relapse[1-4]

~15%-35% of Patients Are Lost in Every Line of Therapy[1]



Additional factors may impact outcomes or limit treatment options for these patients[2-4]

Poor prognostic factors*

Prior therapies

- Relapsed on and/or refractory to IMiD®s and/or PIs

Patient Specific Factors

- High cytogenetic risk
- Renal impairment
- Advanced age

It's important to choose an appropriate treatment regimen that can extend PFS and deepen responses† for individual patients, including those with poor prognostic factors[2,5]

*Poor prognostic factors may include renal insufficiency, advanced age, high cytogenetic risk, and refractoriness to prior therapies[3,4]; †a response of VGPR or better.[6-8]
IMiD®, immunomodulatory drug; PI, proteasome inhibitor.

References: 1. Yong K, et al. *Br J Haematol*. 2016;175(2):252-264. **2.** Moreau P, et al. *Blood Cancer J*. 2019;9(4):38; **3.** Jhaveri M, et al. Poster presented at: Copenhagen 21st Congress of the European Hematology Association, June 9-12, 2016; Copenhagen, Denmark. **4.** Hájek R, et al. *Clin Lymphoma Myeloma Leuk*. 2018;18(6):e219-e240. **5.** Dimopoulos M, et al. Leukemia. 2020. doi:10.1038/s41375-020-01021-3. 6. Fulciniti M, et al. Biomed Res Int. 2015;2015:1-7. doi:10.1155/2015/832049. 7. Lahuerta JJ, et al. J Clin Oncol. 2017;35(25):2900-2910. doi:10.1200/JCO.2016.69.2517. 8. Data on file. sanofi-aventis U.S. LLC.

SARCLISA Is FDA Approved in Two Different Combinations as Early as First Relapse

Indications

SARCLISA + Kd

SARCLISA is indicated, in **combination with carfilzomib and dexamethasone (Kd),** for the treatment of adult patients with relapsed or refractory multiple myeloma who have received 1 to 3 prior lines of therapy

SARCLISA + Pd

SARCLISA is indicated, in **combination with pomalidomide and dexamethasone (Pd),** for the treatment of adult patients with multiple myeloma who have received at least 2 prior therapies including lenalidomide and a proteasome inhibitor

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

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

Both Isatuximab-irfc (SARCLISA) Regimens are National Comprehensive Cancer Network® (NCCN ®) Category 1 Preferred Options for Early Relapse*

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Multiple Myeloma Recommend isatuximab-irfc (SARCLISA) as a Category 1 Preferred Option for Early Relapses*:

- In combination with pomalidomide and dexamethasone
- In combination with carfilzomib and dexamethasone

NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

*1-3 prior therapies

Reference: Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Multiple Myeloma V.1.2022. © National Comprehensive Cancer Network, Inc. 2021. All rights reserved. Accessed [Aug 18, 2021]. To view the most recent and complete version of the guideline, go online to NCCN.org.

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

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.

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

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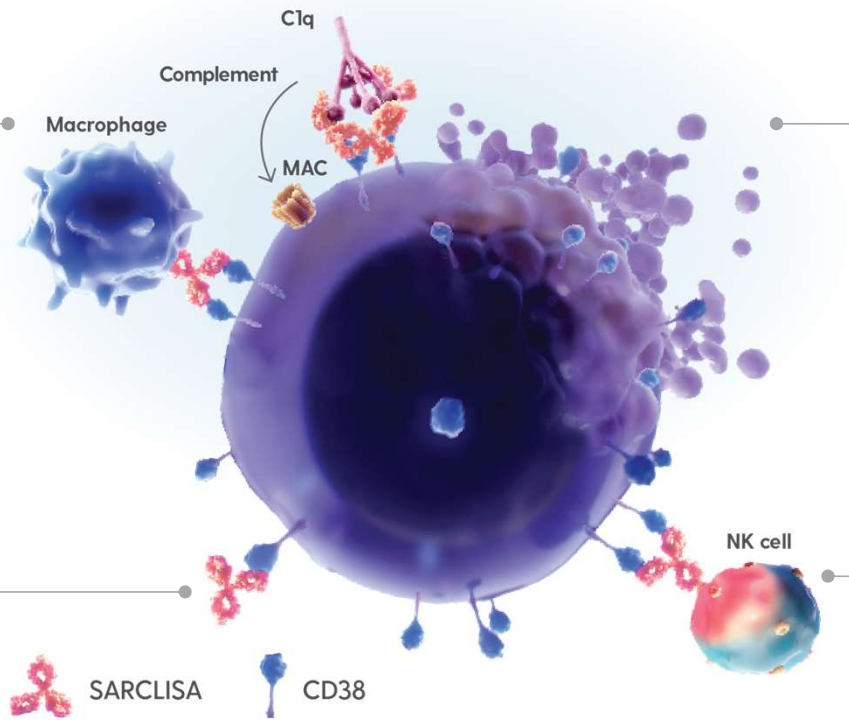
SARCLISA Is a Multimodal Anti-CD38 mAb[1,2]

Targeted Binding to a Specific Epitope Induces Distinct Antitumor Activity[1,2]

Triggers Cancer Cell Death
through **tumor cell targeting,** including ADCC, ADCP, and CDC[1]

Inhibits CD38
enzymatic activity through **suppression of CD38 ectoenzyme**[1,3]



Directly Destroys
myeloma cells through apoptosis, **without the need for crosslinking**[1,3]

Enhances Immune Cell Function
through NK cell **activation and a decrease** in immunosuppressors[1]

ADCC, antibody-dependent cell-mediated cytotoxicity; ADCP, antibody-dependent cellular phagocytosis; CDC, complement-dependent cytotoxicity; NK, natural killer.

References: 1. SARCLISA [prescribing information]. Bridgewater, NJ: sanofi-aventis U.S. LLC. **2.** Martin TG, et al. *Cells*. 2019;8(12):E1522. **3.** Attal M, et al. *Lancet*. 2019;394(10214):2096-2107.

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

SARCLISA Dosing and Schedule

SARCLISA Recommended Dose: 10 mg/kg* IV

Weekly dosing transitions to every other week after the first cycle

Treatment is administered in 28-day cycles and repeated until disease progression or unacceptable toxicity

- No dose reduction of SARCLISA is recommended
- Dose delay may be required to allow recovery of blood counts in the event of hematological toxicity
- SARCLISA should be administered by a healthcare professional with immediate access to emergency equipment and appropriate medical support to manage IRRs if they occur
- For dosing instructions of combination agents administered with SARCLISA, refer to study design descriptions in the SARCLISA Prescribing Information and the respective manufacturer's current Prescribing Information

*Based on actual body weight administered as an IV infusion with Pd or Kd.
For other medicinal products that are administered with SARCLISA, refer to the respective manufacturer's current Prescribing Information.
IRRs, infusion-related reactions; IV, intravenous; Kd, carfilzomib and dexamethasone; Pd, pomalidomide and dexamethasone.
Reference: SARCLISA [prescribing information]. Bridgewater, NJ: sanofi-aventis U.S. LLC.

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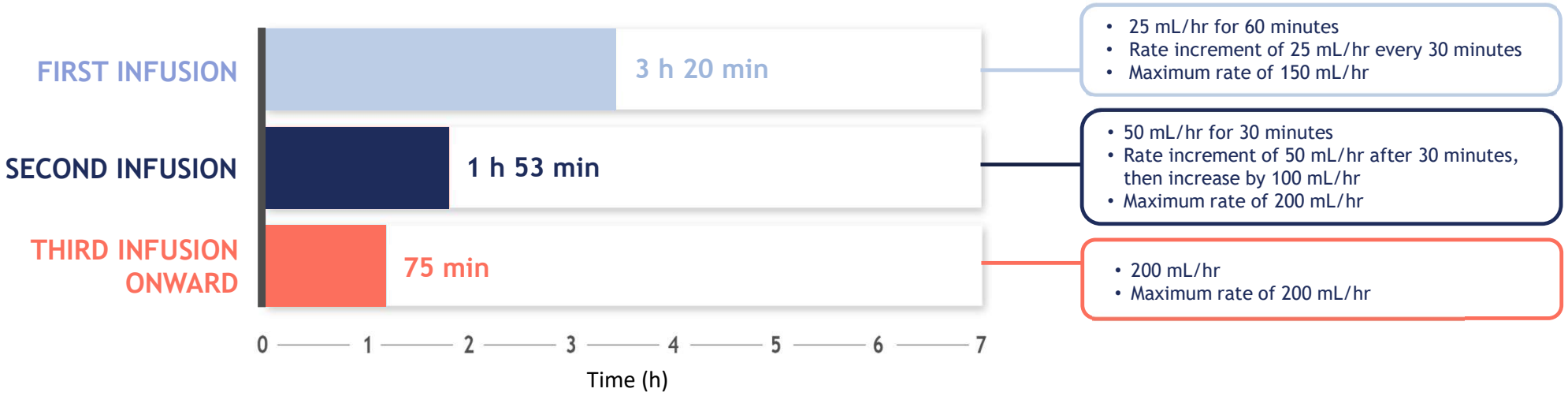
SARCLISA® (isatuximab-irfc)
Injection for IV use | 500 mg/25 mL, 100 mg/5 mL

Infusion Times Decrease to 75 Minutes After Second Infusion

Fixed Infusion Volume of 250 mL

Infusion times reduce after first cycle*



- Following dilution, the SARCLISA infusion should be administered intravenously at the infusion rates presented
- Incremental escalation of the infusion rate should be considered only in the absence of IRRs

*Total time if no rate adjustments
IRRs, infusion-related reactions.
Reference: SARCLISA [prescribing information]. Bridgewater, NJ: sanofi-aventis U.S. LLC.

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Recommended Premedications and Sequencing of Therapies

Recommended Premedication Agents
(administer 15-60 minutes prior)

Dexamethasone
PO or IV

Acetaminophen
650 mg to 1000 mg PO (or equivalent)

Diphenhydramine
Diphenhydramine 25 mg to 50 mg IV or PO (or equivalent). The intravenous route is preferred for at least the first 4 infusions

H_2 Antagonists
Institution-preferred agent

On the days when both SARCLISA and carfilzomib are administered, administer dexamethasone first, followed by SARCLISA infusion, then followed by carfilzomib infusion

No required post-infusion medications following administration of SARCLISA

The above recommended dose of dexamethasone is 40 mg orally or IV (or 20 mg orally or IV for patients ≥75 years of age) when administered in combination with SARCLISA and pomalidomide and 20 mg (IV on the days of SARCLISA and/or carfilzomib infusions and orally on the other days) when administered in combination with SARCLISA and carfilzomib.

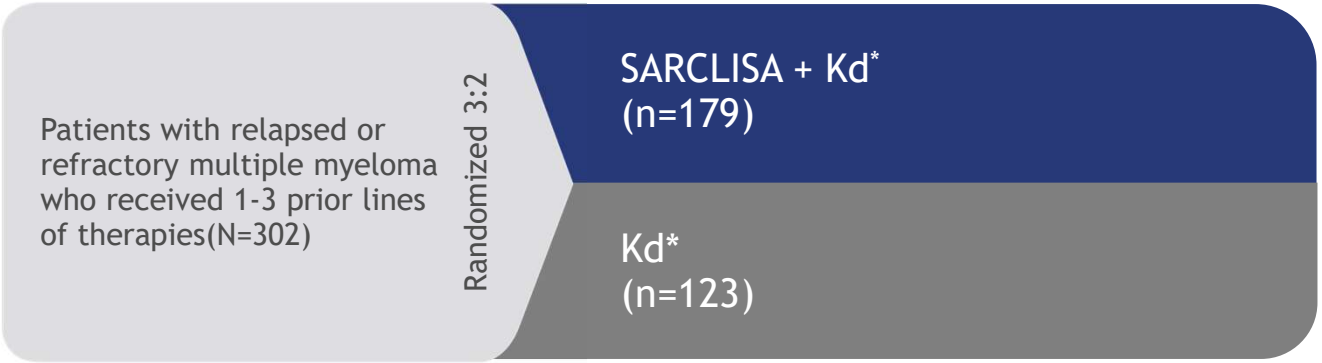
The above recommended dose of dexamethasone (orally or IV) corresponds to the total dose to be administered only once before infusion as part of the premedication and of the backbone treatment, before SARCLISA and pomalidomide or SARCLISA and carfilzomib administration

IV, intravenous; PO, *per os* (by mouth).
Reference: SARCLISA [prescribing information]. Bridgewater, NJ: sanofi-aventis U.S. LLC.

IKEMA Trial: SARCLISA + Carfilzomib and Dexamethasone (Kd) vs Kd Alone[1,2]

IKEMA: SARCLISA + Kd

IKEMA: A Multicenter, Multinational, Open-Label, Randomized, Phase 3 Study[1]



Primary Endpoint[1,2]:
PFS†

Key Secondary Endpoints[1,2]:
ORR, ≥VGPR, CR, MRD negativity, OS

*Carfilzomib was administered during cycle 1 at a dose of 20 mg/m^2 on days 1-2 and at 56 mg/m^2 on days 8, 9, 15, and 16; and during subsequent cycles at 56 mg/m^2 on days 1, 2, 8, 9, 15, and 16 of each 28-day cycle. 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 for each 28-day cycle.[1]

Administration[1]

- 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
- For dosing instructions of combination agents administered with SARCLISA, refer to study design descriptions in the SARCLISA Prescribing Information and the respective manufacturer's current Prescribing Information

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

CR, complete response; DOR, duration of response; IMWG, International Myeloma Working Group; IRC, independent response committee; IV, intravenous; MRD, minimal residual disease; ORR, overall response rate; PFS, progression-free survival; QOL, quality of life; TTP, time to progression; VGPR, very good partial response.

References: 1. SARCLISA [prescribing information]. Bridgewater, NJ: sanofi-aventis U.S. LLC. **2.** Data on file. sanofi-aventis U.S. LLC.

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Adverse Reactions for SARCLISA + Kd[1,2]

IKEMA: SARCLISA + Kd

Adverse Reactions (≥10%) in Patients Receiving SARCLISA + Kd With a Difference Between Arms of ≥5% Compared to 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%

Serious adverse reactions and cardiac events

- 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%) [1]
- Fatal adverse reactions occurred in 3.4% of patients receiving SARCLISA + Kd vs 3.3% of patients receiving Kd[1,2]
  - Those that occurred in >1% of patients receiving SARCLISA + Kd were pneumonia occurring in 1.7% and cardiac failure in 1.1%[1]
- Cardiac failure was reported in 7.3% of patients who received SARCLISA + Kd (grade ≥3 in 4%) and in 6.6% of patients who received Kd (grade ≥3 in 4.1%)[1]
  - Grade ≥3 hypertension was reported in 20% of patients who received SARCLISA + Kd and in 18% of patients who received Kd[1]

[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.
Kd, carfilzomib and dexamethasone; IRR, infusion-related reaction.

References: SARCLISA [prescribing information]. Bridgewater, NJ: sanofi-aventis U.S. LLC.2. Data on file. sanofi-aventis U.S. LLC.

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Adverse Reactions for SARCLISA + Kd (cont'd)[1,2]

IKEMA: SARCLISA + Kd

Hematologic Laboratory Abnormalities During Treatment Period in Patients Receiving SARCLISA + Kd vs Kd Alone[1*]

	SARCLISA + Kd (n=177)			Kd (n=122)		
Laboratory parameter	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%

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.[1]

- The median duration of treatment was 80 weeks for the SARCLISA + Kd group compared to 61 weeks for the Kd group[1]

Permanent Treatment Discontinuation Due to Adverse Reactions, grades 1-4[1,2]

SARCLISA + Kd	Kd
8%	**14%**

- The most frequent adverse reactions requiring permanent discontinuation were infections (2.8% with SARCLISA + Kd vs 4.9% with Kd)[1,2]

Additional Safety Information

- 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%) [1]

*The denominator used to calculate the percentage was based on the safety population.
Kd, carfilzomib and dexamethasone; IRR, infusion-related reaction.
References: 1. SARCLISA [prescribing information]. Bridgewater, NJ: sanofi-aventis U.S. LLC. 2. Data on file. sanofi-aventis U.S. LLC.

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ICARIA-MM Trial: SARCLISA + Pomalidomide and Dexamethasone (Pd) vs Pd Alone[1,2]

ICARIA-MM: SARCLISA + Pd

A Phase 3, Multicenter, Multinational, Open-Label Randomized Study[1]

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

Randomized 1:1

- SARCLISA + Pd* (n=154)
- Pd* (n=153)

Primary Endpoint[1]:
PFS†

Key Secondary Endpoints[1,2]:
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]

Administration[1]

- 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
- For dosing instructions of combination agents administered with SARCLISA, refer to study design descriptions in the SARCLISA Prescribing Information and the respective manufacturer's current Prescribing Information

†PFS results were assessed by an IRC, based on central laboratory data for M-protein, and central radiologic imaging view using IMWG criteria. Median time to follow up was 11.6 months; ‡sCR, CR, VGPR, and PR, which were evaluated by the IRC using IMWG response criteria

CR, complete response; IMWG, International Myeloma Working Group; IRC, independent response committee; IV, intravenous; MM, multiple myeloma; 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.

References: 1. SARCLISA [prescribing information]. Bridgewater, NJ: sanofi-aventis U.S. LLC. **2.** Richardson PG, et al. *Future Oncol*. 2018;14(11):1035-1047. doi: 10.2217/fon-2017-0616. **3.** Attal M, et al. *Lancet*. 2019;394(10214):2096-2107.

Adverse Reactions for SARCLISA + Pd[1,2]

ICARIA-MM: SARCLISA + Pd

Adverse Reactions (≥10%) in Patients Receiving SARCLISA + Pd With a Difference Between Arms of ≥5% Compared to Control Arm[1]

	SARCLISA + Pd (n=152)			Pd (n=149)		
Adverse reactions	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%

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 (those that occurred in more than 1% of patients were pneumonia and other infections [3%]) vs 11% in the Pd arm[1,2]

*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; †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; ‡Dyspnea includes dyspnea, dyspnea exertional, and dyspnea at rest.
IRR, infusion-related reaction; Pd, pomalidomide and dexamethasone.
References: 1. SARCLISA [prescribing information]. Bridgewater, NJ: sanofi-aventis U.S. LLC; 2. Data on file. sanofi-aventis U.S. LLC

Please see Important Safety Information in this presentation and accompanying full Prescribing Information.

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

Adverse Reactions for SARCLISA + Pd (cont'd)[1,2]

ICARIA-MM: SARCLISA + Pd

Hematologic Laboratory Abnormalities During Treatment Period in Patients Receiving SARCLISA + Pd vs Pd Alone[1]*

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

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.[1]

Permanent Treatment Discontinuation Due to Adverse Reactions Grades 1-4[1,2]

SARCLISA + Pd	Pd
7%	12%

- The most frequent adverse reactions requiring permanent discontinuation were infections (2.6% with SARCLISA + Pd vs 5.4% with Pd)[1,2]

Additional safety experience

- Dosage interruptions due to an adverse reaction occurred in 31% of patients who received SARCLISA[1]
  - The most frequent adverse reaction requiring dosage interruption was IRR (28%)[1]

*The denominator used to calculate the percentage was based on the safety population.
IRR, infusion-related reaction; Pd, pomalidomide and dexamethasone.
References: 1. SARCLISA [prescribing information]. Bridgewater, NJ: sanofi-aventis U.S. LLC. 2. Data on file. sanofi-aventis U.S. LLC.

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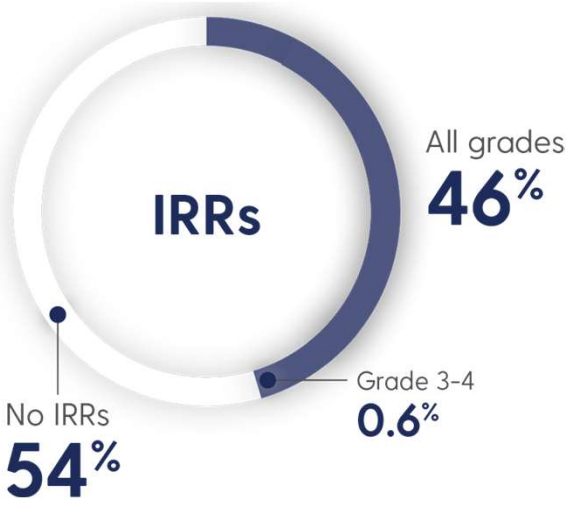
Infusion-Related Reactions* With SARCLISA

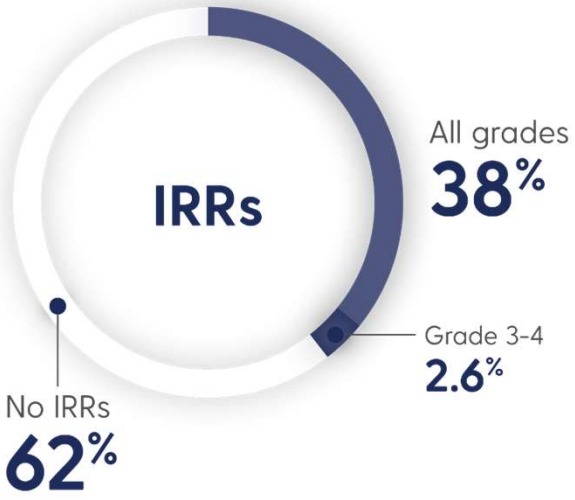
SARCLISA + Kd

- IRRs occurred on the infusion day in 99% of episodes
- 95% of those experiencing an IRR experienced it during the first cycle of treatment
- All IRRs resolved within the same day in 74% of episodes and the day after in 24% of episodes
- Dosage interruption of SARCLISA due to IRRs occurred in 30% of patients
- SARCLISA alone was discontinued in 0.6% of patients due to IRRs



SARCLISA + Pd

- All IRRs started during the first SARCLISA infusion and resolved on the same day in 98% of the cases
- Dosage interruption of SARCLISA due to IRRs occurred in 28% of patients
- SARCLISA alone was discontinued in 3% of patients due to IRRs



The most common symptoms (≥5%) of an infusion-related reaction in ICARIA-MM and IKEMA (N=329) included dyspnea, cough, nasal congestion, and nausea. Serious IRRs, including life-threatening anaphylactic reactions, have occurred with SARCLISA treatment. Severe signs and symptoms included cardiac arrest, hypertension, hypotension, bronchospasm, dyspnea, angioedema, and swelling.

*IRRs are defined as adverse reactions associated with the SARCLISA infusions, with an onset typically within 24 hours from the start of the infusion
IRRs, infusion-related reactions; Kd, carfilzomib and dexamethasone; Pd, pomalidomide and dexamethasone.
Reference: SARCLISA [prescribing information]. Bridgewater, NJ: sanofi-aventis U.S. LLC.

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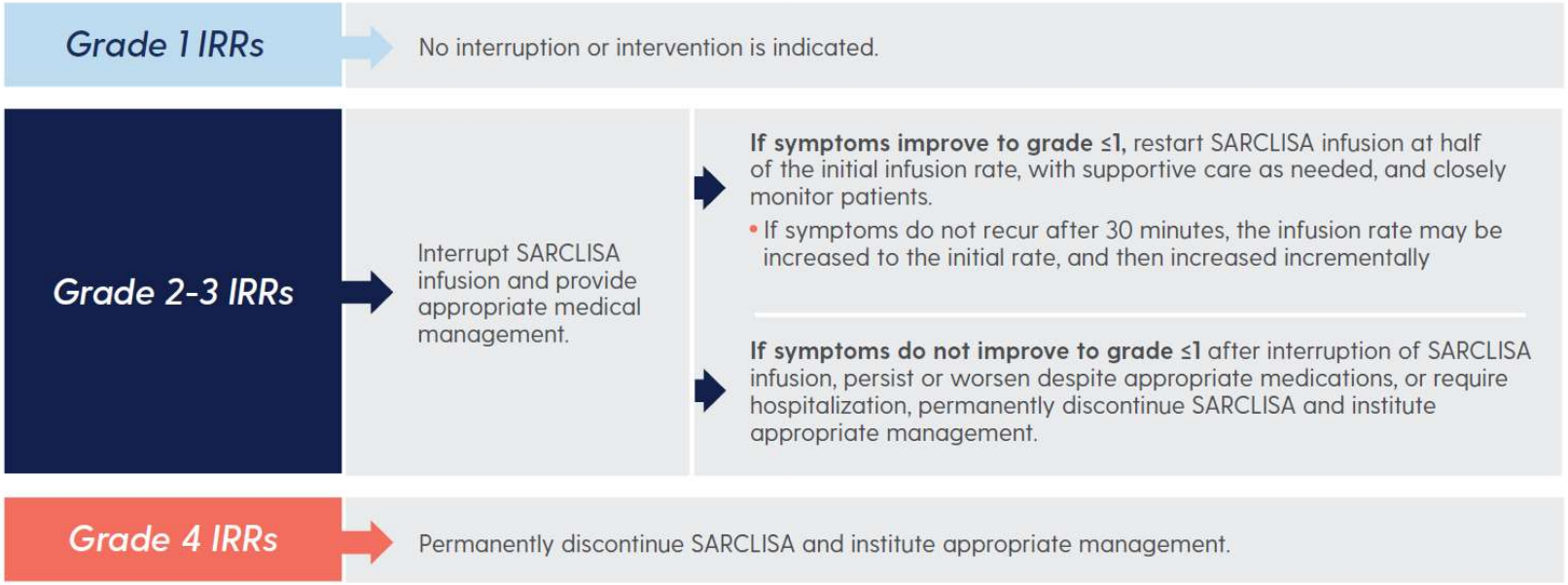
SARCLISA® (isatuximab-irfc)
Injection for IV use | 500mg/25mL, 100mg/5mL

Managing Infusion-Related Reactions* With SARCLISA

- 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



- No interruption is required for grade 1 IRRs
- SARCLISA infusion can be restarted after grade 3 IRRs if symptoms improve

*IRRs are defined as adverse reactions associated with SARCLISA infusions, with an onset typically within 24 hours from start of the infusion
IRRs, infusion-related reactions.

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

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

Important Safety Information (cont'd)

WARNINGS AND PRECAUTIONS

- **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.

Isa-Pd, SARCLISA, pomalidomide, and dexamethasone.

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

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Injection for IV use | 500 mg/25 mL, 100 mg/5 mL

Infections

- The incidence of grade 3 or higher infections was 38% in the SARCLISA + Kd group in the IKEMA trial and 43% in the SARCLISA + Pd group in the ICARIA-MM trial
- Pneumonia was the most commonly reported severe infection across both trials, with grade 3 reported in 19% of patients in the SARCLISA + Kd group compared with 15% in the Kd group, and in 22% of patients in the SARCLISA + Pd group compared with 16% in the Pd group
- Grade 4 was reported in 3.4% of patients in the SARCLISA + Kd group compared with 2.5% in the Kd group, and 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 2.8% of patients in the SARCLISA + Kd group compared with 4.9% in the Kd group, and in 2.6% of patients in the SARCLISA + Pd group compared with 5.4% in the Pd group

- Fatal infections were reported in 2.3% of patients in the SARCLISA + Kd group compared with 0.8% in the Kd group, and in 3.3% of patients in the SARCLISA + Pd group compared with 4% in the Pd group

Kd, carfilzomib and dexamethasone; Pd, pomalidomide and dexamethasone.

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

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Injection for IV use | 500 mg/25 mL, 100 mg/5 mL

Important Safety Information (cont'd)

WARNINGS AND PRECAUTIONS

- **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.

Isa-Pd, SARCLISA, pomalidomide, and dexamethasone.

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

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

Important Safety Information (cont'd)

WARNINGS AND PRECAUTIONS

- **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.

Isa-Pd, SARCLISA, pomalidomide, and dexamethasone.

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

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Injection for IV use | 500 mg/25 mL, 100 mg/5 mL

Important Safety Information (cont'd)

WARNINGS AND PRECAUTIONS

- **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%]).

Isa-Pd, SARCLISA, pomalidomide, and dexamethasone; Pd, pomalidomide and dexamethasone.

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

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Injection for IV use | 500 mg/25 mL, 100 mg/5 mL

Important Safety Information (cont'd)

ADVERSE REACTIONS (cont'd)

- 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.

Isa-Pd, SARCLISA, pomalidomide, and dexamethasone; Pd, pomalidomide and dexamethasone.

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

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CareASSIST by Sanofi Genzyme for SARCLISA

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or visit
SanofiCareAssist.com/hcp/sarclisa to learn more.

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

Sanofi reserves the right to modify or terminate these programs at any time without notice.
*Restrictions apply. Not valid for prescriptions covered by or submitted for reimbursement under Medicare, Medicaid, VA, DoD, Tricare, or similar federal or state programs including any state pharmaceutical assistance programs. Not valid where prohibited by law. Savings may vary depending on patient's out-of-pocket costs. Please visit SanofiCareAssist.com/hcp/sarclisa for full program details.

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

SARCLISA Is an Anti-CD38 mAb With Distinct Anti-Tumor Activity That Can Be Used as Early as First Relapse[1,2]

SAFETY

IKEMA: SARCLISA + Kd
Phase 3 Study

- The most common adverse reactions with SARCLISA + Kd were upper respiratory tract infection, infusion-related reactions, fatigue, hypertension, diarrhea, pneumonia, dyspnea, insomnia, bronchitis, cough, and back pain[1]
- The addition of SARCLISA to Kd did not increase treatment discontinuations due to adverse reactions vs Kd alone[1,2]
  - 8% discontinuation rate was seen with SARCLISA + Kd vs 14% with Kd alone[1,2]

ICARIA: SARCLISA + Pd
Phase 3 Study

- The most common adverse reactions with SARCLISA + Pd were upper respiratory tract infection, infusion-related reactions, pneumonia, and diarrhea[1]
- The addition of SARCLISA to Pd did not increase treatment discontinuations due to adverse reactions vs Pd alone[1,2]
  - 7% discontinuation rate was seen with SARCLISA + Pd vs 12% with Pd alone[1,2]

DOSING

Weight-based Dosing: 10 mg/kg IV in Combination with Kd or Pd
- Weekly dosing for first cycle, followed by every other week for subsequent cycles

No post-infusion medications required
- Premedication is administered prior to infusion to reduce the risk and severity of IRRs

75-minute infusion time starting after the second infusion in the absence of IRRs*
- SARCLISA alone was discontinued in 3% of patients in the ICARIA-MM trial and in 0.6% of patients in the IKEMA trial due to IRRs

*Incremental escalation of the infusion rate should be considered only in the absence of infusion reactions for the first and second infusions.
IRRs, infusion-related reactions; Kd, carfilzomib and dexamethasone; Pd, pomalidomide and dexamethasone.
References: 1. SARCLISA [prescribing information]. Bridgewater, NJ: sanofi-aventis U.S. LLC.

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Questions

Appendix

Definition of Clinical Relapse and Biochemical Relapse

IMWG Criteria for Significant Biochemical Relapse*: Any One or More of the Following Criteria

Doubling of the M-component in 2 consecutive measurements separated by 2 months with the reference value of 5 g/L, or

- In 2 consecutive measurements, any of the following increases:
  - the absolute levels of serum M-protein by ≥10 g/L, or
  - an increase of urine M-protein by ≥500 mg/24 h, or
  - an increase of involved FLC level by ≥20 mg/dL (plus an abnormal FLC ratio) or 25% increase (whichever is greater)

IMWG Criteria for Clinical Relapse: Any One or More of the Following Criteria

Development of new soft-tissue plasmacytomas or bone lesions

- Definite increase (≥50%) in size of existing plasmacytomas or bone lesions
- Hypercalcemia (≥11.5 mg/dL; 2.875 mmol/L)
- Decrease in hemoglobin of ≥2 g/dL (1.25 mmol/L), or of <10 g/dL because of myeloma
- Rise in serum creatinine by ≥2 mg/dL (≥177 mmol/L), due to myeloma
- Hyperviscosity requiring therapeutic intervention

Treatment is Indicated

*If asymptomatic, a careful "watch and wait" approach is justified.
IMVG, International Multiple Myeloma Working Group.

References: 1. Kumar S, et al. *Lancet Oncol*. 2016;17(8):e328-e346. **2.** Sonneveld P. *Hematology Am Soc Hematol Educ Program*. 2017;2017(1):508-517.

Preparation and Administration

Prepare the solution for infusion using an aseptic technique

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

Example dose calculations

Dose x 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**

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

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Injection for IV use | 500 mg/25 mL, 100 mg/5 mL

Preparation and Administration (cont'd)

- 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 concentration of SARCLISA 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

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

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Injection for IV use | 500 mg/25 mL, 100 mg/5 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)

The infusion solution should be administered for a period of time that will depend on the infusion rate (see table on slide 10). 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

On days where both SARCLISA and carfilzomib are administered, administer dexamethasone first, followed by SARCLISA infusion, then followed by carfilzomib infusion

DEHP=di-(2-ethylhexyl) phthalate; IV=intravenous; PE=polyethylene; PVC=polyvinyl chloride

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

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Infusion Times With Rate Increments

Incremental escalation of the infusion rate should be considered only in the absence of IRRs[1]

Week 1

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**			

Week 2

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**			

Week 3

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**			

IRR=infusion-related reaction,

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

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

Defining Infusion-Related Reaction* Grades

Grade 1	Mild transient reaction.
Grade 2	Therapy or infusion interruption indicated, but IRR responds promptly to symptomatic treatment (eg, antihistamines, NSAIDs, narcotics, IV fluids); prophylactic medications indicated for ≤24 hours.
Grade 3	Prolonged (ie, not rapidly responsive to symptomatic medication and/or brief interruption of infusion); recurrence of symptoms following initial improvement; hospitalization indicated for clinical sequelae.
Grade 4	Life-threatening consequences; urgent intervention indicated.

*IRRs are defined as adverse reactions associated with SARCLISA infusions, with an onset typically within 24 hours from start of the infusion
IRRs, infusion-related reactions.

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

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Injection for IV use | 500 mg/25 mL, 100 mg/5 mL

Dose Modifications

- 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

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

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

SARCLISA Is a Multimodal Anti-CD38 Monoclonal Antibody[1,2]

Click MOA Video Image Below

ADCC, antibody-dependent cell-mediated cytotoxicity; ADCP, antibody-dependent cellular phagocytosis; CDC, complement-dependent cytotoxicity; NK, natural killer.

References: 1. SARCLISA [prescribing information]. Bridgewater, NJ: sanofi-aventis U.S. LLC; **2.** Attal M, et al. *Lancet*. 2019;394(10214):2096-2107.

Please see Important Safety Information in this presentation and accompanying full Prescribing Information.

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