IN THE TREATMENT OF **RELAPSED REFRACTORY MULTIPLE MYELOMA**
IN COMBINATION WITH **POMALIDOMIDE AND DEXAMETHASONE (Pd)**

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

ACHIEVE **GREATER OUTCOMES** FOR YOUR PATIENTS

SARCLISA is an anti-CD38 therapy proven to deliver **superior PFS (median PFS, 11.53 months with SARCLISA + Pd vs 6.47 months with Pd alone**, HR=0.596, 95% CI: 0.44, 0.81, *P*=0.0010). SARCLISA also demonstrated a **significant increase in ORR** (60.4% with SARCLISA + Pd [95% CI: 52.2%, 68.2%] vs 35.3% with Pd alone [95% CI: 27.8%, 43.4%], *P*<0.0001)[1]*

*ORR included sCR, CR, VGPR, and PR. sCR, CR, VGPR, and PR were evaluated by an IRC using the IMWG response criteria.

CR=complete response; IMWG=International Myeloma Working Group; IRC=independent response committee; ORR=overall response rate; PFS=progression-free survival; PR=partial response; sCR=stringent complete response; VGPR=very good partial response.

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.

SANOFI GENZYME

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

MAT-US-2016918-v2.0-01/2021

NCCN Guidelines® Category 1, *Preferred* Recommendation for Isatuximab-irfc (SARCLISA)

NCCN

CATEGORY 1 PREFERRED

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) recommend isatuximab-irfc (SARCLISA) as a preferred option for previously treated multiple myeloma in combination with pomalidomide and dexamethasone with Category 1 evidence[2]

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.

Important Safety Information (cont'd)

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.

SANOFI GENZYME

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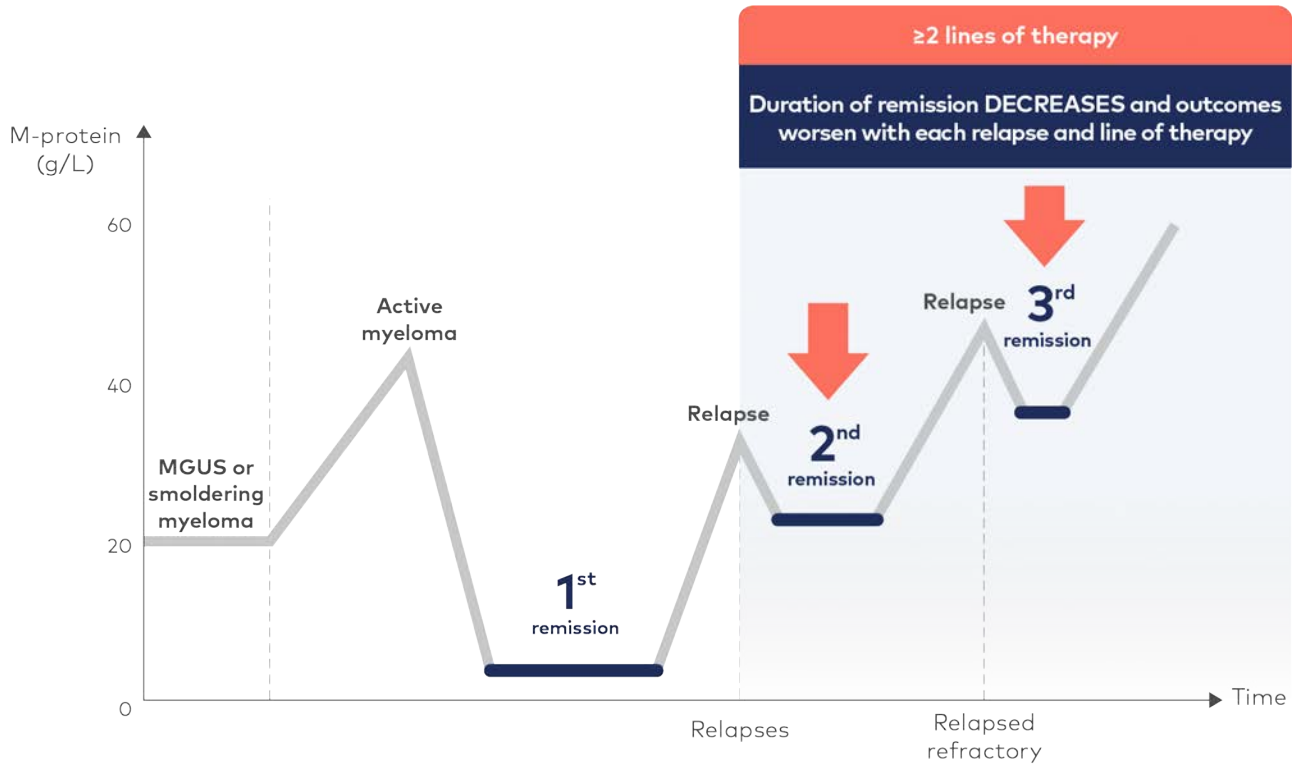
A Significant Unmet Need Remains in Patients With Relapsed Refractory Multiple Myeloma

Multiple myeloma is an incurable disease characterized by continual relapses, requiring multiple lines of therapy[3,4]

Patients with relapsed refractory multiple myeloma will inevitably relapse and/or become refractory to certain treatments[3,5-7]



Additional factors may impact outcomes or limit treatment options for these patients[3]

- Refractory to IMiD®s or PIs
- Disease stage
- High cytogenetic risk
- Age
- Renal impairment

Effective treatment options are needed for patients with poor prognosis[3]

IMiD=immunomodulatory drug; MGUS=monoclonal gammopathy of undetermined significance; M-protein=myeloma protein; PI=proteasome inhibitor.

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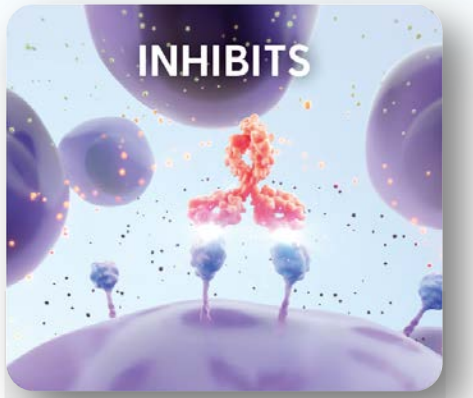
SARCLISA Is a Multimodal Anti-CD38 mAb

Targeted binding to a specific epitope induces distinct antitumor activity[1,8,9]



Inhibits CD38 enzymatic activity

Triggers cell death through **tumor cell targeting**, including ADCC, ADCP, and CDC

Enhances the immune system through NK cell **activation and downregulation** of immunosuppressors

Directly destroys myeloma cells through apoptosis, **without the need for crosslinking**

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.

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

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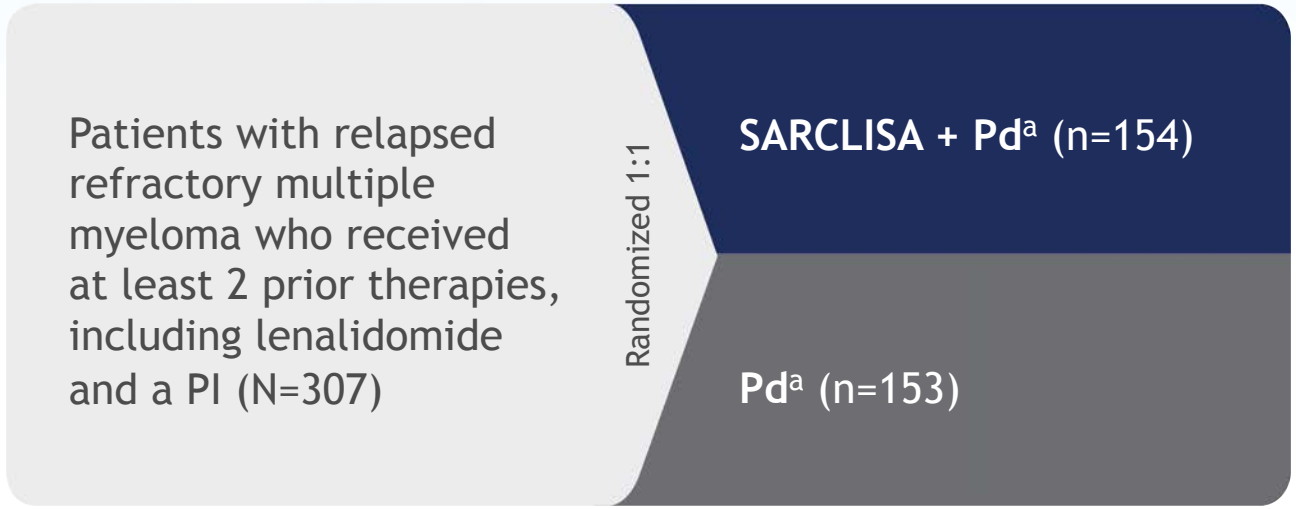
SARCLISA Is the First Anti-CD38 Antibody Studied in a Phase 3 Trial in Combination With Pd vs Pd Alone

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



- 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

[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.

Important Safety Information (cont'd)

Infusion-Related Reactions (cont'd)

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.

*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.

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The Phase 3 ICARIA-MM Trial Included a Broad and Diverse Patient Population

The phase 3 ICARIA-MM trial included patients with poor prognostic factors[1,9,10]

Treatment history

- **93%** Refractory to lenalidomide
- **73%** Refractory to IMiD + PI
- **56%** Received prior ASCT

Patient factors

- **36%** Impaired renal function
- **20%** High-risk chromosomal abnormalities
- **20%** ≥75 years

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%).

ASCT=autologous stem cell transplant; IMiD=immunomodulatory drug; PI=proteasome inhibitor.

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Baseline Characteristics in the ICARIA-MM Trial Were Similar Across Treatment Arms[1,9,10]

	SARCLISA + Pd (n=154)	Pd (n=153)
Age		
<65 y	35%	46%
65-74 y	44%	35%
≥75 y	21%	19%
R-ISS stage at study entry		
I	25%	20%
II	64%	64%
III	10%	16%
Cytogenetic risk		
High[a]	16%	24%
Standard	67%	51%
Missing	18%	26%
Renal function		
<60 mL/min/1.73 m^2	39%	34%

	SARCLISA + Pd (n=154)	Pd (n=153)
History of COPD or asthma at study entry		
Yes	10%	11%
ECOG PS		
0 or 1	90%	90%
2	10%	11%
Prior lines of therapy		
Median (range)	3 (2-11)	3 (2-10)
Patient refractory to		
PI	77%	75%
Lenalidomide	94%	92%
IMiD	96%	94%
IMiD + PI	73%	72%
Last regimen	97%	99%
Prior ASCT		
Yes	54%	59%

[a]Of the patients who had high-risk chromosomal abnormalities at study entry, del(17p), t(4;14), and t(14;16) were present in 12.1%, 8.5%, and 1.6% of patients, respectively.
ASCT=autologous stem cell transplant; COPD=chronic obstructive pulmonary disease; ECOG PS=Eastern Cooperative Oncology Group performance status; IMiD=immunomodulatory drug; Pd=pomalidomide and dexamethasone; PI=proteasome inhibitor; R-ISS=Revised International Staging System.

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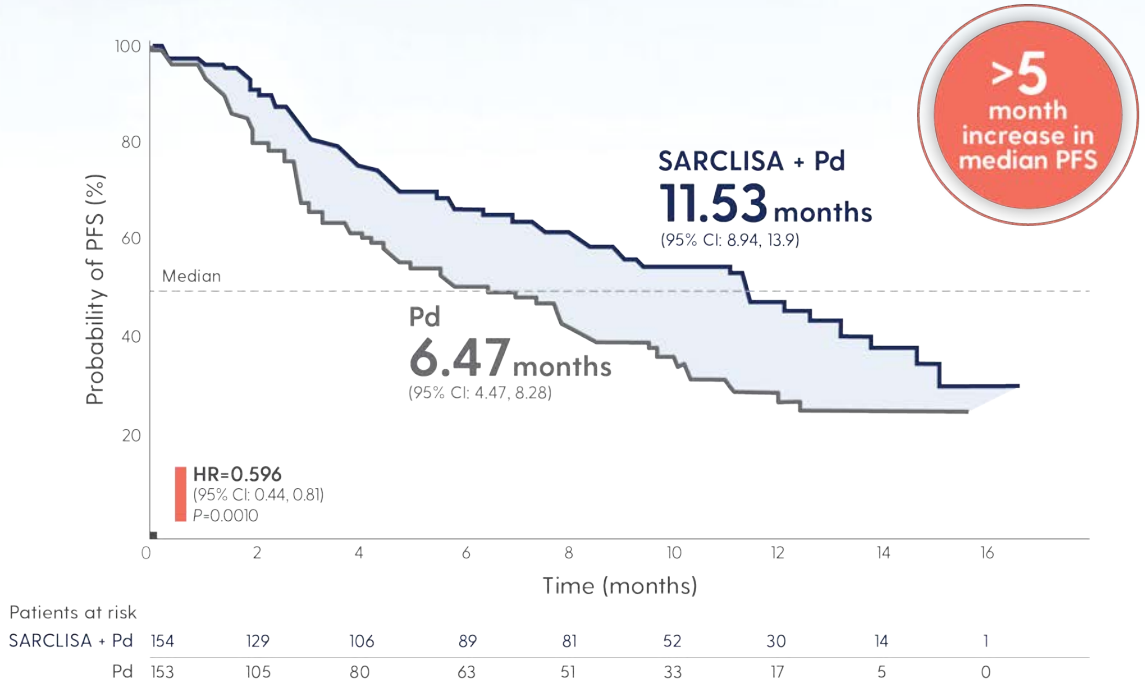
SARCLISA + Pd Extended Median PFS to ~1 Year

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



>5 month increase in median PFS

GREATER THAN 40%

reduction in the risk of progression or death in patients receiving 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]

Important Safety Information (cont'd)

Neutropenia (cont'd)

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

OS=overall survival; Pd=pomalidomide and dexamethasone; PFS=progression-free survival.

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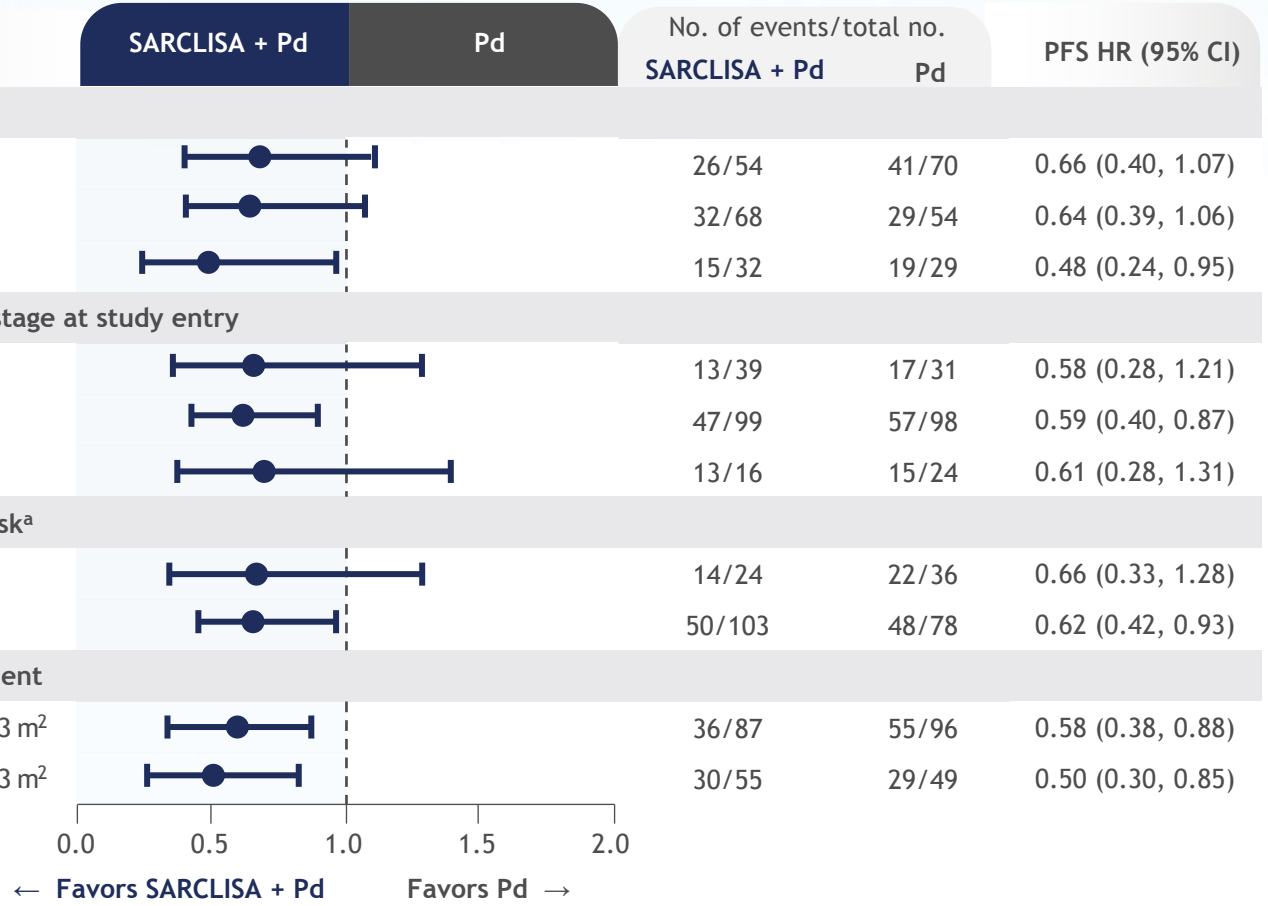
The ICARIA-MM Trial Demonstrated Consistent PFS Across Subgroups[9]

ICARIA-MM population included those with difficult-to-treat disease*



Subgroup	No. of events/total no. SARCLISA + Pd	No. of events/total no. Pd	PFS HR (95% CI)
Age			
<65 y	26/54	41/70	0.66 (0.40, 1.07)
65-74	32/68	29/54	0.64 (0.39, 1.06)
≥75 y	15/32	19/29	0.48 (0.24, 0.95)
R-ISS disease stage at study entry			
I	13/39	17/31	0.58 (0.28, 1.21)
II	47/99	57/98	0.59 (0.40, 0.87)
III	13/16	15/24	0.61 (0.28, 1.31)
Cytogenetic risk[a]			
High[b]	14/24	22/36	0.66 (0.33, 1.28)
Standard	50/103	48/78	0.62 (0.42, 0.93)
Renal Impairment			
≥60 mL/min/1.73 m^2	36/87	55/96	0.58 (0.38, 0.88)
<60 mL/min/1.73 m^2	30/55	29/49	0.50 (0.30, 0.85)

Study limitations

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

Important Safety Information (cont'd)

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.

ISS=International Staging System; Pd=pomalidomide and dexamethasone; PFS=progression-free survival; R-ISS=Revised International Staging System.

*Difficult-to-treat disease included patients with renal insufficiency, advanced age, high cytogenetic risk, and advanced ISS stage at study entry.[3,9]

[a] Cytogenetic risk information was missing for 18% of patients in the SARCLISA + Pd arm and 26% of patients in the Pd arm.[9]

[b] Of the patients who had high-risk chromosomal abnormalities at study entry, del(17p), t(4;14), and t(14;16) were present in 12%, 8%, and 2% of patients, respectively.[1]

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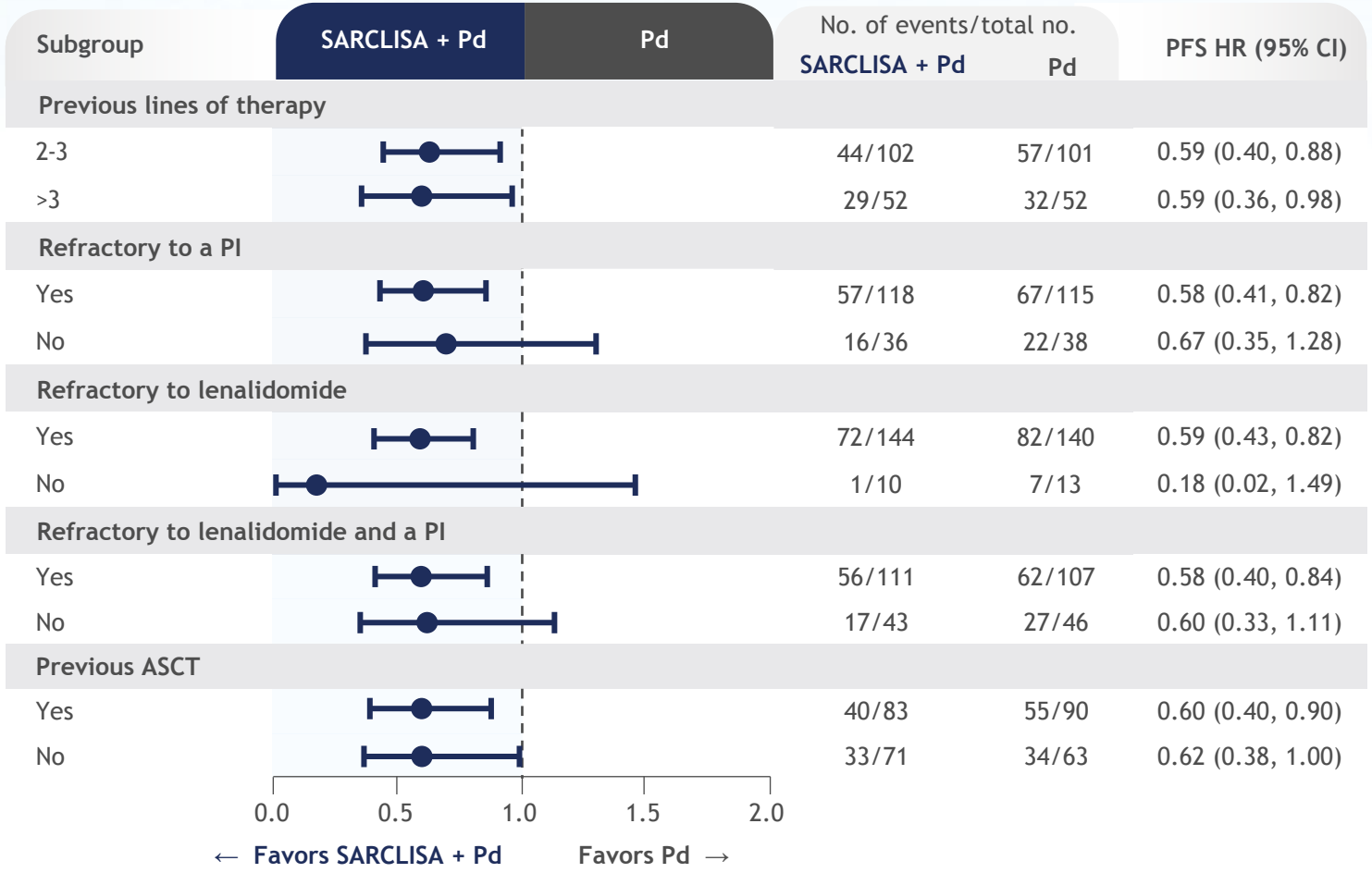
The ICARIA-MM Trial Demonstrated Consistent PFS Across Subgroups (cont'd)[9]

ICARIA-MM population included those with difficult-to-treat disease*



Subgroup	No. of events/total no. SARCLISA + Pd	No. of events/total no. Pd	PFS HR (95% CI)
Previous lines of therapy			
2-3	44/102	57/101	0.59 (0.40, 0.88)
>3	29/52	32/52	0.59 (0.36, 0.98)
Refractory to a PI			
Yes	57/118	67/115	0.58 (0.41, 0.82)
No	16/36	22/38	0.67 (0.35, 1.28)
Refractory to lenalidomide			
Yes	72/144	82/140	0.59 (0.43, 0.82)
No	1/10	7/13	0.18 (0.02, 1.49)
Refractory to lenalidomide and a PI			
Yes	56/111	62/107	0.58 (0.40, 0.84)
No	17/43	27/46	0.60 (0.33, 1.11)
Previous ASCT			
Yes	40/83	55/90	0.60 (0.40, 0.90)
No	33/71	34/63	0.62 (0.38, 1.00)

Study limitations

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

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.

ASCT=autologous stem cell transplant; ISS=International Staging System; Pd=pomalidomide and dexamethasone; PI=proteasome inhibitor; PFS=progression-free survival.

*Difficult-to-treat disease included patients with renal insufficiency, advanced age, high cytogenetic risk, and advanced ISS stage at study entry.[3,9]

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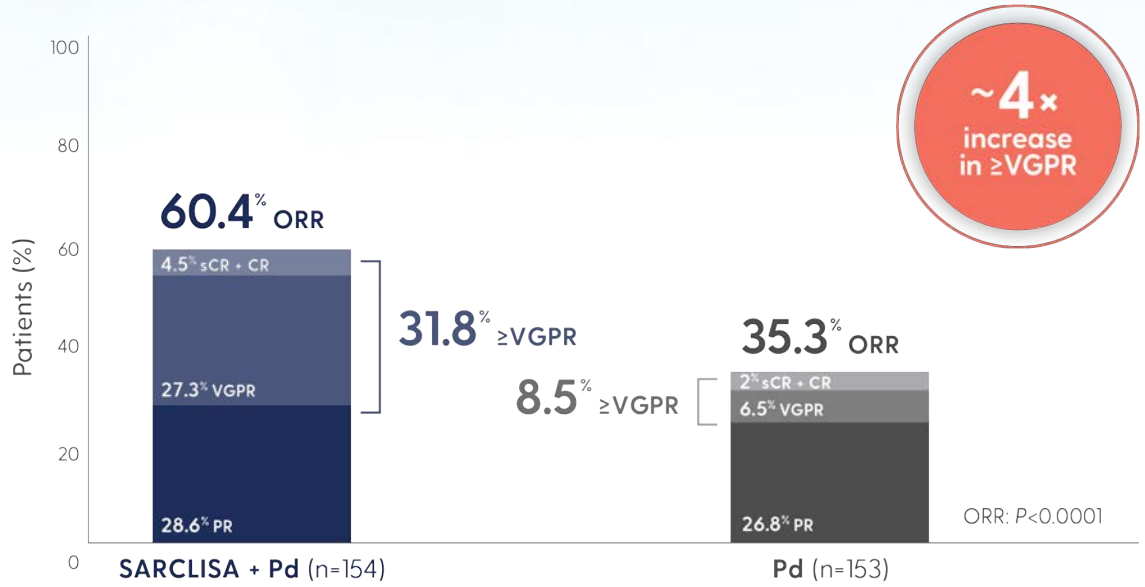
SARCLISA + Pd Showed a Significant Increase in ORR

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



~4× increase in ≥VGPR

Median time to first response was 35 days with SARCLISA + Pd vs 58 days with Pd alone among responders[1]

ORR: SARCLISA + Pd (95% CI: 52.2%, 68.2%), Pd (95% CI: 27.8%, 43.4%). 95% CI estimated using the Clopper-Pearson method.

Important Safety Information (cont'd)

Laboratory Test Interference (cont'd)

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.

CR=complete response; ORR=overall response rate; Pd=pomalidomide and dexamethasone; PR=partial response; sCR=stringent complete response; VGPR=very good partial response.

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Adverse Reactions for SARCLISA + Pd

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.
IRR=infusion-related reaction; Pd=pomalidomide and dexamethasone.

SANOFI GENZYME

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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]

	SARCLISA + Pd (n=152)			Pd (n=149)		
Laboratory parameter	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%

Important Safety Information (cont'd)

Laboratory Test Interference (cont'd)

Interference with Serum Protein Electrophoresis and Immunofixation Tests

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

Pd=pomalidomide and dexamethasone.

SANOFI GENZYME

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Adverse Reactions for SARCLISA + Pd (cont'd)

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
  - Discontinuations from treatment due to infection were reported in 2.6% of patients receiving SARCLISA + Pd vs 5.4% of patients receiving Pd alone
  - SARCLISA alone was discontinued in 3% of patients due to IRRs

IRR=infusion-related reaction; Pd=pomalidomide and dexamethasone.

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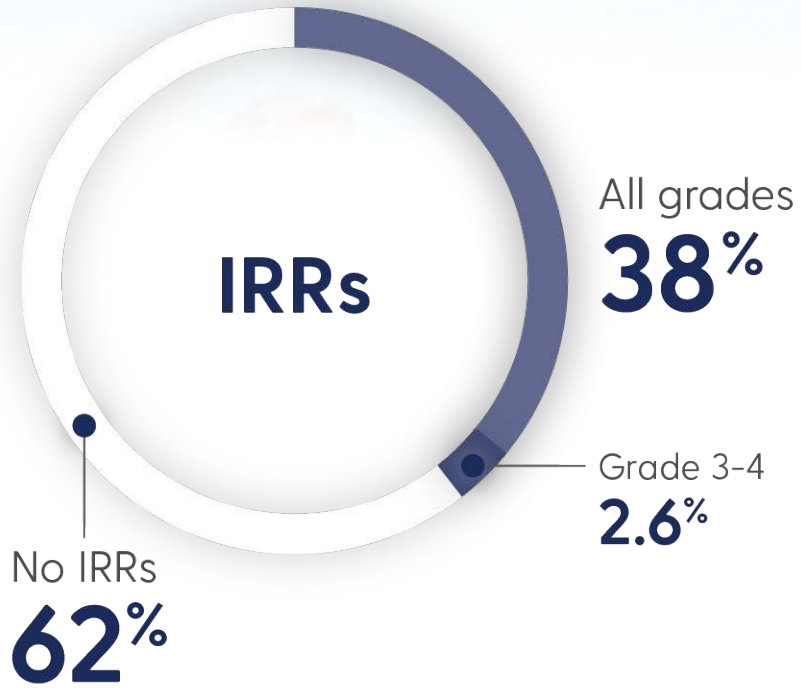
IRRs in Patients Receiving SARCLISA + Pd[1,9]

- All patients who experienced IRRs experienced them during the first SARCLISA infusion, with an onset typically within 24 hours from the start of the infusion. IRRs resolved on the same day in 98% of cases
- All IRRs were reversible
- No delayed reactions were observed
- The incidence of infusion interruptions because of IRRs was 29.6%. The median time to infusion interruption was 55 minutes
- The most common symptoms of an IRR included dyspnea, cough, chills, and nausea. Signs and symptoms of grade 3 or higher IRRs included dyspnea, hypertension, and bronchospasm



IRRs are defined as adverse reactions associated with the SARCLISA infusion, with an onset typically within 24 hours from the start of the infusion.
IRR=infusion-related reaction; Pd=pomalidomide and dexamethasone.

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Infusion Times Decrease to 75 Minutes After the Second Infusion

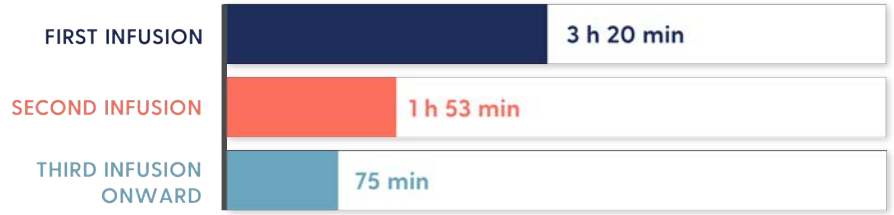
Recommended dose[1]

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

Infusion times reduce after first cycle[1]

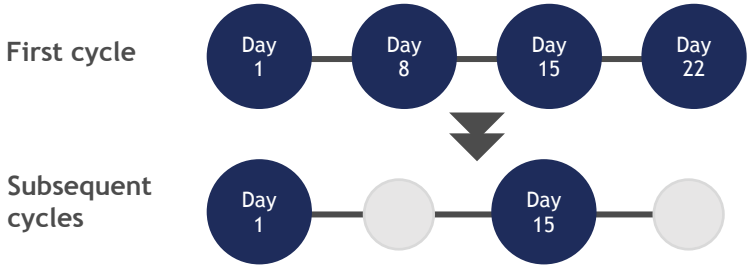
Calculated infusion times

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



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

Treatment is administered in 28-day cycles



Important Safety Information (cont'd)

Embryo-Fetal Toxicity

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

IRR=infusion-related reaction; IV=intravenous; Pd=pomalidomide and dexamethasone.

SANOFI GENZYME

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

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

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	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.

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

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 (those that occurred in more than 1% of patients were pneumonia and other infections [3%]).

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Infusion Rates of SARCLISA Administration[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). Note that more than one SARCLISA vial may be necessary to obtain the required dose for the patient.

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**

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

Important Safety Information (cont'd)

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.

IRR=infusion-related reaction.

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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.

CareASSIST® Patient Support by Sanofi Genzyme

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

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

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IN THE TREATMENT OF
RELAPSED REFRACTORY MULTIPLE MYELOMA IN COMBINATION WITH Pd

Achieve Greater Outcomes for Your Patients

The first phase 3 trial of an anti-CD38 mAb in combination with Pd vs Pd alone[1]

A significant increase in responses shown with SARCLISA + Pd*†

SARCLISA + Pd (n=154)		Pd (n=153)
11.53 mo mPFS	HR=0.596 *P*=0.0010	**6.47** mo mPFS
60.4% ORR	*P*<0.0001	**35.3%** ORR
31.8% ≥VGPR	~4x increase	**8.5%** ≥VGPR
35 days	Median time to first response among responders	**58** days

*mPFS (95% CI: 0.44, 0.81): SARCLISA + Pd (95% CI: 8.94, 13.9), Pd (95% CI: 4.47, 8.28).
†ORR included sCR, CR, VGPR, and PR. ORR: SARCLISA + Pd (95% CI: 52.2%, 68.2%), Pd (95% CI: 27.8%, 43.4%).

- 7% of patients receiving SARCLISA + Pd permanently discontinued treatment due to adverse reactions
- Infusion time decreases to 75 minutes starting after the second infusion in the absence of IRRs

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.

CR=complete response; IRR=infusion-related reaction; mAb=monoclonal antibody; mPFS=median progression-free survival; ORR=overall response rate; Pd=pomalidomide and dexamethasone; PR=partial response; sCR=stringent complete response; VGPR=very good partial response.

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

Thank you

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.4.2021. © National Comprehensive Cancer Network, Inc. 2020. All rights reserved. Accessed December 17, 2020. To view the most recent and complete version of the guideline, go online to NCCN.org. **3.** Hájek R, Jarkovsky J, Maisnar V, et al. Real-world outcomes of multiple myeloma: retrospective analysis of the Czech Registry of Monoclonal Gammopathies. *Clin Lymphoma Myeloma Leuk*. 2018;18(6):e219-e240. **4.** Nijhof IS, van de Donk NW, Zweegman S, Lokhorst HM. Current and new therapeutic strategies for relapsed and refractory multiple myeloma: an update. *Drugs*. 2018;78(1):19-37. **5.** Yong K, Delforge M, Driessen C, et al. Multiple myeloma: patient outcomes in real-world practice. *Br J Haematol*. 2016;175(2):252-264. **6.** Kurtin SE. Relapsed or relapsed/refractory multiple myeloma. *J Adv Pract Oncol*. 2013;4(suppl1):5-14. **7.** Hájek R. Strategies for the treatment of multiple myeloma in 2013: moving toward the cure. In: Hájek R, ed. *Multiple Myeloma: A Quick Reflection on the Fast Progress*. InTechOpen; April 2013. doi:10.5772/56515. **8.** Martin TG, Corzo K, Chiron M, et al. Therapeutic opportunities with pharmacological inhibition of CD38 with isatuximab. *Cells*. 2019;8(12):E1522. doi:10.3390/cells8121522. **9.** Attal M, Richardson PG, Rajkumar SV, et al; on behalf of the ICARIA-MM study group. Isatuximab plus pomalidomide and low-dose dexamethasone versus pomalidomide and low-dose dexamethasone in patients with relapsed and refractory multiple myeloma (ICARIA-MM): a randomised, multicentre, open-label, phase 3 study. *Lancet*. 2019;394(10214):2096-2107. **10.** Data on file. sanofi-aventis U.S. LLC.

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

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