HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use SARCLISA safely and effectively. See full prescribing information for SARCLISA.

SARCLISA® (isatuximab-irfc) injection, for intravenous use

Initial U.S. Approval: 2020

INDICATIONS AND USAGE
SARCLISA is a CD38-directed cytolytic antibody indicated, in combination with pomalidomide and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least three prior therapies including lenalidomide and a proteasome inhibitor.

CONTRAINDICATIONS
Injection:

- Premedicate with dexamethasone, acetaminophen, H2 antagonists, and diphenhydramine.

- The recommended dose of SARCLISA is 10 mg/kg as an intravenous infusion every week for 4 weeks followed by every 2 weeks in combination with pomalidomide and dexamethasone until disease progression or unacceptable toxicity.

- See Full Prescribing Information for instructions on preparation and administration.

DOSE FORMS AND STRENGTHS

- 100 mg/5 mL (20 mg/mL) solution in single-dose vial
- 500 mg/25 mL (20 mg/mL) solution in single-dose vial

WARNINGS AND PRECAUTIONS

- Infusion-Related Reactions: Interrupt SARCLISA and manage medically. Permanently discontinue for grade ≥3 reactions.

ADVERSE REACTIONS

The most common adverse reactions (in ≥20% of patients) were neutropenia, infusion-related reactions, pneumonia, upper respiratory tract infection, and diarrhea.

The most common hematology laboratory abnormalities (in ≥80% of patients) were anemia, neutropenia, lymphopenia, and thrombocytopenia.

To report SUSPECTED ADVERSE REACTIONS, contact sanofi-aventis U.S. LLC at 1-800-633-1610 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

USE IN SPECIFIC POPULATIONS

Lactation: Advise not to breastfeed.

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling

Revised: 03/2020

Each treatment cycle consists of a 28-day period. Treatment is repeated until disease progression or unacceptable toxicity.

SARCLISA is used in combination with pomalidomide and dexamethasone.

Missed SARCLISA Doses

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.

2.2 Recommended Premedications

Administer the following premedications prior to SARCLISA infusion to reduce the risk and severity of infusion-related reactions.

- Dexamethasone 40 mg orally or intravenously (or 20 mg orally or intravenously for patients ≥75 years of age).
- Acetaminophen 650 mg to 1000 mg orally (or equivalent).
- H2 antagonists.
- Diphenhydramine 25 mg to 50 mg orally or intravenously (or equivalent).

The intravenous route is preferred for at least the first 4 infusions. The above recommended dose of dexamethasone (orally or intravenously) corresponds to the total blood counts in the event of hematological toxicity.
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.

2.4 Preparation

Prepare the solution for infusion using aseptic technique as follows:

Calculate the dose (mg) of required SARCLISA based on actual patient weight (measured prior to each cycle to have the administered dose adjusted accordingly) [see Dosage and Administration (2.1)]. More than one SARCLISA vial may be necessary to obtain the required dose for the patient.

- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.
- Remove the volume of diluent from the 250 mL Sodium Chloride Injection, USP, or 5% Dextrose Injection, USP diluent bag that is equal to the required volume of SARCLISA injection.
- Withdraw the necessary volume of SARCLISA injection and dilute by adding to the infusion bag of 0.9% Sodium Chloride Injection, USP or 5% Dextrose Injection, USP to achieve the appropriate SARCLISA concentration for infusion.
- The infusion bag must be made of polyolefins (PO), polyethylene (PE), polypropylene (PP), polyvinyl chloride (PVC) with di-(2-ethylhexyl) phthalate (DEHP) or ethyl vinyl acetate (EVA).
- Gently homogenize the diluted solution by inverting the bag. Do not shake.

2.5 Administration

- Administer the infusion solution by intravenous infusion using an intravenous tubing infusion set (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 divide the infusion rate by the required dose (see Table 2). Use prepared SARCLISA infusion solution within 48 hours when stored refrigerated at 2°C–8°C, followed by 8 hours (including the infusion time) at room temperature.
- Do not administer SARCLISA infusion solution concomitantly in the same intravenous line with other agents.

Infusion Rates

Following dilution, administer the SARCLISA infusion solution intravenously at the infusion rates presented in Table 2. Incremental escalation of the infusion rate should be considered only in the absence of infusion-related reactions [see Warnings and Precautions (5.1) and Adverse Reactions (6.1)].

<table>
<thead>
<tr>
<th>Dilution Volume</th>
<th>Initial Rate</th>
<th>Absence of Infusion-Related Reaction</th>
<th>Rate Increment</th>
<th>Maximum Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>First infusion</td>
<td>250 mL</td>
<td>25 mL/hour For 60 minutes</td>
<td>25 mL/hour</td>
<td>150 mL/hour</td>
</tr>
<tr>
<td>Second infusion</td>
<td>250 mL</td>
<td>50 mL/hour For 30 minutes</td>
<td>50 mL/hour</td>
<td>200 mL/hour</td>
</tr>
<tr>
<td>Subsequent infusions</td>
<td>250 mL</td>
<td>200 mL/hour</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3 DOSE FORMS AND STRENGTHS

SARCLISA is a clear to slightly opalescent, colorless to slightly yellow solution, essentially free of viable particulates available as:

- Injection: 100 mg/mL (20 mg/mL) in a single-dose vial
- Injection: 50 mg/mL (20 mg/mL) in a single-dose vial

4 CONTRAINDICATIONS

SARCLISA is contraindicated in patients with severe hypersensitivity to iatustimab-irfc or to any of its excipients [see Warnings and Precautions (5.1)].

5 WARNINGS AND PRECAUTIONS

5.1 Infusion-Related Reactions

Infusion-related reactions have been observed in 39% of patients treated with SARCLISA [see Adverse Reactions (6.1)]. All infusion-related reactions started during the first SARCLISA infusion and resolved on the same day in 98% of the cases. The most common symptoms of an infusion-related reaction included dyspnea, cough, chills, and nausea. The most common severe signs and symptoms included hypotension and dyspnea [see Adverse Reactions (6.1)].

To decrease the risk and severity of infusion-related reactions, premedicate patients prior to SARCLISA infusion with acetaminophen, H2 antagonists, diphenhydramine, or equivalent; dexamethasone [see Dosage and Administration (2.2)]. Monitor vital signs frequently during the entire SARCLISA infusion. For patients with grade 1 or 2 reactions, interrupt SARCLISA infusion and provide appropriate medical support. If symptoms improve, restart SARCLISA infusion at half of the initial infusion rate, with supportive care as needed, and closely monitor patients. If symptoms do not recur after 30 minutes, the infusion rate may be increased to the initial rate, and then increased incrementally, as shown in Table 2 [see Dosage and Administration (2.2)]. In case symptoms do not improve or recur after interruption, permanently discontinue SARCLISA and institute appropriate management. Permanently discontinue SARCLISA therapy if a grade 3 or higher infusion-related reaction occurs and institute appropriate medical management.

5.2 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 were 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%) [see Adverse Reactions (6.1)].
Table 4 summarizes the hematology laboratory abnormalities in ICARIA-MM.

<table>
<thead>
<tr>
<th>Parameter n (%)</th>
<th>SARCLISA + Pomalidomide + Dexamethasone (Isa-Pd) (N=152)</th>
<th>Pomalidomide + Dexamethasone (Pd) (N=149)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Grades (%)</td>
<td>Grade 3 (%)</td>
<td>Grade 4 (%)</td>
</tr>
<tr>
<td>Neutropenia</td>
<td>31 (22)</td>
<td>2 (3)</td>
</tr>
<tr>
<td>Pneumonia†</td>
<td>31 (22)</td>
<td>2 (3)</td>
</tr>
<tr>
<td>Upper respiratory tract infection†</td>
<td>57 (9)</td>
<td>0</td>
</tr>
<tr>
<td>Dyspnea‡</td>
<td>17 (5.0)</td>
<td>0</td>
</tr>
</tbody>
</table>

Gastrointestinal disorders

Dysphagia 26 (2) 0 19 (7.7) 0

Nausea 15 (0) 0 9 (0) 0

Vomiting 12 (1.3) 0 3 (0.4) 0

Table 4 summarizes the laboratory abnormalities in ICARIA-MM.

<table>
<thead>
<tr>
<th>Laboratory Parameter n (%)</th>
<th>SARCLISA + Pomalidomide + Dexamethasone (Isa-Pd) (N=152)</th>
<th>Pomalidomide + Dexamethasone (Pd) (N=149)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Grades (%)</td>
<td>Grade 3 (%)</td>
<td>Grade 4 (%)</td>
</tr>
<tr>
<td>Anemia</td>
<td>151 (99)</td>
<td>48 (32)</td>
</tr>
<tr>
<td>Neutropenia</td>
<td>146 (96)</td>
<td>37 (24)</td>
</tr>
<tr>
<td>Lymphopenia</td>
<td>140 (92)</td>
<td>64 (42)</td>
</tr>
</tbody>
</table>

Description of Selected Adverse Reactions

In ICARIA-MM, infusion-related reactions (defined as adverse reactions associated with the SARCLISA infusions, with an onset typically within 24 hours from the start of the infusion) were reported in 58 patients (38%) treated with SARCLISA. All patients who experienced infusion-related reactions, experienced them during the 1st infusion of SARCLISA, with 3 patients (2%) also having infusion-related reactions at their 2nd infusion, and 2 patients (1.3%) at their 4th infusion. Grade 3 severe infusion-related reactions were reported in 1 patient (0.7%), Grade 2 in 3%, Grade 4 in 1.3% of the patients. Signs and symptoms of Grade 3 or higher infusion-related reactions included dyspnea, hypertension, and bronchosppasm. The incidence of infusion interruptions because of infusion-related reactions was 29.6%. The median time to infusion interruption was 55 minutes. In a separate study (TCI 14079 Part B) with SARCLISA 10 mg/kg administered from a 250 mL fixed-volume infusion in combination with Pd, infusion-related reactions (all Grade 2) were reported in 40% of patients, at the first administration, the day of the infusion. Overall, the infusion-related reactions of SARCLISA 10 mg/kg administered as a 250 mL fixed-volume infusion in combination with Pd, infusion-related reactions (all Grade 2) were reported in 40% of patients, at the first administration, the day of the infusion. Overall, the infusion-related reactions of SARCLISA 10 mg/kg administered as a 250 mL fixed-volume infusion were similar to that of SARCLISA as administered in ICARIA-MM.

Fibrosis

In ICARIA-MM, the incidence of Grade 3 or higher fibrosis was 43% in Isa-Pd group. Pneumonia was the most commonly reported severe infection with Grade 3 reported in 22% of patients in Isa-Pd group compared to 16% in Pd group, and Grade 4 in 3.3% of patients in Isa-Pd group compared to 2.7% in Pd group. Discontinuations from treatment due to infection were reported in 2.6% of patients in Isa-Pd group compared to 5.4% in Pd group. Fatal infections were reported in 3.3% of patients in Isa-Pd group and in 4% in Pd group.

6.5 Immunogenicity

As with all therapeutic proteins, there is a potential for immunogenicity. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors, including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies in the studies described below with the incidence of antibodies in other studies or to other isatuximab-irfc products may be misleading.

In ICARIA-MM, no patients tested positive for antidrug antibodies (ADA). Therefore, the neutralizing ADA status was not determined. Overall, across 6 clinical studies in multiple myeloma (MM) with SARCLISA single agent and combination therapies including ICARIA-MM (N=564), the incidence of treatment emergent ADA was 2.3%. No clinically significant differences in the pharmacokinetics, safety, or efficacy of isatuximab-irfc were observed in patients with ADAs.

7. Drug Interactions

7.1 Laboratory Test Interference

Interference with Serological Testing

SARCLISA, an anti-CD38 antibody, may interfere with blood bank serologic tests with false positive reactions in indirect antiglobulin tests (indirect Coombs tests), antibody detection (screening) tests, antibody identification panels, and antihuman globulin crossmatches in patients treated with SARCLISA [see Warnings and Precautions (5.4)]. Interference with Serum Protein Electrophoresis and Immunofixation Tests

SARCLISA may be incriminated by serum protein electrophoresis and immunofixation assays used for the monitoring of M-proteins and may interfere with accurate response classification based on International Myeloma Working Group (IMWG) criteria [see Warnings and Precautions (5.4)].
Each vial contains either 100 mg/5 mL or 500 mg/25 mL of isatuximab-irfc at a concentration of 20 mg/mL with a pH of 6.0. Each mL of solution contains 20 mg isatuximab-irfc, histidine (1.46 mg), histidine hydrochloride monohydrate (2.22 mg), polysorbate 80 (0.2 mg), sucrose (100 mg), and water for injection.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action
Isatuximab-irfc is an IgG1-derived monoclonal antibody that binds to CD38 expressed on the surface of hematopoietic and tumor cells, including multiple myeloma cells. Isatuximab-irfc induces apoptosis of tumor cells and activation of immune effector mechanisms including antibody-dependent cell-mediated cytotoxicity (ADCC), antibody-dependent cellular phagocytosis (ADCP), and complement-dependent cytotoxicity (CDC). Isatuximab-irfc inhibits the ADP-ribosyl-ribosylation activity of CD38. Isatuximab-irfc can activate natural killer (NK) cells in the absence of CD38-positive target tumor cells and suppresses CD38-positive T-regulatory cells.

The combination of isatuximab-irfc and pomalidomide enhanced ADCC activity and direct tumor cell killing compared to that of isatuximab-irfc alone in vitro, and enhanced antitumor activity compared to the activity of isatuximab-irfc or pomalidomide alone in a human multiple myeloma xenograft model.

12.2 Pharmacodynamics
In multiple myeloma patients treated with SARCLISA combined with pomalidomide and dexamethasone, a decrease in absolute numbers of total NK cells (including inflammatory CD16<sup>hi</sup> CD56<sup>hi</sup> NK cells) and CD19<sup>+</sup> B cells was observed in peripheral blood. Cardiac Electrophysiology

Up to 2 times the approved recommended dose, SARCLISA does not prolong the QT interval to any clinically relevant extent. A relationship between isatuximab-irfc exposure and overall response rate and progression-free survival was observed. No apparent relationship was observed between an increase in isatuximab-irfc exposure and adverse reactions.

12.3 Pharmacokinetics
Following the administration of isatuximab-irfc at the recommended dose and schedule, the steady state isatuximab-irfc mean (CV %) predicted peak plasma concentration (C<sub>P</sub>(max)) was 351 µg/mL (30.6%) and area under the plasma-time curve (AUC) was 72,600 µg·h/mL (51.7%). The median time to reach steady state of isatuximab-irfc was 8.1 with a 31.1 fold accumulation. Isatuximab-irfc AUC increases in a dose proportional manner over a dosage range from 1 mg/kg to 20 mg/kg (0.1 to 2 times the approved recommended dosage) every 2 weeks. Isatuximab-irfc dosing increases proportionally over a dosage range from 5 mg/kg to 20 mg/kg (0.5 to 2 times the approved recommended dosage) every week for 4 weeks followed by every 2 weeks.

Distribution
The mean (CV %) predicted total volume of distribution of isatuximab-irfc is of 8.13 L (26.2%).

Metabolism
Isatuximab-irfc is expected to be metabolized into small peptides by catabolic pathways. Elimination
Isatuximab-irfc total clearance decreased with increasing dose and with multiple doses. At steady state, the near elimination (>98%) of isatuximab-irfc from plasma after the last dose is predicted to occur in approximately 3 months. The elimination of isatuximab-irfc was similar when given as a single agent or as combination therapy.

Specific Populations
Isatuximab-irfc exposure (AUC) at steady state decreases with increasing body weight. The following factors have no clinically meaningful effect on the exposure of isatuximab-irfc: age (36 to 65 years, 70 patients were >75 years old), sex, race (Caucasian, Black, Asian), renal impairment (eGFR <90 mL/min/1.73 m<sup>2</sup>), and mild hepatic impairment (total bilirubin 1 to 1.5 times upper limit of normal [ULN] or aspartate amino transferase [AST] > ULN). The effect of moderate (total bilirubin 1.5 to 3 times ULN and any AST) and severe (total bilirubin >3 times ULN and any AST) hepatic impairment on isatuximab-irfc pharmacokinetics is unknown. No dose adjustments are recommended in these specific patient populations.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
Carcinogenicity and genotoxicity studies have not been conducted with isatuximab-irfc. Fertility studies have not been conducted with isatuximab-irfc.

14 CLINICAL STUDIES

14.1 Multiple Myeloma
ICARIA-MM
The efficacy and safety of SARCLISA in combination with pomalidomide and low-dose dexamethasone (Isa-Pd) were evaluated in ICARIA-MM (NCT02990338), a multicenter, multinational, randomized, open-label, 2-arm, phase 3 study in patients with relapsed and refractory multiple myeloma. Patients had received at least two prior therapies including lenalidomide and a proteasome inhibitor.

A total of 307 patients were randomized in a 1:1 ratio to receive either SARCLISA in combination with pomalidomide and low-dose dexamethasone (SARCLISA + Pomalidomide + Dexamethasone) or pomalidomide and low-dose dexamethasone (Pomalidomide + Dexamethasone).

Table 5: Efficacy of SARCLISA in Combination with Pomalidomide and Low-Dose Dexamethasone versus Pomalidomide and Dexamethasone in the Treatment of Multiple Myeloma (ICARIA-MM)

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>SARCLISA + Pomalidomide + Dexamethasone</th>
<th>Pomalidomide + Dexamethasone</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=154</td>
<td></td>
<td></td>
</tr>
<tr>
<td>N=153</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Progression-Free Survival</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median (months)</td>
<td>11.53</td>
<td>6.47</td>
</tr>
<tr>
<td>[95% CI]</td>
<td>[8.94–13.9]</td>
<td>[4.47–8.28]</td>
</tr>
<tr>
<td>Hazard ratio [95% CI]</td>
<td>0.596</td>
<td>[0.44–0.81]</td>
</tr>
<tr>
<td>p-value (stratified log-rank test)</td>
<td>0.0010</td>
<td></td>
</tr>
<tr>
<td>Overall Response Rate&lt;sup&gt;1&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Responders (sCR+CR+VGPR+PR)</td>
<td>n (%)</td>
<td>93 (60.4)</td>
</tr>
<tr>
<td>[95% CI]&lt;sup&gt;2&lt;/sup&gt;</td>
<td>[52.2%–68.2%]</td>
<td>[27.8%–43.4%]</td>
</tr>
<tr>
<td>p-value (stratified Cochran-Mantel-Haenszel)</td>
<td>&lt;0.0001</td>
<td></td>
</tr>
<tr>
<td>Very Good Partial Response (VGPR)</td>
<td>n (%)</td>
<td>42 (27.3)</td>
</tr>
<tr>
<td>Partial Response (PR)</td>
<td>n (%)</td>
<td>44 (28.6)</td>
</tr>
</tbody>
</table>

*Stratified on age (<75 versus ≥75 years) and number of previous lines of therapy (2 or 3 versus >3) according to IRF.
†CR, VGPR and PR were evaluated by the IRC using the IMWG response criteria.
‡Estimated using Clopper-Pearson method.

The median time to first response in responders was 35 days in Isa-Pd group versus 58 days in Pd group. The median duration of response was 13.3 months (95% CI: 10.6-NCR) in the Isa-Pd group versus 11.1 months (95% CI: 8.5-NCR) in the Pd group. Median overall survival was not reached for either treatment group. At a median follow-up time of 11.6 months, 43 (27.9%) patients on Isa-Pd and 56 (36.6%) patients on Pd had died. The OS results at interim analysis did not reach statistical significance.

Figure 1: Kaplan-Meier Curves of PFS – ITT Population – ICARIA-MM (assessment by the IRC)
17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Infusion-Related Reaction

Instruct patients to immediately report any occurrence of symptoms occurring within 24 hours of start of infusion to their healthcare provider [see Warnings and Precautions (5.1)].

Neutropenia

Inform patients about the risk of neutropenia and infection during SARCLISA treatment and the importance of reporting immediately any fever or symptoms of infection to their healthcare provider [see Warnings and Precautions (5.2) and Adverse Reactions (6.1)].

Second Primary Malignancies

Inform patients of the risk of developing second primary malignancies during treatment with SARCLISA in combination with pomalidomide and low-dose dexamethasone [see Warnings and Precautions (5.3)].

Interference with Laboratory Tests

Advise patients to inform healthcare providers and transfusion center personnel that they are treated with SARCLISA in case a red blood cell transfusion is planned [see Warnings and Precautions (5.4) and Drug Interactions (7.1)].

Embryo-Fetal Toxicity

Advise women of the potential hazard to a fetus and to avoid becoming pregnant during treatment and for at least 5 months after the last dose of SARCLISA [see Use in Specific Populations (8.1, 8.3)].

Advertise patients that pomalidomide has the potential to cause fetal harm and has specific requirements regarding contraception, pregnancy testing, blood and sperm donation, and transmission in sperm.

Advise patients to report suspected or known pregnancies. Pomalidomide is only available through a pregnancy registry [see Warnings and Precautions (5.1)].

Pomalidomide is a registered trademark of Sanofi

SARCLISA is a prescription medicine used in combination with other medicines called pomalidomide and dexamethasone. You should also read the Medication Guide that comes with pomalidomide. You can ask your healthcare provider or pharmacist for information about dexamethasone.

What is SARCLISA?

SARCLISA is a prescription medicine used in combination with pomalidomide and dexamethasone to treat adults who have received at least 2 prior therapies, including lenalidomide and a proteasome inhibitor, to treat multiple myeloma.

It is not known if SARCLISA is safe and effective in children.

Do not receive SARCLISA if you have a history of a severe allergic reaction to isatuximab-irfc or any of the ingredients in SARCLISA. See the end of this leaflet for complete list of ingredients in SARCLISA.

Before receiving SARCLISA, tell your healthcare provider about all of your medical conditions, including if you:

• are pregnant or plan to become pregnant. SARCLISA may harm your unborn baby. You should not receive SARCLISA during pregnancy.
• females who are able to become pregnant should use an effective method of birth control during treatment and for 5 months after your last dose of SARCLISA. Talk to your healthcare provider about birth control methods that you can use during this time.

Tell your healthcare provider right away if you think you are pregnant or become pregnant during treatment with SARCLISA.

• are breastfeeding or plan to breastfeed. It is not known if SARCLISA passes into your breast milk. You should not breastfeed during treatment with SARCLISA.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive SARCLISA?

• SARCLISA will be given to you by your healthcare provider by intravenous (IV) infusion into your vein.

• SARCLISA is given in treatment cycles of 28 days (4 weeks), together with the medicines pomalidomide and dexamethasone.
• in cycle 1, SARCLISA is usually given weekly.
• starting in cycle 2, SARCLISA is usually given every 2 weeks.

Your healthcare provider will decide how long you should receive SARCLISA.

• If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.

• Your healthcare provider will give you medicines before each dose of SARCLISA, to help reduce the risk of infusion reactions (make them less frequent and severe).

What are the possible side effects of SARCLISA?

SARCLISA may cause serious side effects including:

• Infusion reactions. Infusion reactions are common with SARCLISA and can sometimes be severe.
• Your healthcare provider will prescribe medicines before each infusion of SARCLISA to help decrease your risk for infusion reactions or to help make any infusion reaction less severe. You will be monitored for infusion reactions during each dose of SARCLISA.

• Your healthcare provider may slow down or stop your infusion, or completely stop treatment with SARCLISA if you have an infusion reaction.

Tell your healthcare provider right away if you develop any of the following symptoms of infusion reaction during or within 24 hours after an infusion of SARCLISA:

• feeling short of breath or chills
• nausea or cough

• Decreased white blood cell counts. Decreased white blood cell counts are common with SARCLISA and certain white blood cells can be severely decreased. You may have an increased risk of getting certain infections, such as upper and lower respiratory infections.

Your healthcare provider will check your blood cell counts during treatment with SARCLISA. Your healthcare provider may prescribe an antibiotic or antiviral medicine to help prevent infection, or a medicine to help increase your white blood cell counts during treatment with SARCLISA.

Tell your healthcare provider right away if you develop any fewer or symptoms of infection during treatment with SARCLISA.

• Risk of new cancers. New cancers have happened in people during treatment with SARCLISA. Your healthcare provider will monitor you for new cancers during treatment with SARCLISA.

• Change in blood tests. SARCLISA can affect the results of blood tests to match your blood type. Your healthcare provider will do blood tests to match your blood type before you start treatment with SARCLISA. Tell all of your healthcare providers that you are being treated with SARCLISA before receiving blood transfusions.

The most common side effects of SARCLISA include:

• lung infection (pneumonia)
• decreased red blood cell counts (anemia)
• upper respiratory tract infection
• decreased platelet counts (thrombocytopenia)

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These are not all the possible side effects of SARCLISA. For more information, ask your healthcare provider or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**General information about the safe and effective use of SARCLISA.**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your pharmacist or healthcare provider for information about SARCLISA that is written for health professionals.

**What are the ingredients in SARCLISA?**

**Active ingredient:** isatuximab-irfc

**Inactive ingredients:** histidine, histidine hydrochloride monohydrate, polysorbate 80, sucrose, and water for injection.

Manufactured by: sanofi-aventis U.S. LLC, Bridgewater, NJ 08807, A SANOFI COMPANY, U.S. License No. 1752

SARCLISA is a registered trademark of Sanofi ©2020 sanofi-aventis U.S. LLC

For more information, go to www.sanofi-aventis.us or call 1-800-633-1610.

This Patient Information has been approved by the U.S. Food and Drug Administration. 

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