Arcalyst®
(rilonacept) For Injection

Are your patients with recurrent pericarditis suffering in silence?

With recurrent pericarditis (RP), patients may think they just have to live with it.

But you can treat it.

ARCALYST is the *first and only* FDA-approved therapy to treat RP and reduce the risk of recurrence in patients 12 years and older.[1]

INDICATION

ARCALYST is indicated for the treatment of recurrent pericarditis (RP) and reduction in risk of recurrence in adults and pediatric patients 12 years and older.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- Interleukin-1 (IL-1) blockade may interfere with the immune response to infections. Treatment with another medication that works through inhibition of IL-1 or inhibition of tumor necrosis factor (TNF) is not recommended as this may increase the risk of serious infection. Serious, life-threatening infections have been reported in patients taking ARCALYST. Do not initiate treatment with ARCALYST in patients with an active or chronic infection.

Please see Important Safety Information throughout and full Prescribing Information at ARCALYST.com/PI.

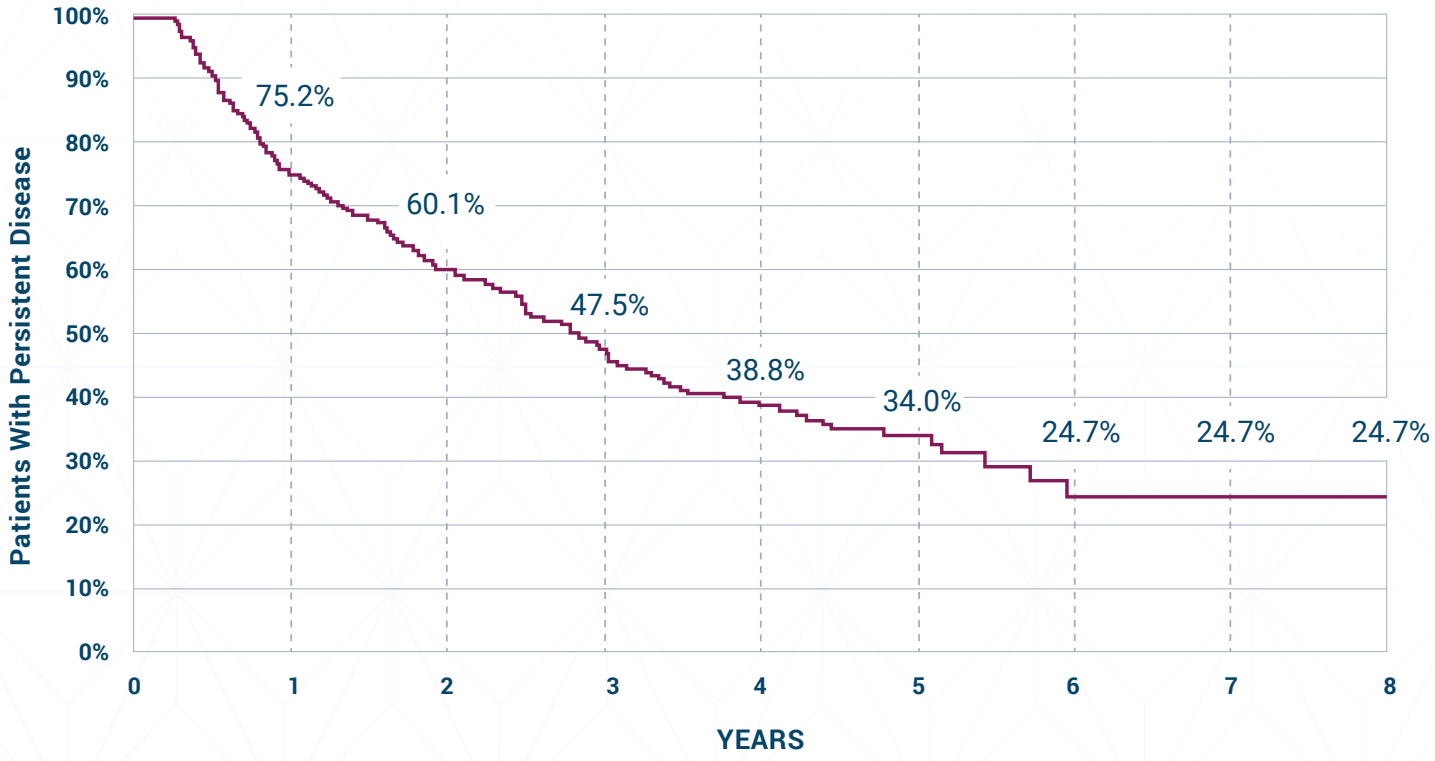
Patients with RP often suffer for years

Despite treatment with traditional therapies, up to **30%** of individuals with an initial episode of pericarditis will experience a recurrence within 18 months.[2,3]

Approximately
40,000
people in the United States seek treatment for RP annually.

An estimated
14,000
have ≥2 recurrences.

While the duration of first-episode pericarditis lasts up to 4 to 6 weeks, for those with ≥2 recurrences, this disease may last for years.[4,5]*



*Data from Optum Health Care Solutions, Inc., collected from January 1, 2007, through March 31, 2017, were analyzed for this observational study (N=375 patients with ≥2 recurrences of RP).

Patients with RP face increased risks

With each episode, **the risk of recurrence increases**[6†]:

RISK OF RECURRENCE
Risk of recurrence nearly doubles after the first recurrence

AFTER THE 1st EPISODE
28%
(2096 of 7502 patients)

AFTER 1st RECURRENCE
47%
(994 of 2096 patients)

AFTER 2nd RECURRENCE
54%
(541 of 994 patients)

Risk of serious complications is 2 to 3 times higher in patients with RP vs those with a first episode.[6†]

COMPLICATION	FIRST EPISODE OF PERICARDITIS (n=7502)	RECURRENT PERICARDITIS (n=2096)	LEVEL OF RISK
Pericardial effusion, %	18.1	49.7	~3x greater
Cardiac tamponade, %	5.1	8.9	~2x greater
Constrictive pericarditis, %	1.7	3.9	~2x greater

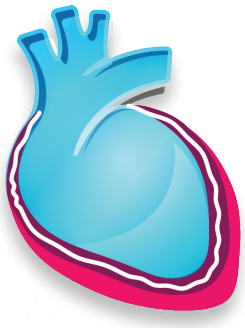
[†]Klein et al. *JAHA* 2020. Data from the PharMetrics Plus database, collected between January 1, 2013, and March 31, 2018, were used for this retrospective analysis (N=7502 patients with pericarditis, 2096 of whom experienced ≥1 recurrence).

RP is associated with longer duration and higher risk vs a first episode of pericarditis due to its distinct pathogenesis.[4-7]

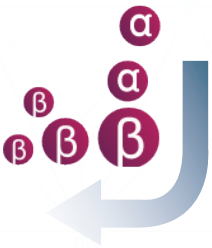
RP is driven by an interleukin-1 (IL-1)–mediated cycle of autoinflammation

The first episode of pericarditis may be caused by several factors, including viral illness and post-cardiac injury. **RP is driven by a self-perpetuating cycle of IL-1–mediated autoinflammation.**[4,7]

1. *Pericardial cell damage causes release of IL-1α.*



2. *IL-1α binds to macrophages causing the release of IL-1β.*



3. *IL-1α and IL-1β bind to vascular endothelial cells causing inflammation and additional cell damage.*

4. *Additional cell damage causes the cycle of autoinflammation to continue.*

Treatment of RP requires a paradigm shift: *FROM* not only relieving pain and inflammation associated with a flare *TO* preventing future flares by breaking the IL-1–mediated cycle of autoinflammation that drives the disease.[5,8]

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

- Discontinue ARCALYST if a patient develops a serious infection.

Please see Important Safety Information throughout and full Prescribing Information at ARCALYST.com/PI.

Arcalyst® (rilonacept) For Injection

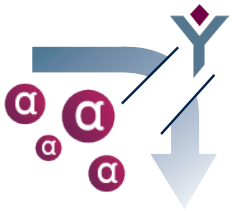
Control of RP requires a targeted treatment approach

ARCALYST breaks the IL-1–mediated cycle of autoinflammation that drives RP.[1,7]

ARCALYST binds to both IL-1α and IL-1β, blocking IL-1 signaling

ARCALYST breaks the IL-1–mediated cycle of autoinflammation

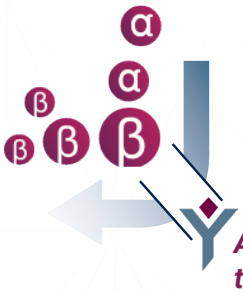
1. *Pericardial cell damage causes release of IL-1α.*



ARCALYST traps IL-1α

2. *IL-1α binds to macrophages causing the release of IL-1β.*

3. *IL-1α and IL-1β bind to vascular endothelial cells causing inflammation and additional cell damage.*



ARCALYST traps IL-1β

4. *Additional cell damage causes the cycle of autoinflammation to continue.*

ARCALYST traps IL-1α and IL-1β

Nonsteroidal anti-inflammatory drugs (NSAIDs), colchicine, and corticosteroids do not specifically target the IL-1–mediated cycle of autoinflammation, and patients may continue to have recurrences.[4,9]

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

- It is possible that taking drugs such as ARCALYST that block IL-1 may increase the risk of tuberculosis (TB) or other atypical or opportunistic infections.

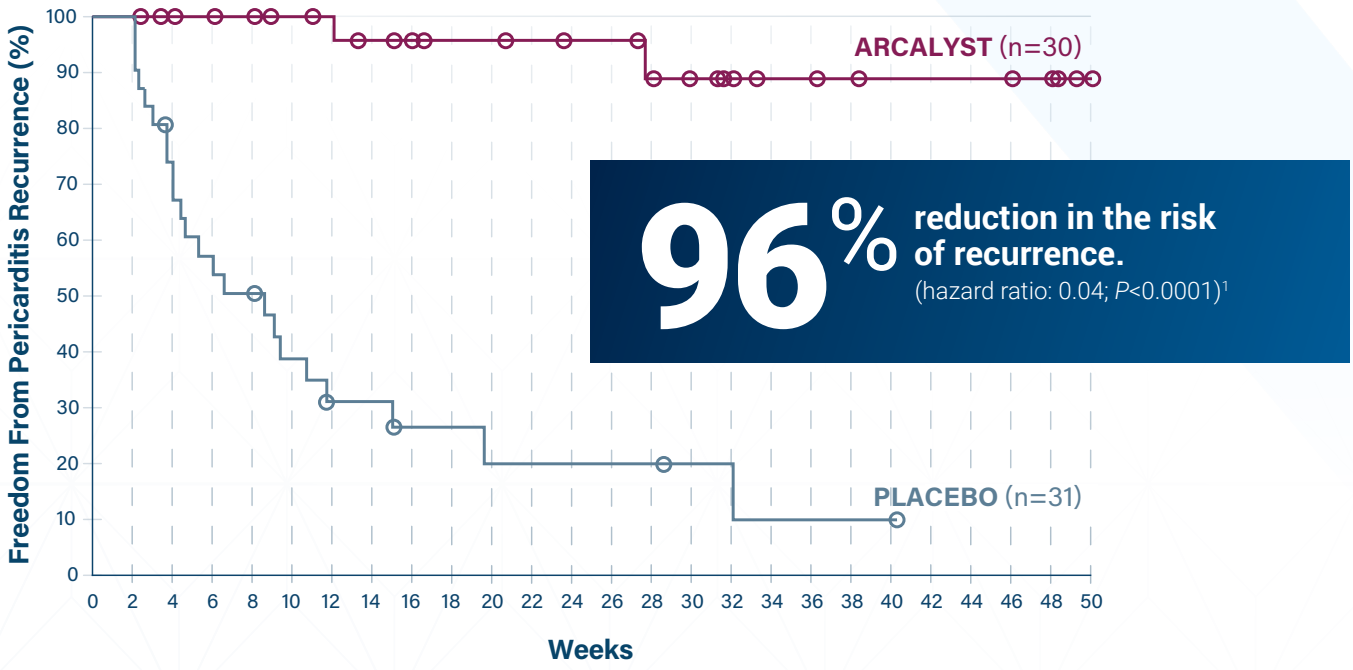
Please see Important Safety Information throughout and full Prescribing Information at ARCALYST.com/PI.

Arcalyst® (rilonacept) For Injection

ARCALYST was proven to prevent recurrences

In the randomized-withdrawal (RW) period (primary efficacy end point):

ARCALYST significantly reduced the risk of pericarditis recurrence.[10]



The median time to recurrence on ARCALYST could not be estimated due to the low number of recurrences[10]**:**

- **2 of 30** patients treated with ARCALYST experienced a recurrence
- The 2 pericarditis recurrences occurred **during temporary treatment interruptions** of 1 to 3 weekly ARCALYST doses

The median time to recurrence on placebo was 8.6 weeks (95% CI: 4.0, 11.7)[10]**:**

- **74% (23 of 31)** of patients treated with placebo experienced a recurrence at the time the event-driven RW portion of the trial was closed

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

- Although the impact of ARCALYST on infections and the development of malignancies is not known, treatment with immunosuppressants, including ARCALYST, may result in an increase in the risk of malignancies.

Please see Important Safety Information throughout and full Prescribing Information at ARCALYST.com/PI.

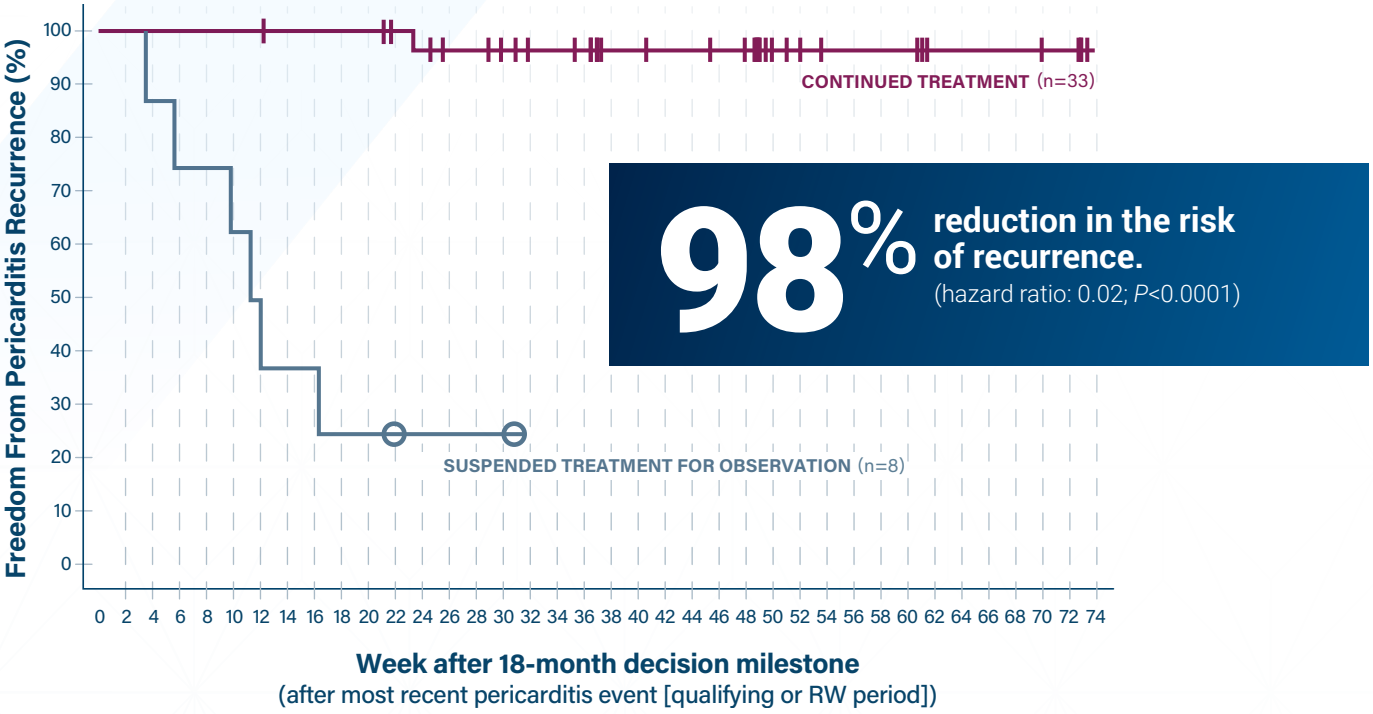
Arcalyst® (rilonacept) For Injection

Consistent results:

Continued ARCALYST treatment resulted in continued recurrence prevention

In the long-term extension (LTE) period:

ARCALYST continued to significantly reduce recurrences past the 18-month decision milestone.[11,12]



Week after 18-month decision milestone
(after most recent pericarditis event [qualifying or RW period])

- Recurrence rate was 3.0% (1/33) in patients who continued ARCALYST treatment vs 75% (6/8) in patients who suspended treatment for observation
- The only recurrence in the group treated with ARCALYST was associated with a treatment interruption of 4 weeks
- The median time to recurrence after suspended ARCALYST treatment was 11.8 weeks

These results are consistent with the primary efficacy end point of RHAPSODY.[11]

LTE patient population: 74 of 75 eligible patients chose to enter the LTE (59 directly from the RW period and 15 in the run-in [RI] period after enrollment in the RW period closed). 52 patients reached the 18-month decision milestone (33 continued open-label ARCALYST, 8 suspended treatment for observation, and 11 exited the study). 22 patients discontinued the LTE prior to reaching the 18-month decision milestone: 18 US participants transitioning to commercial ARCALYST at the time of US approval; 4 (US/ex-US) participants due to: lost to follow-up (1), adverse event (AE) (2), and withdrawal of consent (1).[11-13]

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

- Hypersensitivity reactions associated with ARCALYST occurred in clinical trials. Discontinue ARCALYST and initiate appropriate therapy if a hypersensitivity reaction occurs.

Please see Important Safety Information throughout and full Prescribing Information at ARCALYST.com/PI.

Arcalyst® (rilonacept) For Injection

ARCALYST rapidly relieved pain, resolved inflammation, and was steroid sparing

In the RI period *(secondary efficacy end point):*

97% **of patients achieved treatment response,* most as early as after the first dose.**[1,10]

Median time to **treatment response**
5.0 days (95% CI: 4.0, 7.0)

Median time to **pain response**
5.0 days (95% CI: 4.0, 6.0)

Median time to **CRP normalization**
7.0 days (95% CI: 5.0, 8.0)

In the RW period *(secondary efficacy end points assessed at Week 16):*

Patients reported **92%** **of trial days with minimal or no pericarditis pain (NRS ≤2)** compared with **40%** for patients on placebo (P<0.0001).[1]

100% **of patients receiving corticosteroids at RI baseline successfully transitioned off steroids soon after starting ARCALYST.**[10]

- Of the 86 patients enrolled, 41 (48%) were on treatment with corticosteroids at baseline
- Median time to ARCALYST monotherapy was **7.9 weeks** from traditional therapies, including NSAIDs, colchicine, or corticosteroids (alone or in combination)

CRP, C-reactive protein; NRS, Numerical Rating Scale.

*Time to treatment response was defined as the time from the first dose to the first day when pericardial pain was NRS ≤2 and CRP ≤0.5 mg/dL (measured within 7 days before or after the pain response).

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

- Increases in non-fasting lipid profile parameters occurred in patients treated with ARCALYST in clinical trials. Patients should be monitored for changes in their lipid profiles.

Please see Important Safety Information throughout and full Prescribing Information at ARCALYST.com/PI.

Arcalyst® (rilonacept) For Injection

ARCALYST has a proven safety profile

ARCALYST was generally well tolerated across all 3 study periods of RHAPSODY.[10]

Injection-site reactions and upper respiratory tract infections were the most common adverse events (AEs) associated with use of ARCALYST.

AEs (RI & RW)†

EVENT	RUN-IN PERIOD	RANDOMIZED-WITHDRAWAL PERIOD				TOTAL (N=86)
		Including Bailout		Before Bailout		
	ARCALYST (N=86)	ARCALYST (N=30)	Placebo (N=31)	ARCALYST (N=30)	Placebo (N=31)	
	← number of patients with event (percent) →					
Any AE	69 (80)	24 (80)	22 (71)	24 (80)	13 (42)	74 (86)
AEs according to maximum severity‡						
Mild	52 (60)	16 (53)	17 (55)	16 (53)	9 (29)	47 (55)
Moderate	15 (17)	8 (27)	5 (16)	8 (27)	4 (13)	25 (29)
Severe	2 (2)	0	0	0	0	2 (2)
Serious AE	1 (1)	1 (3)	3 (10)	1 (3)	1 (3)	5 (6)
AE leading to death	0	0	0	0	0	0
AE leading to dose interruption	0	1 (3)	0	1 (3)	0	1 (1)
AE leading to discontinuation of ARCALYST or placebo	4 (5)	0	0	0	0	4 (5)
Cancer§	0	1 (3)	0	1 (3)	0	1 (1)
Injection-site reaction	28 (33)	6 (20)	2 (6)	5 (17)	0	29 (34)
Infection or infestation	14 (16)	12 (40)	7 (23)	12 (40)	3 (10)	29 (34)
Upper respiratory tract infection	12 (14)	7 (23)	2 (6)	7 (23)	0	19 (22)

†Patients with multiple events were counted once in each appropriate category.
‡Counted once, according to the maximum severity of the AE.
§Cancer was an event of special interest.

In the LTE period (n=74), 62 patients (83.8%) experienced any treatment-emergent adverse event (TEAE), 5 patients (6.8%) experienced a serious TEAE related to study drug, 3 patients (4.1%) discontinued treatment, and there were no AEs leading to death.

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

- Since no data are available, avoid administration of live vaccines while patients are receiving ARCALYST. ARCALYST may interfere with normal immune response to new antigens, so vaccines may not be effective in patients receiving ARCALYST. It is recommended that, prior to initiation of therapy with ARCALYST, patients receive all recommended vaccinations, as appropriate.

Please see Important Safety Information throughout and full Prescribing Information at ARCALYST.com/PI.

Arcalyst® (rilonacept) For Injection

Treating your patients with ARCALYST

Pericarditis treatment pathway.[10]

Type	Treatment
First or single event	**Traditional therapies:** • NSAIDs and/or colchicine
Recurrent pericarditis 	**ARCALYST monotherapy uninterrupted for the duration of disease:** • In the clinical trial, RHAPSODY, patients were transitioned off all traditional therapies* —Median time to monotherapy was 7.9 weeks • ARCALYST significantly reduced the risk of recurrence (hazard ratio: 0.04; *P*<0.0001)

*At baseline, all patients were being treated with NSAIDs, colchicine, or corticosteroids, alone or in combination.

Consider ARCALYST before corticosteroids

- **Corticosteroids have broad anti-inflammatory actions, but are associated with AEs**[9,14]
  - —Reduction in dose or premature cessation of therapy to minimize AEs may unmask the underlying autoinflammatory process and result in a recurrence
- **In RHAPSODY, 52% of patients were not on corticosteroids at baseline and initiated ARCALYST after NSAIDs and/or colchicine**[1]

IMPORTANT SAFETY INFORMATION (continued)

Adverse Reactions

- The most common adverse reactions (≥10%) include injection-site reactions and upper respiratory tract infections.

Please see Important Safety Information throughout and full Prescribing Information at ARCALYST.com/PI.

Arcalyst®
(rilonacept) For Injection

Control of RP requires continued blockade of IL-1 signaling for the duration of disease

Traditionally, the decision to stop a therapy depends on symptomatology and biochemical markers.[10,15]

- However, ARCALYST relieves pain and resolves inflammation, so absence of abnormality in NRS score or CRP level while on treatment has limited value for predicting future recurrence should treatment be stopped

Duration of treatment with ARCALYST relies on understanding of the natural history of RP and clinical experience with ARCALYST.

RP is a chronic autoinflammatory disease, mediated by IL-1, that can last for several years[5]

Patients with RP received long-term treatment with ARCALYST in RHAPSODY[11,12]

—Participants in the LTE were treated with ARCALYST for a **median of ~24 months** (including RI)

ARCALYST has been proven to prevent recurrences as long as there are no interruptions in therapy[10-12]

Consider treating your patients with ARCALYST for at least 24 months to maintain prevention of recurrences.†

†The duration of a patient's ARCALYST treatment should be determined by the prescribing physician.

IMPORTANT SAFETY INFORMATION (continued)

Drug Interactions

- In patients being treated with CYP450 substrates with narrow therapeutic indices, therapeutic monitoring of the effect or drug concentration should be performed, and the individual dose of the medicinal product may need to be adjusted.

Please see Important Safety Information throughout and full Prescribing Information at ARCALYST.com/PI.

Arcalyst® (rilonacept) For Injection

Starting your patients on ARCALYST

Clinician

Pre-enrollment

- Ensure your patient's vaccination history is up-to-date, including pneumonia and flu vaccines
- Refer to current practice guidelines for evaluation and treatment of possible latent tuberculosis infections before initiating ARCALYST
- ARCALYST should not be initiated in patients with an active or chronic infection

Treatment team

Enrollment Form completion

- A **Kiniksa OneConnect™** Enrollment Form will be provided by your Kiniksa Clinical Sales Specialist or can be downloaded at ARCALYST.com/enrollment
- Fax completed Enrollment Form to the Kiniksa OneConnect™ program at 1-781-609-7826

Kiniksa OneConnect™

Fulfillment

- Your patient will be contacted by a **Kiniksa OneConnect™** Patient Access Lead (PAL) to arrange delivery from select specialty pharmacies
- Their PAL can help them set up injection training sessions with an ARCALYST Clinical Educator, with options to meet in person or virtually

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- Interleukin-1 (IL-1) blockade may interfere with the immune response to infections. Treatment with another medication that works through inhibition of IL-1 or inhibition of tumor necrosis factor (TNF) is not recommended as this may increase the risk of serious infection. Serious, life-threatening infections have been reported in patients taking ARCALYST. Do not initiate treatment with ARCALYST in patients with an active or chronic infection.

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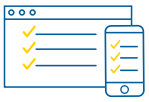
Arcalyst® (rilonacept) For Injection

Comprehensive support for you and your patients

The Kiniksa OneConnect™ program was designed to support your patients and your practice through every step of authorization and treatment.

Once you have enrolled your patient in the program, a dedicated PAL will be assigned to you and your patient. **Your PAL will assist with:**



Coordinating, verifying, and explaining the benefits verification process

Guiding your office through the prior authorization process

Coordinating delivery of therapy

Identifying financial assistance for eligible patients

Facilitating injection training with an ARCALYST Clinical Educator

Providing ongoing support

Low out-of-pocket cost and high commercial access

$10

Eligible, commercially insured patients pay as little as $10 per month for ARCALYST treatment with the copay assistance program*

≥92%

of prior authorization requests have been approved*†

*Based on final coverage approval.
†From approval in March 2021 to January 1, 2023.

Call 1-833-KINIKSA (1-833-546-4572) Monday through Friday, 8 AM to 8 PM ET
Visit KiniksaOneConnect.com

KINIKSA oneconnect™

ARCALYST is a patient-administered, once-weekly, subcutaneous (SC) injection[1]

The loading dose of ARCALYST should be performed under the supervision of a healthcare professional.

ADULTS (18 years and older)	ADOLESCENTS (12 to 17 years)
Loading dose: **320 mg** given as two 2-mL injections of 160 mg each	**Loading dose:** **4.4 mg/kg** given as 1 or 2 injections, up to a maximum of 320 mg (up to 4 mL)
Weekly maintenance dose: **160 mg** given as a once-weekly 2-mL injection	**Weekly maintenance dose:** **2.2 mg/kg** given as a once-weekly injection, to a maximum of 160 mg (up to 2 mL)

ARCALYST is supplied in sterile, single-use glass vials.[1]

- Each vial contains 220 mg of rilonacept, a sterile, white to off-white, preservative-free, lyophilized powder
- Reconstitution with 2.3 mL of Sterile Water for Injection is required prior to SC administration of the drug
- The reconstituted ARCALYST is a viscous, clear, colorless to pale yellow, 80 mg/mL solution, free from particulates

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

- Discontinue ARCALYST if a patient develops a serious infection.

Please see Important Safety Information throughout and full Prescribing Information at ARCALYST.com/PI.

Arcalyst® (rilonacept) For Injection

References: 1. ARCALYST. Package insert. Kiniksa Pharmaceuticals (UK), Ltd.; 2021. **2.** Data on file #1. Kiniksa Pharmaceuticals (UK), Ltd. **3.** Cremer PC, Kumar A, Kontzias A, et al. Complicated pericarditis: understanding risk factors and pathophysiology to inform imaging and treatment. *J Am Coll Cardiol*. 2016;68(21):2311-2328. doi:10.1016/j.jacc.2016.07.785 **4.** Chiabrando JG, Bonaventura A, Vecchié A, et al. Management of acute and recurrent pericarditis. *J Am Coll Cardiol*. 2020;75(1):76-92. **5.** Lin D, Laliberté F, Majeski C, et al. Disease and economic burden associated with recurrent pericarditis in a privately insured United States population. *Adv Ther*. 2021;38(10):5127-5143. doi:10.1007/s12325-021-01868-7 **6.** Klein A, Cremer P, Kontzias A, et al. US database study of clinical burden and unmet need in recurrent pericarditis. *J Am Heart Assoc*. 2021;10:e018950. doi:10.1161/JAHA.120.018950 **7.** Dinarello CA, Simon A, van der Meer JWM. Treating inflammation by blocking interleukin-1 in a broad spectrum of diseases. *Nat Rev Drug Discov*. 2012;11(8):633-652. doi:10.1038/nrd3800 **8.** Vecchié A, Del Buono MG, Mauro AG, et al. Advances in pharmacotherapy for acute and recurrent pericarditis. *Expert Opin Pharmacother*. 2002;23(6):681-691. **9.** Klein A, Cremer P, Kontzias A, et al. Clinical burden and unmet need in recurrent pericarditis: a systematic literature review. *Cardiol Rev*. 2022;30(2):59-69. doi:10.1097/CRD.0000000000000356 **10.** Klein AL, Imazio M, Cremer P, et al. Phase 3 trial of interleukin-1 trap rilonacept in recurrent pericarditis. *N Engl J Med.* 2021;384(1):31-41. **11.** Imazio M, Klein AL, et al. Prolonged rilonacept treatment in RHAPSODY long-term extension provided persistent reduction of pericarditis recurrence risk. Poster 2223. Presented at: American Heart Association Scientific Sessions; November 5-7, 2022; Chicago, IL. **12.** Imazio M, Klein AL, et al. Abstract 11653: Prolonged rilonacept treatment in RHAPSODY long-term extension provided persistent reduction of pericarditis recurrence risk. *Circulation*. Published October 30, 2022. Accessed December 7, 2022. https://www.ahajournals.org/doi/abs/10.1161/circ.146.suppl_1.11653 **13.** Data on file. Kiniksa Pharmaceuticals (UK), Ltd. **14.** Imazio M, Lazaros G, Brucato A, Gaita F. Recurrent pericarditis: new and emerging therapeutic options. *Nat Rev Cardiol*. 2016;13(3):99-105. **15.** Kumar S, Khubber S, Reyaldeen R, et al. Advances in imaging and targeted therapies for recurrent pericarditis. *JAMA Cardiology*. 2022;7(9):975. doi:10.1001/jamacardio.2022.2584

Arcalyst® (rilonacept) For Injection

Break the IL-1–mediated cycle of autoinflammation with ARCALYST

- **RP is a chronic autoinflammatory disease, mediated by IL-1, that can last for several years**[5]
- **ARCALYST has been proven to prevent recurrences as long as there are no interruptions in therapy**[10-12]
  - —**96% reduction in risk** of pericarditis recurrence vs placebo during the RW period (hazard ratio: 0.04; *P*<0.0001)
  - —**98% reduction in risk** of recurrence for patients who continued ARCALYST **past the LTE 18-month decision milestone, consistent with the RW period** (hazard ratio: 0.02; *P*<0.0001)
- **Eligible, commercially insured patients pay as little as $10 per month for treatment**

Consider treating your patients with ARCALYST for at least 24 months to maintain prevention of recurrences.*

*The duration of a patient's ARCALYST treatment should be determined by the prescribing physician.

RHAPSODY trial design: The efficacy and safety of ARCALYST were evaluated in RHAPSODY, a Phase 3, multicenter, double-blind, placebo-controlled, event-driven, RW study of patients with acute symptoms of RP despite treatment with NSAIDs, colchicine, corticosteroids, or any combination thereof. The RW period was preceded by a 12-week RI period in which ARCALYST was initiated and patients transitioned to monotherapy. The RW period was followed by an LTE in which eligible patients could choose to be treated with ARCALYST for up to an additional 24 months. During the LTE, there was a prespecified 18-month decision milestone at which time a determination was made for each patient, based on clinical status and investigator discretion, whether they would continue open-label ARCALYST, suspend treatment for observation, or exit the study.[10-12]

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

- It is possible that taking drugs such as ARCALYST that block IL-1 may increase the risk of tuberculosis (TB) or other atypical or opportunistic infections.

Please see Important Safety Information throughout and full Prescribing Information at ARCALYST.com/PI.

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03/23 ARC-US-00101-23

www.ARCALYST.com/HCP

Arcalyst® (rilonacept) For Injection

RHAPSODY: Landmark trial evaluating ARCALYST for the treatment of recurrent pericarditis (RP)

Trial design[1-3]:

A Phase 3, multicenter, double-blind, event-driven, randomized-withdrawal (RW) trial of ARCALYST in RP patients with acute symptoms of at least a second recurrence **despite treatment with traditional therapies (NSAIDs, colchicine, or corticosteroids, alone or in combination)**.

Trial began with a 4-week screening period to establish trial eligibility and was followed by 3 periods, run-in (RI), RW, and long-term extension (LTE).

12-week RI	Event-driven, double-blind RW	LTE
Initiation of ARCALYST and transition to monotherapy	*Treatment with ARCALYST or placebo**	*Eligible patients were offered open-label ARCALYST for up to 24 additional months*
▪ 1-week stabilization ▪ 9 weeks weaning from background therapies ▪ 2 weeks ARCALYST monotherapy	▪ 1:1 randomization to weekly ARCALYST or placebo ▪ Continued until the prespecified number of primary efficacy end point events	▪ 18 months after the most recent pericarditis event (qualifying or RW period), a decision was made for each patient to†: —Continue open-label ARCALYST —Suspend treatment for observation (ARCALYST rescue for recurrence allowed) —Exit the study

NSAIDs, nonsteroidal anti-inflammatory drugs.

*For patients who met the prespecified clinical response criteria for ARCALYST.

†Based on clinical status and at investigator discretion.

INDICATION

ARCALYST is indicated for the treatment of recurrent pericarditis (RP) and reduction in risk of recurrence in adults and pediatric patients 12 years and older.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- Interleukin-1 (IL-1) blockade may interfere with the immune response to infections. Treatment with another medication that works through inhibition of IL-1 or inhibition of tumor necrosis factor (TNF) is not recommended as this may increase the risk of serious infection. Serious, life-threatening infections have been reported in patients taking ARCALYST. Do not initiate treatment with ARCALYST in patients with an active or chronic infection.
- Discontinue ARCALYST if a patient develops a serious infection.
- It is possible that taking drugs such as ARCALYST that block IL-1 may increase the risk of tuberculosis (TB) or other atypical or opportunistic infections.
- Although the impact of ARCALYST on infections and the development of malignancies is not known, treatment with immunosuppressants, including ARCALYST, may result in an increase in the risk of malignancies.

Please see Important Safety Information throughout and full Prescribing Information at ARCALYST.com/PI.

Arcalyst® (rilonacept) For Injection

RHAPSODY study population

Baseline characteristics of clinical trial participants[1,4]:

- Total population: **86**
- Mean patient age: **45 years (range 13-78)**
  - —57% female
- Diagnosis of "idiopathic" pericarditis: **73 (85%)**
  - —Remainder: post-cardiac injury pericarditis
- Medications for qualifying event:
  - —NSAIDs/colchicine/corticosteroids
- Mean duration of disease: **2.4 years**
- Mean pericarditis events per year: **4.4**
  - —Including the qualifying pericarditis event*
- Mean qualifying NRS pain score: **6.2**
- Mean qualifying CRP level: **6.2 mg/dL**

CRP, C-reactive protein; NRS, Numerical Rating Scale.

*Qualifying pericarditis event: 0-10 point NRS ≥4 and CRP ≥1 mg/dL.

References: 1. Klein AL, Imazio M, Cremer P, et al. Phase 3 trial of interleukin-1 trap rilonacept in recurrent pericarditis. *N Engl J Med*. 2021;384(1):31-41. **2.** Imazio M, Klein AL, et al. Prolonged rilonacept treatment in RHAPSODY long-term extension provided persistent reduction of pericarditis recurrence risk. Poster 2223. Presented at: American Heart Association Scientific Sessions; November 5-7, 2022; Chicago, IL. **3.** Imazio M, Klein AL, et al. Abstract 11653: Prolonged rilonacept treatment in RHAPSODY long-term extension provided persistent reduction of pericarditis recurrence risk. *Circulation*. Published October 30, 2022. Accessed December 7, 2022. https://www.ahajournals.org/doi/abs/10.1161/circ.146.suppl_1.11653. **4.** ARCALYST. Package insert. Kiniksa Pharmaceuticals (UK), Ltd.; 2021.

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

- Hypersensitivity reactions associated with ARCALYST occurred in clinical trials. Discontinue ARCALYST and initiate appropriate therapy if a hypersensitivity reaction occurs.
- Increases in non-fasting lipid profile parameters occurred in patients treated with ARCALYST in clinical trials. Patients should be monitored for changes in their lipid profiles.
- Since no data are available, avoid administration of live vaccines while patients are receiving ARCALYST. ARCALYST may interfere with normal immune response to new antigens, so vaccines may not be effective in patients receiving ARCALYST. It is recommended that, prior to initiation of therapy with ARCALYST, patients receive all recommended vaccinations, as appropriate.

Adverse Reactions

- The most common adverse reactions (≥10%) include injection-site reactions and upper respiratory tract infections.

Drug Interactions

- In patients being treated with CYP450 substrates with narrow therapeutic indices, therapeutic monitoring of the effect or drug concentration should be performed, and the individual dose of the medicinal product may need to be adjusted.

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03/23 ARC-US-00101-23

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