Arcalyst®
(rilonacept) For Injection

Once your patients have experienced ≥2 recurrences, data show that recurrent pericarditis (RP) may last for years.[1]

THE TREATMENT YOU CHOOSE TODAY COULD MAKE A DIFFERENCE FOR THOSE YEARS

You are no longer limited to an episodic treatment approach for patients with RP.

ARCALYST treats flares and can be used long-term to prevent recurrences.[2,3]

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.

THERE ARE AN ESTIMATED **160,000 INDIVIDUALS WITH PERICARDITIS** IN THE UNITED STATES[4]

Despite treatment with traditional therapies, up to **30%** of individuals with an initial episode of pericarditis will experience a recurrence within 18 months.[5]

~30%
of patients with a first episode of pericarditis will develop RP[5]

Approximately
40,000
people in the United States seek care for RP annually[5]

There are an estimated
20,000
new cases of RP in the United States each year[5]

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).

If you treat pericarditis, it is likely that a patient in your practice has RP or will develop it.

A diagnosis of RP follows the same criteria as acute pericarditis, plus a symptom-free interval of 4 to 6 weeks or longer since documented first event.[6]

Diagnosis of acute pericarditis requires 2 of the 4 following criteria:	Additional supporting findings:	The following tests are recommended for diagnosis of pericarditis:
1. Pericardial chest pain	◆ Elevation of markers of inflammation (eg, CRP, ESR, and white blood cell count)	◆ ECG
2. New widespread ST elevation or PR depression on ECG	◆ Evidence of pericardial inflammation by an imaging technique (eg, CT, CMR)	◆ TTE
3. Pericardial rubs		◆ Chest x-ray
4. Pericardial effusion *(new or worsening)*		◆ Assessment of markers of inflammation (eg, CRP) and myocardial injury (eg, CK, troponin)

Diagnosing subsequent recurrences of pericarditis in patients with an established history of RP is challenging as these patients often[7]:

- Have chest pain regardless of their recurrence status
- Lack enough clinical evidence to meet the diagnostic criteria of pericarditis because they are on multiple anti-inflammatory medications

A recent study found that **~50% of patients** had a less clear presentation of recurrence.[7]

CK, creatine kinase; CMR, cardiac magnetic resonance; CRP, C-reactive protein; CT, computed tomography; ECG, electrocardiogram; ESR, erythrocyte sedimentation rate; TTE, transthoracic echocardiogram.

RP NEGATIVELY IMPACTS PATIENTS BOTH DURING AND BETWEEN RECURRENCES

Watch Cathy tell her story.

RP may:

- Impair **physical functioning** and **mental well-being**[8]
- **Restrict activities** of daily living such as the ability to care for family, attend family or social events, and exercise[6,8]
- Result in **hospitalizations, emergency room visits, outpatient visits, procedures**, and **pharmacotherapy** due to flares[1]
- Impact indirect costs due to **absenteeism** and **impaired work productivity**[8]

"I would miss my children's school events, I would miss birthday parties, I would miss holidays."

–Cathy, living with RP

In a Harris Poll survey of 125 patients diagnosed with RP[9]:

86% of patients worry that **they could have a flare at any time**.

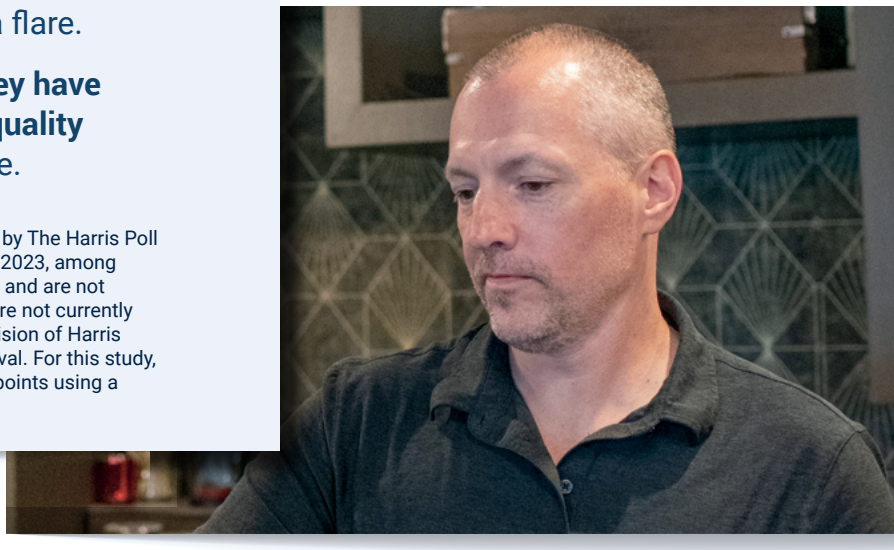
74% of patients **have withdrawn from many aspects of life** due to fear or anxiety about having a flare.

80% of patients **agree that they have not regained their prior quality of life** since having a flare.

This survey was conducted online within the United States by The Harris Poll on behalf of Kiniksa Pharmaceuticals from May 4–June 1, 2023, among 125 US adults ages 18+ who have been diagnosed with RP and are not currently pregnant or breastfeeding and have never used/are not currently using an interleukin-1 (IL-1) antagonist. The sampling precision of Harris online polls is measured by using a Bayesian credible interval. For this study, the sample data are accurate to within +/- 8.7 percentage points using a 95% confidence level.

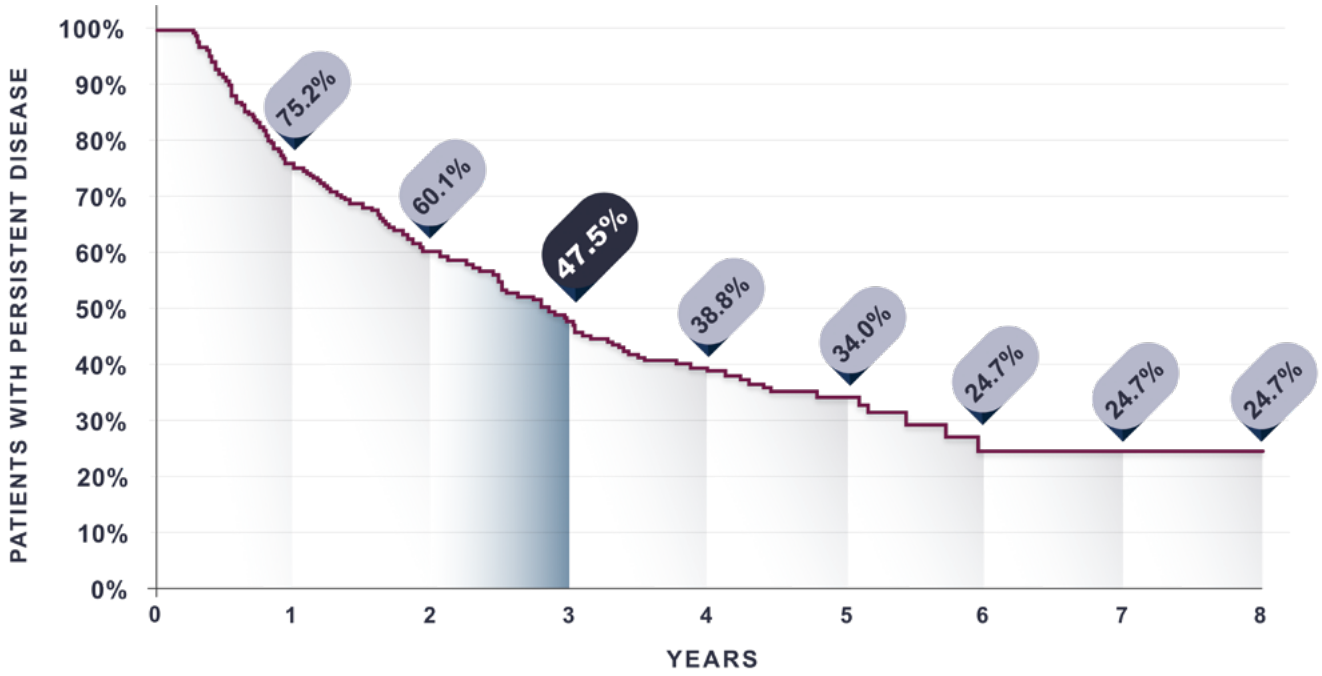
"Everything changed. Having a flare would affect every part of my life—home, work, family, friends, even our dogs."

–Gary, living with RP



A FIRST EPISODE OF PERICARDITIS AND RECURRENT PERICARDITIS (RP) ARE DISTINCT ENTITIES WITH DIFFERENT TREATMENT NEEDS

The disease duration of RP is often underestimated. Unlike a first episode of pericarditis, which may last 4 to 6 weeks, **a patient who experiences ≥2 recurrences may suffer for years**.[1,6]



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).

Were you aware the risk of recurrence increases with every episode?[5]*

WITH EACH EPISODE, THE RISK OF ANOTHER RECURRENCE INCREASES.

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)

With multiple events, risk of recurrence increases while time to recurrence decreases.[5]

*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). Pharmacotherapy included colchicine, nonsteroidal anti-inflammatory drugs (NSAIDs), and corticosteroids, alone or in combination.

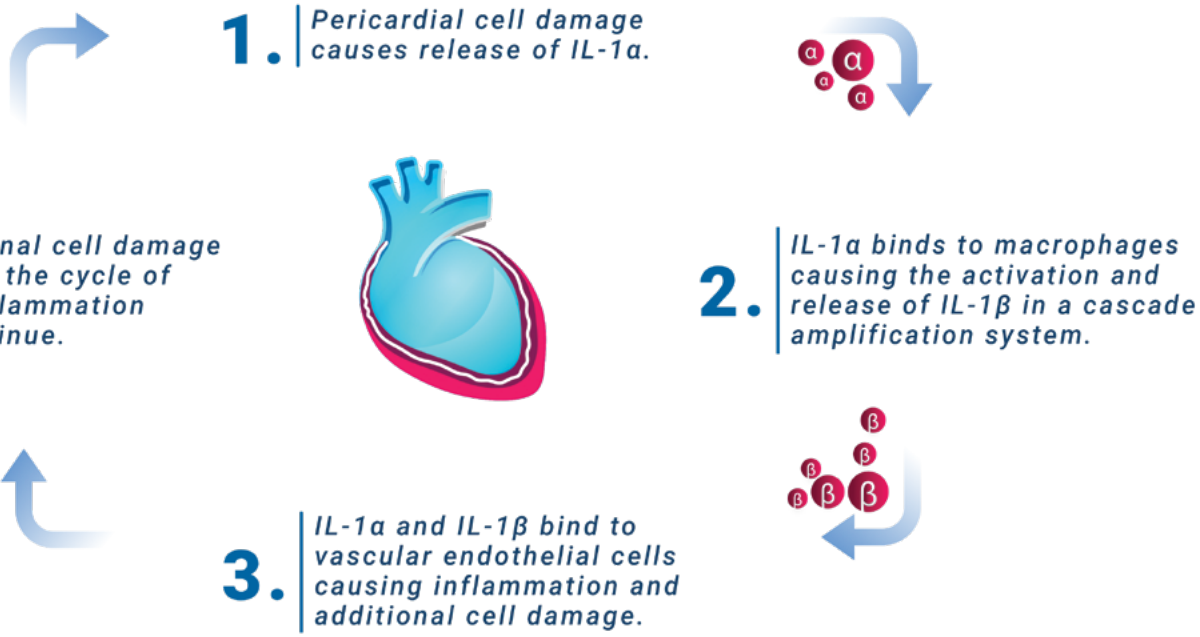
RP HAS AN INCREASED RISK OF COMPLICATIONS AND A DISTINCT PATHOGENESIS FROM A FIRST EPISODE

Risk of serious complications is 2 to 3 times higher in patients with RP.[5]*

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

Therapeutic intervention may help reduce the risk of complications.[10]

While the etiology of single- or first-episode pericarditis may be caused by several factors, including viral illness and post cardiac injury, **RP is a chronic autoinflammatory disease driven by a self-perpetuating cycle of IL-1–mediated autoinflammation.**[6,11]

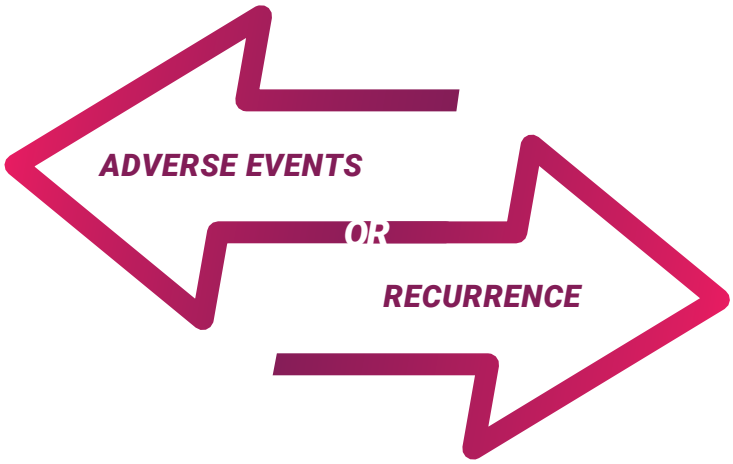


NSAIDs, colchicine, and corticosteroids do not specifically target the IL-1–mediated cycle of autoinflammation and may not be suitable for long-term use.[12,13]

GIVEN THE PATHOGENESIS AND CHRONICITY OF RP, THE RISKS AND BENEFITS OF A LONG-TERM TREATMENT STRATEGY MUST BE WEIGHED

- Corticosteroids do not specifically target the IL-1 mechanism of RP, and their **broad systemic activity can be associated with adverse events (AEs)**[12,13]
  - —The longer the duration of corticosteroid therapy, the greater the risk of AEs[14,15]
    - RP is a chronic disease, and it is estimated that with each additional week of corticosteroid treatment there is a 1.11-fold increased risk of related AEs
- Reduction in dose or **premature cessation of therapy** to minimize AEs may unmask the underlying autoinflammatory process and **result in recurrence**[13]

The use of corticosteroids to treat RP may lead to difficult choices for both HCPs and patients.[15]



Patients report a strong desire for maintenance therapy over an episodic approach.

In a Harris Poll survey of 125 patients diagnosed with RP[9]:

89% were afraid of the potential **long-term risks associated with repeated flares**.

90% **would be willing to take a medication for several years** in order to not experience another recurrence.

Top 3 Patient-Reported Goals for RP Treatment:

Prevent future flares	Reduce or prevent pain	More control over their RP

This survey was conducted online within the United States by The Harris Poll on behalf of Kiniksa Pharmaceuticals from May 4–June 1, 2023, among 125 US adults ages 18+ who have been diagnosed with RP and are not currently pregnant or breastfeeding and have never used/are not currently using an IL-1 antagonist. The sampling precision of Harris online polls is measured by using a Bayesian credible interval. For this study, the sample data are accurate to within +/– 8.7 percentage points using a 95% confidence level.

TREATMENT OF RP REQUIRES A PARADIGM SHIFT FROM JUST TREATING THE FLARE TO TREATING THE DISEASE[1,6,16]

Paradigm shift in the treatment of RP:

FROM:

Temporarily addressing pain and inflammation associated with a flare.

TO:

Preventing future flares by breaking the self-perpetuating cycle of IL-1-mediated autoinflammation that drives the disease.

Are your patients with RP suffering in silence?

ICD-10 CODE†	
I30.0	I30.8
I30.9	I31.9

Although there are no *ICD-10* codes for RP, the codes provided here are associated with pericarditis.

Using these codes along with parameters of prescription refills for colchicine and/or corticosteroids in an electronic health records search may assist you in identifying patients who required repeated therapy to treat recurrences associated with RP.

ICD-10, International Statistical Classification of Diseases, Tenth Revision.

*The codes are informational and not intended to be directive or guarantee of reimbursement. Other codes may be more appropriate given prescribers' internal system guidelines, practice patterns, and services rendered.

References: 1. 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 **2.** ARCALYST. Package insert. Kiniksa Pharmaceuticals; 2021. **3.** 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. **4.** Luis SA, LeWinter MM, Magestro M, et al. Estimating the US pericarditis prevalence using national health encounter surveillance databases. *Curr Med Res Opin*. 2022;38(8):1385-1389. **5.** 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 **6.** Adler Y, Charron P, Imazio M, et al. 2015 ESC guidelines for the diagnosis and management of pericardial diseases: The Task Force for the Diagnosis and Management of Pericardial Diseases of the European Society of Cardiology (ESC). *Eur Heart J*. 2015;36(42):2921-2964. **7.** Kumar A, Sato K, Verma BR, et al. Quantitative assessment of pericardial delayed hyperenhancement helps identify patients with ongoing recurrences of pericarditis. *Open Heart*. 2018;5(2):e000944. **8.** LeWinter M, Kontzias A, Lin D, et al. Burden of recurrent pericarditis on health-related quality of life. *Am J Cardiol*. 2021;141:113-119. doi:10.1016/j.amjcard.2020.11.018 **9.** Data on file. Kiniksa Pharmaceuticals. **10.** Pericarditis. Mayo Clinic. April 30, 2022. Accessed March 13, 2024. https://www.mayoclinic.org/diseases-conditions/pericarditis/symptoms-causes/syc-20352510 **11.** 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 **12.** Chiabrando JG, Bonaventura A, Vecchié A, et al. Management of acute and recurrent pericarditis. *J Am Coll Cardiol*. 2020;75:76-92. **13.** 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 **14.** Schwier NC, Luis SA, Hu X, et al. Risk factors associated with recurrence and corticosteroid-associated adverse events in patients with recurrent pericarditis. *Value in Health*. 2021;24(5)(suppl 1):S67. Abstract PCV5. **15.** Brucato A, Wheeler A, Luis SA, et al. Transition to rilonacept monotherapy from oral therapies in patients with recurrent pericarditis. *Heart*. 2023;109:297-304. **16.** Imazio M, Mardigyan V, Andreis A, Franchin L, De Biasio M, Collini V. New developments in the management of recurrent pericarditis. *Can J Cardiol*. 2023;39(8):1103-1110. doi:10.1016/j.cjca.2023.04.008

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SUSTAINED PREVENTION

ARCALYST has been proven to prevent recurrences as long as there are no interruptions in therapy.[1,2]

In both the randomized-withdrawal (RW) and long-term extension (LTE) portions of RHAPSODY, the only adjudicated recurrences observed in the ARCALYST treatment arms occurred during temporary treatment interruptions.

- In the RW period, 2 of 30 patients treated with ARCALYST experienced a recurrence, both during treatment interruptions of 1 to 3 weekly doses vs 23 of 31 patients treated with placebo
- In the LTE period beyond 18 months of treatment, 1 of 33 patients who continued ARCALYST treatment experienced a recurrence during a treatment interruption of 4 weekly doses vs 6 of 8 patients who suspended treatment for observation

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

- 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.

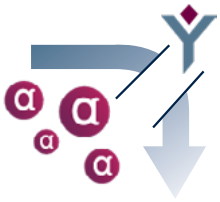
Please see Important Safety Information throughout and full Prescribing Information at ARCALYST.com/PI.

ARCALYST BREAKS THE SELF-PERPETUATING CYCLE OF IL-1–MEDIATED AUTOINFLAMMATION[3,4]

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

ARCALYST breaks the IL-1–mediated cycle of autoinflammation

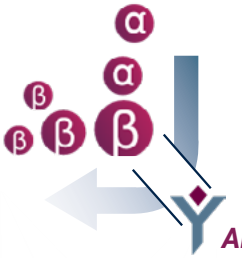
1. *Pericardial cell damage causes release of IL-1α.*



ARCALYST traps IL-1α

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

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



ARCALYST traps IL-1α and IL-1β

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

ARCALYST traps IL-1β

Both RP pain relief and flare prevention may be achieved through continued blockade of IL-1 signaling for the duration of the disease.[3,5]

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.

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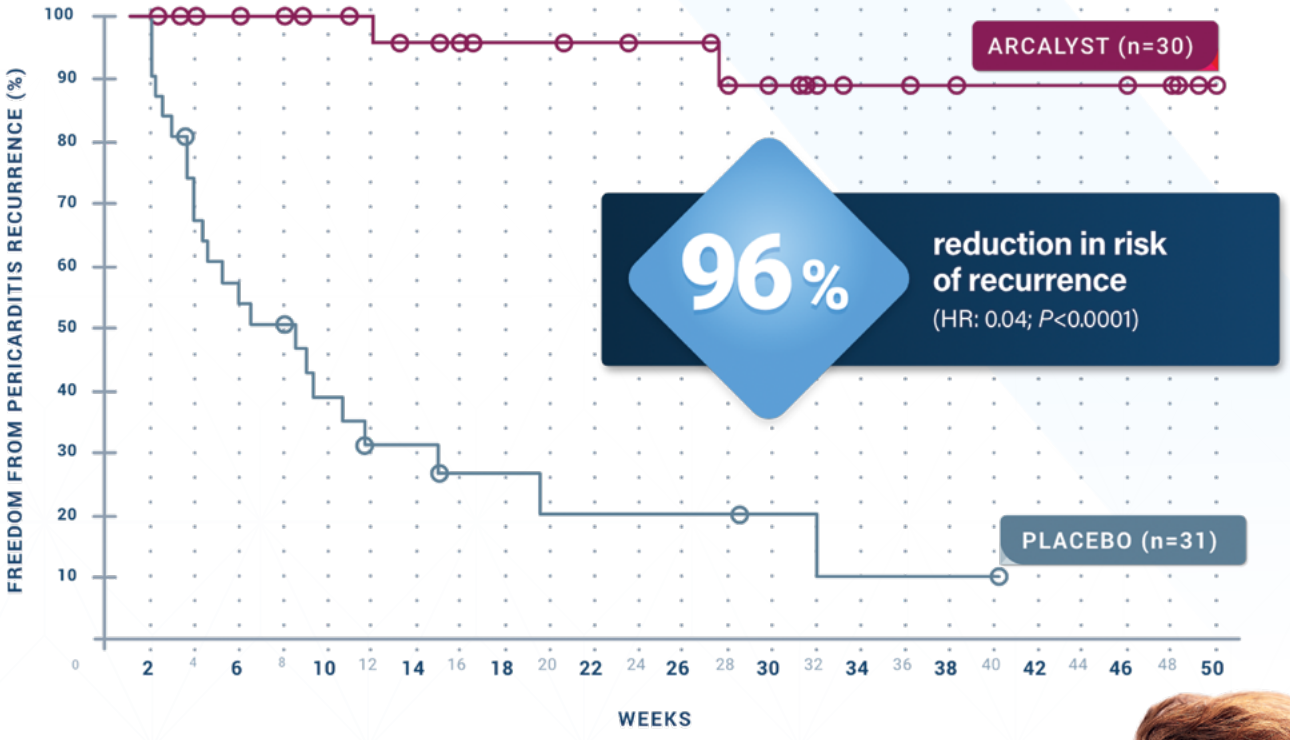
RHAPSODY RW period:

ARCALYST SIGNIFICANTLY REDUCED RISK OF PERICARDITIS RECURRENCE[1,3]

Primary efficacy endpoint: time to first adjudicated pericarditis recurrence in the RW period



- **7% (2 of 30) of patients treated with ARCALYST** experienced a recurrence (**both during treatment interruptions** of 1 to 3 weekly doses)
  - —The median time to recurrence could not be estimated due to low number
- **74% (23 of 31) of patients treated with placebo** experienced a recurrence by the time the event-driven RW portion of the trial was closed
  - —The median time to recurrence on placebo was 8.6 weeks (95% CI: 4.0, 11.7)

HR, hazard ratio.

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.

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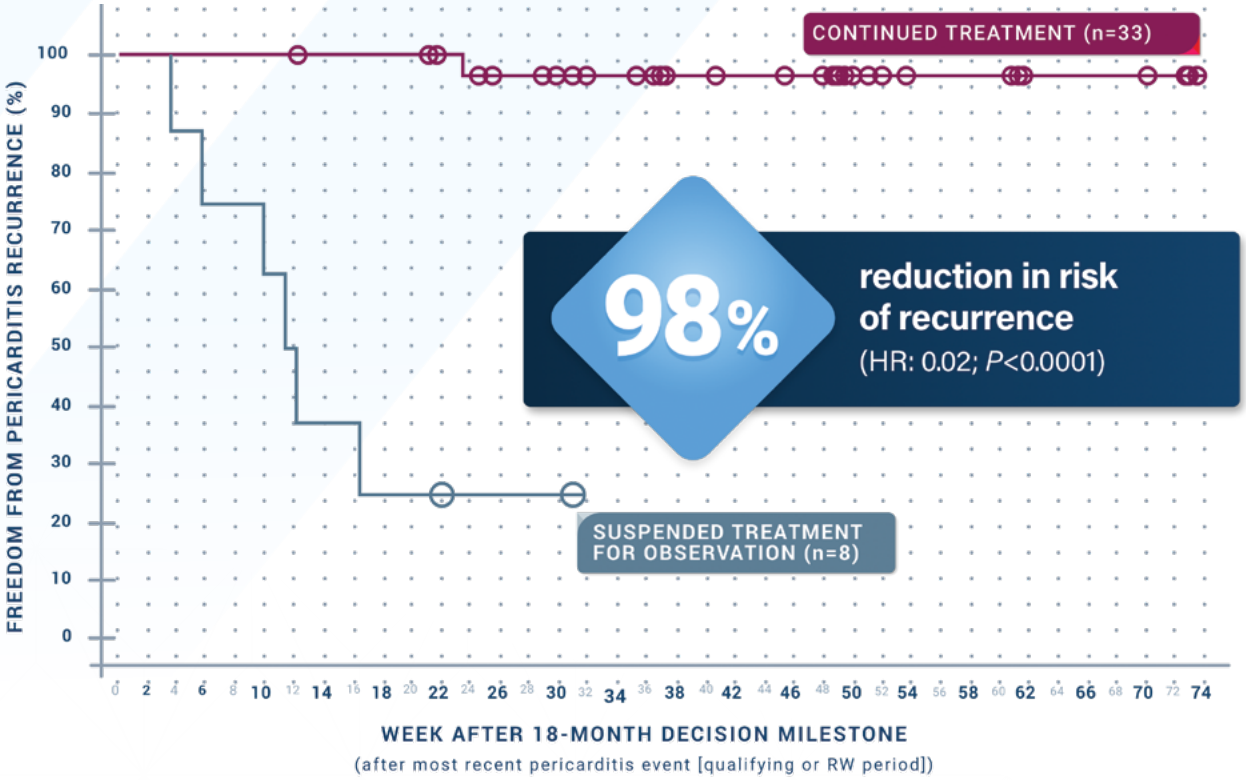
RHAPSODY LTE:

TREATMENT WITH ARCALYST REDUCED THE RISK OF PERICARDITIS RECURRENCES OVER THE LONG-TERM[2]

Efficacy past the 18-month decision milestone



- **3% (1 of 33) of patients** who continued ARCALYST treatment experienced a recurrence (during a treatment interruption of 4 weekly doses)
  - —The median time to recurrence could not be estimated due to low number
- **75% (6 of 8) of patients** who suspended treatment for observation experienced a recurrence
  - —The median time to recurrence after suspension of ARCALYST treatment was 11.8 weeks (95% CI: 3.7-NE weeks)

These results are consistent with the primary efficacy end point.[1]

IMPORTANT SAFETY INFORMATION (continued)

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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IN RHAPSODY, ARCALYST WAS STEROID SPARING

100% **of 41 patients receiving corticosteroids at baseline were able to transition off corticosteroids soon after initiating therapy.**[1,3]

- **48% (41 of 86) of patients** with RP entered RHAPSODY with a qualified pericarditis flare **despite taking corticosteroids***†
- **97% (77 of 79) of patients** achieved treatment response with ARCALYST, regardless of corticosteroid treatment at baseline

  —Median time to ARCALYST monotherapy was 7.9 weeks from traditional therapies

No patient in the RW period had a reintroduction of corticosteroid therapy.

*Medications used at baseline: NSAIDs (58), colchicine (69), or corticosteroids (41), alone or in combination.
†Pericarditis flare included at least a second recurrence and Numerical Rating Scale (NRS) ≥4 and C-reactive protein (CRP) ≥1 mg/dL within 7 days prior to administration of the first dose of ARCALYST.

In the run-in (RI) period (secondary efficacy end point):

ARCALYST relieved pain and resolved inflammation as early as after the first dose.[1‡]

5 DAYS Median time to **pain response** (95% CI: 4.0, 6.0)

7 DAYS Median time to **CRP normalization** (95% CI: 5.0, 8.0)

‡Time to treatment response was defined as the time from the first dose to the first day when pericardial pain was NRS ≤2 (0-10) and CRP ≤0.5 mg/dL (measured within 7 days before or after the pain response).

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 [0-10])** compared with 40% for patients on placebo ($P \leq 0.0001$).[3]

IMPORTANT SAFETY INFORMATION (continued)

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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CONSIDER ARCALYST BEFORE CORTICOSTEROIDS

Pericarditis treatment pathway[1-3]

TYPE	TREATMENT
First or single event	**Traditional therapies:** NSAIDs and/or colchicine
For recurrent pericarditis CONSIDER ABC ARCALYST BEFORE CORTICOSTEROIDS	**ARCALYST monotherapy uninterrupted for the duration of disease:** In RHAPSODY, patients were transitioned off all traditional therapies* • Median time to monotherapy was 7.9 weeks • **52% of patients were not on corticosteroids at baseline** ARCALYST significantly reduced risk of recurrence by 96% (HR: 0.04; *P*<0.0001) ARCALYST significantly reduced risk of recurrence by 98% in the LTE period (HR: 0.02; *P*<0.0001), **consistent with the primary efficacy end point** *Medication use at baseline: NSAIDs (58), colchicine (69), or corticosteroids (41), alone or in combination ***Consider treating your patients with ARCALYST for at least 24 months to maintain prevention of recurrences.***

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

- 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.
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PRACTICAL CONSIDERATIONS FOR DURATION OF THERAPY WITH ARCALYST

A low NRS score and/or absence of elevated CRP levels while on treatment with ARCALYST **have limited value for guiding treatment duration or predicting future recurrences should treatment be stopped.**[3]

- Data show that RP can last for years in patients with ≥2 recurrences[6]
- Premature cessation of ARCALYST therapy may result in the unmasking of the underlying disease, leading to recurrences[2]

IF PREMATURELY DISCONTINUED, ARCALYST MAY BE REINITIATED

In both the RW and LTE periods, all patients who reinitiated ARCALYST after a flare experienced resolution[1,2]:

- In the RW period, all patients who had a recurrence (25) reinitiated ARCALYST and experienced resolution of their flare
- In the LTE period, all patients who had a recurrence and reinitiated ARCALYST (6/7) experienced resolution of their flare*

Tell your patients to watch for signs and symptoms of a potential recurrence.[7]

- In a secondary analysis of RHAPSODY, **patients who experienced recurrence in the RW period reported incremental increases in average daily NRS scores in the 2 weeks before the event**
- Patients who experienced a recurrence and received ARCALYST bailout reported resolution of pain within 1 to 2 weeks

*1 patient experienced a recurrence, but did not reinitiate ARCALYST.

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.

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ARCALYST HAS A PROVEN SAFETY PROFILE WITH LONG-TERM DATA[8]

Treatment-emergent adverse events (TEAEs) occurring in ≥5% of subjects RI + RW overall (safety analysis set)

	RI	RW Period		RI + RW Overall
Preferred Term†	ARCALYST, N=86; n (%)	ARCALYST before bailout, N=30; n (%)	Placebo before bailout, N=31; n (%)	ARCALYST or placebo, N=86; n (%)
Subject with any TEAEs	70 (81.4)	25 (83.3)	13 (41.9)	74 (86.0)
Injection-site erythema	18 (20.9)	6 (20.0)	0 (0.0)	21 (24.4)
Arthralgia	8 (9.3)	1 (3.3)	0 (0.0)	10 (11.6)
Myalgia	9 (10.5)	1 (3.3)	0 (0.0)	10 (11.6)
Injection site pruritus	5 (5.8)	4 (13.3)	0 (0.0)	8 (9.3)
Nasopharyngitis	6 (7.0)	2 (6.7)	0 (0.0)	8 (9.3)
Headache	7 (8.1)	0 (0.0)	0 (0.0)	7 (8.1)
Musculoskeletal chest pain	3 (3.5)	1 (3.3)	4 (12.9)	7 (8.1)
Back pain	3 (3.5)	1 (3.3)	1 (3.2)	6 (7.0)
Cough	5 (5.8)	1 (3.3)	0 (0.0)	6 (7.0)
Injection-site swelling	5 (5.8)	1 (3.3)	0 (0.0)	6 (7.0)
Diarrhea	5 (5.8)	0 (0.0)	0 (0.0)	5 (5.8)
Fatigue	2 (2.3)	2 (6.7)	0 (0.0)	5 (5.8)

†MedDRA v21.0. A subject could only be counted once within a preferred term.

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.

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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

Use this QR code or visit ARCALYST.com/enrollment to download the enrollment form

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

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:

Call 1-833-KINIKSA
(1-833-546-4572)

Monday-Friday
(8 AM - 8 PM ET)

LOW *out-of-pocket* **COST** **$0**

Eligible, commercially insured patients pay as little as **$0 per month** for ARCALYST treatment with the copay assistance program*

High *commercial* **access** **96%** PA approval

A significant majority of PA requests for ARCALYST have been approved*†

Contact a PAL for more information regarding financial assistance below:

The QuickStart Program supports your patients with ARCALYST treatment initiation if they experience a delay in coverage.

- The program is offered for up to 60 days while awaiting coverage determination. Prior authorization submission required

The Patient Assistance Program supports eligible patients with limited or no coverage for treatment.

- Qualified patients can receive monthly shipments of ARCALYST for up to 12 months of treatment at no cost
- Visit kiniksapolicies.com/pap to review additional eligibility criteria

*Based on final coverage approval.
†From approval in March 2021 to September 30, 2024.

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.

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Arcalyst® (rilonacept) For Injection

ARCALYST IS A PATIENT-ADMINISTERED, ONCE-WEEKLY, SC INJECTION[3]

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 SC injections of 160 mg each	**Loading dose:** **4.4 mg/kg** given as 1 or 2 SC injections, up to a maximum of 320 mg (up to 4 mL)
Weekly maintenance dose: **160 mg** given as a once-weekly 2-mL SC injection	**Weekly maintenance dose:** **2.2 mg/kg** given as a once-weekly SC injection, up to a maximum of 160 mg (up to 2 mL)

SC, subcutaneous.

ARCALYST is supplied in sterile, single-use, 20-mL glass vials.

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

IMPORTANT SAFETY INFORMATION (continued)

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.

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

Arcalyst® (rilonacept) For Injection

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.

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 recurrent pericarditis 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.

Arcalyst® (rilonacept) For Injection

YOU ARE NO LONGER LIMITED TO AN EPISODIC TREATMENT APPROACH FOR PATIENTS WITH RP. TREAT THE DISEASE BY TARGETING AND BLOCKING THE UNDERLYING CAUSE

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

- **RP is an IL-1–driven, chronic, autoinflammatory disease that often lasts for several years and represents a tremendous burden for patients**[4,6]
- Treatment of RP requires a paradigm shift from temporarily addressing pain and inflammation associated with each flare **to preventing flares for the duration of the disease**[5,6,9]
- By targeting and blocking IL-1, ARCALYST **breaks the self-perpetuating cycle of autoinflammation** that drives RP[3]
- **In RHAPSODY, ARCALYST was proven to prevent recurrences as long as there are no interruptions in therapy**[2,3]

reduction in risk of pericarditis recurrence vs placebo during the RW period (HR: 0.04; *P*<0.0001).

reduction in risk of recurrence for patients who continued ARCALYST past the LTE 18-month decision milestone, **consistent with the primary efficacy end point** (HR: 0.02; *P*<0.0001).

- Eligible commercially insured patients **pay as little as $0/month** for ARCALYST

Consider ARCALYST for at least 24 months to treat RP and maintain prevention of recurrences.

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precaution (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.

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, Brucato A, et al. Sustained pericarditis recurrence risk reduction with long-term rilonacept. *J Am Heart Assoc*. 2024;13(6):e032516. doi:10.1161/JAHA.123.032516 **3.** ARCALYST. Package insert. Kiniksa Pharmaceuticals; 2021. **4.** 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 **5.** Imazio M, Mardigyan V, Andreis A, Franchin L, De Biasio M, Collini V. New developments in the management of recurrent pericarditis. *Can J Cardiol*. 2023;39(8):1103-1110. doi:10.1016/j.cjca.2023.04.008 **6.** 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 **7.** Brucato A, Lim-Watson MZ, Klein A, et al; RHAPSODY Investigators. Interleukin-1 trap rilonacept improved health-related quality of life and sleep in patients with recurrent pericarditis: results from the phase 3 clinical trial RHAPSODY. *J Am Heart Assoc*. 2022;11(20):e023252. doi:10.1161/JAHA.121.0232526 **8.** Data on file. Kiniksa Pharmaceuticals. **9.** Adler Y, Charron P, Imazio M, et al. 2015 ESC guidelines for the diagnosis and management of pericardial diseases: The Task Force for the Diagnosis and Management of Pericardial Diseases of the European Society of Cardiology (ESC). *Eur Heart J*. 2015;36(42): 2921-2964. doi:10.1097/CRD.0000000000000356

KINIKSA

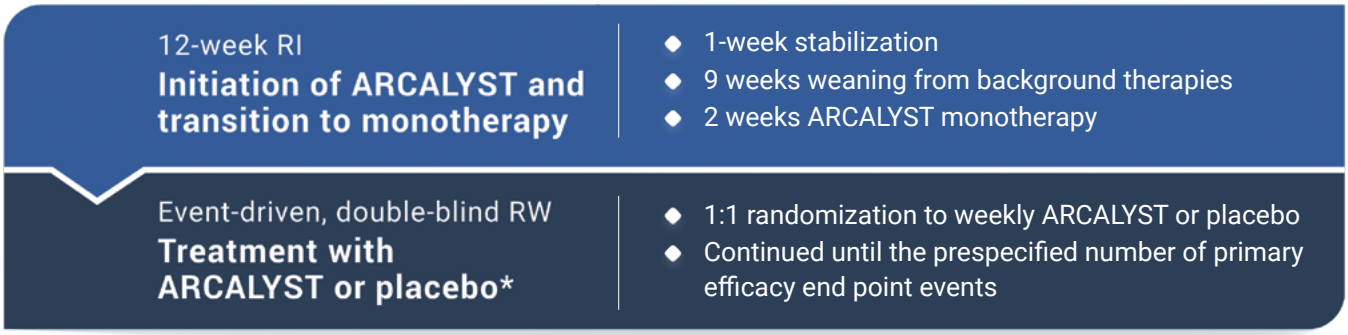
Visit www.ARCALYST.com/HCP to learn more.

Arcalyst® (rilonacept) For Injection

ARCALYST WAS STUDIED IN THE LANDMARK PHASE 3 CLINICAL TRIAL RHAPSODY[1]

Trial design: A Phase 3, multicenter, double-blind, event-driven, 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 a run-in (RI) period and randomized-withdrawal (RW) period.



RHAPSODY TRIAL POPULATION

Select characteristics of clinical trial participants[1,2]

- Total population: **86**
- Mean patient age: **45 years** (range 13-78)
  - **57%** female
- Diagnosis of "idiopathic" pericarditis: **85%** (n=73)
  - Remainder: post-pericardiotomy syndrome and Dressler syndrome
- Medications used at baseline (alone or in combination):
  - NSAIDs: **n=58**
  - Colchicine: **n=69**
  - Corticosteroids: **n=41**
- 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; NSAID, nonsteroidal, anti-inflammatory drug; RP, recurrent pericarditis.
*For patients who met the prespecified clinical response criteria for ARCALYST.

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

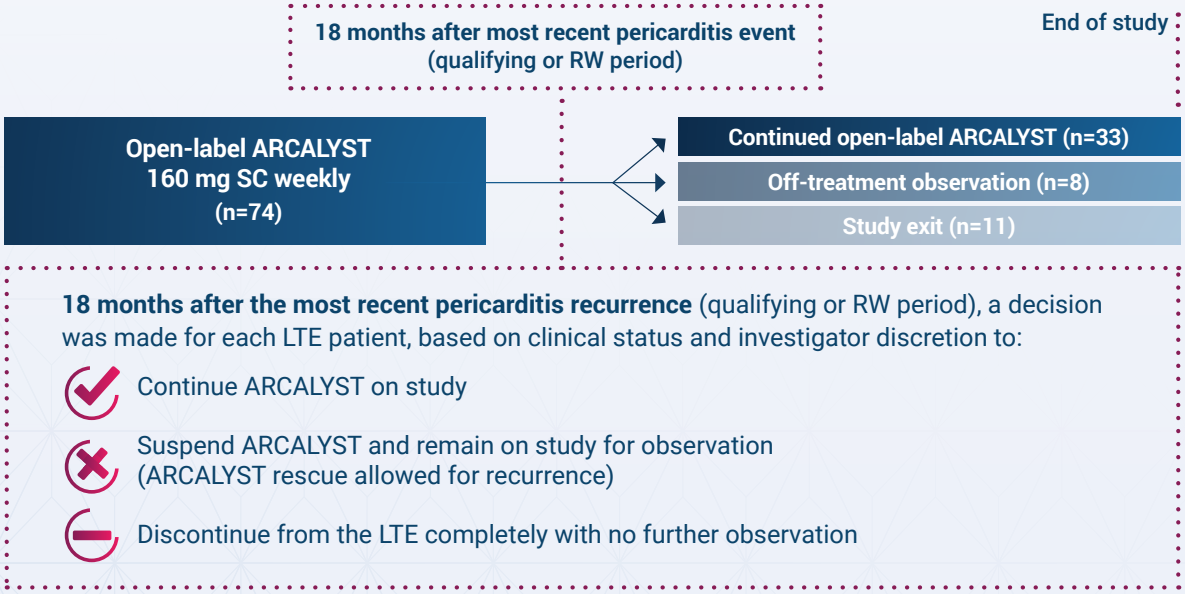
- Interleukin-1 (IL-1) blockade may interfere with the immune response to infections. Treatment with another medication that works through inhibition of IL-1 or inhibition of tumor necrosis factor (TNF) is not recommended as this may increase the risk of serious infection. Serious, life-threatening infections 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.

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

Arcalyst® (rilonacept) For Injection

LONG-TERM EXTENSION (LTE)

Eligible patients were offered open-label ARCALYST for up to an additional 24 months*[3]



SC, subcutaneous.
*22 patients discontinued the LTE prior to reaching the 18-month decision milestone; 18 US participants transitioned to commercial ARCALYST at the time of US approval; 4 (US/ex-US) participants due to lost to follow-up (1), AE (2), and withdrawal of consent (1).[4]

IMPORTANT SAFETY INFORMATION

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.
- 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.

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

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.** ARCALYST. Package insert. Kiniksa Pharmaceuticals; 2021. **3.** Imazio M, Klein AL, Brucato A, et al. Sustained pericarditis recurrence risk reduction with long-term rilonacept. *J Am Heart Assoc*. 2024;13(6):e032516. doi:10.1161/JAHA.123.032516 **4.** Data on file. Kiniksa Pharmaceuticals.

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