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Sponsored Abstract

Prolonged Rilonacept Treatment in RHAPSODY Long-Term Extension Provided Persistent Reduction of Pericarditis Recurrence Risk

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Introduction: Rilonacept reduced pericarditis recurrence in the phase 3 trial RHAPSODY. The long-term extension (LTE) enabled further insights into efficacy, safety, and clinical decision making.

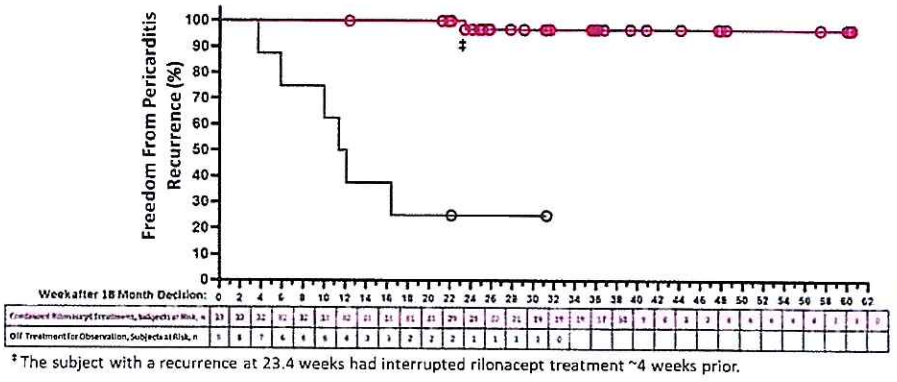
Methods: The RHAPSODY run-in (RI) and randomized-withdrawal periods were followed by an LTE that enabled open-label rilonacept treatment up to 24 additional months. A decision at 18 months after the most recent recurrence was based on clinical status at investigator discretion:

1) continue rilonacept on-study, 2) suspend rilonacept for observation or 3) discontinue from the LTE without observation. Endpoints included recurrence and quality of life.

Results: In May 2020, 74 of 75 eligible subjects continued to the LTE; US subjects (n=45) switched to commercial therapy or discontinued in April 2021 (treatment duration from RI baseline [median; maximum] 18; 27 months). Non-US subjects (n=29) completed the LTE in June 2022 (treatment duration from RI baseline [median; maximum] 27; 33 months). Concomitant oral medications during LTE: 22% NSAIDS, 20% colchicine, 0% corticosteroids, 43% none. Inflammation signs (CRP), RP symptoms (PGIPS), and recurrences were low on-treatment. Before the 18-month decision (n=74), there were 3 investigator-assessed recurrences (0.04 per patient-year). At the 18-month decision (n=52), 64% (n=33) continued rilonacept on-study, 15% (n=8) suspended rilonacept for observation, and 21% (n=11) discontinued the study without observation, of whom 7 switched to commercial rilonacept. There was a 75% recurrence rate (n=6/8) in the off-treatment observation group (median time to event 11.8 [3.7, Not-Estimable (NE)] weeks) but only 1 recurrence in subjects on rilonacept (time to event NE [too few events]) associated with a 4-week interruption; HR 0.018, p<0.0001; Figure 1.

Conclusion: Continued rilonacept treatment resulted in continued treatment response, whereas treatment suspension at 18 months may be associated with pericarditis recurrence.

Figure 1. Continued rilonacept treatment beyond 18 months resulted in continued treatment response



‡ The subject with a recurrence at 23.4 weeks had interrupted rilonacept treatment ~4 weeks prior.

Hazard Ratio = 0.018
Log-rank p-value < 0.0001
Risk reduction = 98.2%

Continued Rilonacept Treatment

Off-treatment for Observation

	N	Number of Subjects with Recurrence* n (%)	Number of Weeks to Recurrence* Median (95% CI)
Continued Rilonacept Treatment	33	1 (3)	NE (NE, NE)
Off-Treatment for Observation	8	6 (75)	11.8 (3.7, NE)

*After 18 month decision
NE, not estimable