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SESSION TITLE: EXPERIMENTAL AND THERAPEUTIC APPROACHES FOR CARDIOVASCULAR DISEASE

Abstract 12851: Efficacy and Safety of Riloncept in Recurrent Pericarditis: A Multicenter Phase 2 Clinical Trial

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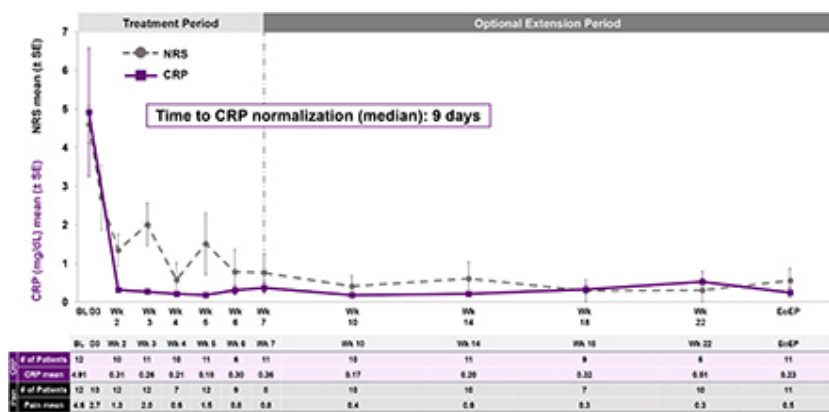
Abstract

Introduction: Interleukin-1 (IL-1) mediates innate autoinflammation and is implicated in recurrent pericarditis (RP). We report final data from a Phase 2 study of riloncept (IL-1 α /IL-1 β inhibitor) in RP.

Methods: Symptomatic or corticosteroid (CS)-dependent asymptomatic pts with idiopathic or post-pericardiectomy RP received open-label riloncept (320mg SC load; 160mg SC weekly) during a 6-wk treatment period (TP) and an optional 18-wk extension period (EP). Baseline NSAIDs, colchicine, and/or CS were continued during TP and weaned optionally during EP. Efficacy endpoints were change in pericardial pain (NRS) and CRP (symptomatic RP) and disease activity after CS taper (CS-dependent asymptomatic RP).

Results: Of 25 adults with RP (21 idiopathic, 4 post-pericardiectomy, mean age 42.8 y, mean 2.6 prior recurrences, 20/25 pts on > 2 pericarditis medications), 23 completed 6 months of riloncept treatment. One pt chose not to continue into EP, and 1 discontinued TP due to a serious adverse event (SAE). In symptomatic RP pts with CRP >1mg/dL, lower pain and CRP levels were observed after the first injection and maintained to the end of study (Fig 1). Improvement/resolution of other pericarditis manifestations (pericardial effusion, ECG changes, pericardial rub) and improvements in global physical and mental health scores were observed. No subject had pericarditis recurrence in EP, and of 12 pts on CS at baseline completing EP, 1 reduced CS dose and 10 stopped CS during EP. Two SAEs were reported: skin abscess resulting in riloncept discontinuation and atypical chest pain; both resolved. Most common adverse events were injection site reactions, all mild and none resulting in riloncept discontinuation.

Conclusions: Patient-reported and clinical measures of RP improved after first rilonacept injection. CSs were dose-reduced or discontinued. Observed AEs were consistent with known rilonacept safety profile. RHAPSODY, a Phase 3 trial, is enrolling.



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