The phase II open-label MAvERIC-Pilot study investigated the impact of CardiolRx™ (oral solution of pharmaceutically manufactured cannabidiol) administered to patients with symptomatic recurrent pericarditis. The study enrolled 27 participants (average age of 53 years; 67% female) at eight clinical sites across the United States.

Main Patient Characteristics

Prior to trial entry, MAvERIC-Pilot study participants had an average disease duration of 2.7 years, and they had experienced 5.8 pericarditis episodes per year.

At entry into the study participants' baseline average pericarditis pain score was 5.8 out of 10 and the average C-reactive protein (CRP) level was 2.0 mg/dL (normal is 0.5 mg/dL or less), indicative of notable chest pain and inflammation, respectively.

Additional Patient Characteristics

In addition to pericarditis chest pain, participants also experienced other manifestations of pericarditis: pericardial effusion in 21 patients (78%), pericardial rub in 4 patients (15%), and abnormal electrocardiogram [(ECG); ST-segment elevation or PR depression) in 5 patients (19%).

At study entry, participants were on stable doses of medications for recurrent pericarditis, in any combination, including:

- colchicine - 85% of patients,
- non-steroidal anti-inflammatory drugs (NSAIDS) - 78% of patients,
- corticosteroids - 41% of patients

Study Treatment

The study was 26 weeks in duration and consisted of an 8-week treatment period followed by an 18-week extension period. During the first 10 days of the treatment period, CardiolRx™ was added to the background recurrent pericarditis medications and up-titrated to 10 mg/kg twice daily (or the maximum tolerated dose). Throughout the treatment period, patients continued receiving this concomitant therapy but were then weaned off their background medications during the extension period in order to assess pericarditis recurrence while only being administered CardiolRx™.

Study Endpoints

Primary endpoint: Change in patient-reported pericarditis pain score [measured using an 11-point numerical rating scale (NRS*); scored from 0-10] at 8 weeks

Secondary endpoints: i) Pain score at 26 weeks, ii) freedom from pericarditis recurrence, iii) change in CRP and, iv) CRP normalization

Summary of Results

The primary endpoint of pericardial pain showed an average reduction of 3.7 points, from 5.8 at baseline to 2.1 at week 8.

The median time to resolution/ near resolution of pain (defined as a score of 2 or less on the NRS) was rapid, observed just 5 days following initiation of CardiolRx™ treatment.

Reduction in pain was maintained throughout the duration of the trial with an average reduction of 4.3 points, from 5.8 at baseline to 1.5 at week 26.

At week 8 (end of the treatment period), 93% of patients (25 of 27) reported a pain score reduction.

Of the patients with an elevated CRP (at least 1 mg/dL) at baseline, CRP normalized (i.e., 0.5 mg/dL or less) at week 8 in 80% of patients (8 of 10), with a substantial average reduction of 5.4 mg/dL (from 5.7 mg/dL to 0.3 mg/dL).

CRP levels for the entire group of patients were reduced from 2.0 mg/dL at baseline to 0.74 mg/dL at week 8 and 0.55 at week 26, with a median time to CRP normalization of 21 days.

71% of patients (17 of 24) were free from recurrence during the 18-week extension period when CardiolRx™ was continued and patients were weaned off background medications. For those patients experiencing a recurrence, the median time to an episode was 7.7 weeks during the extension period.

The number of pericarditis episodes per year was markedly reduced from 5.8 episodes per year prior to study to 0.9 episodes per year during the study.

CardiolRx™ was shown to be safe and well tolerated with 89% of patients (24 of 27) progressing to the extension period and overall study drug compliance reported at 95%.

**The NRS pain score is a validated clinical tool used across multiple conditions with acute and chronic pain, including previous studies of recurrent pericarditis*.