



## Interferon Beta-1b in Patients With Chronic Viral Cardiomyopathy (CVC)

**BACKGROUND:** Viral genomes are present in about 50% of myocardial biopsies from pts with DCM.

Pilot data suggests interferon treatment might be beneficial in pts with CVC. **PURPOSE:** To evaluate the efficacy & safety of two different doses of interferon beta-1b (4 MIU & 8 MIU) vs placebo in pts with biopsy-proven CVC with adenovirus, enterovirus and/or parvovirus at 12 & 24 weeks in order to find the most suitable dose for a future phase III study.

**DESIGN:** Randomized, double-blind, placebo-controlled trial of 143 pts.

**Primary Endpoints:** Virus elimination or reduction of virus load

**Secondary Endpoints:**

Change in NYHA functional class; Composite clinical endpoint (NYHA functional class, pt global assessment, major adverse events); QOL (MLHF); 6-minute walking test; Echo assessment of LV function & dimensions

**Results:**

**Primary Endpoint:** Virus Reduction: Placebo = 18.8%, 4 MIU = 32.7%, 8 MIU = 37%, Interferon total = 34.7%, p = 0.048 (Figure)

**Secondary Endpoints:**

Change in NYHA functional class & QOL = improvement in Beta-I grps

6-minute walk test & Echo assessment of LV function & dimensions = NS

**Conclusion:** These data implicate a biopsy-based specific & causal therapy for CVC. Final confirmation including prognosis requires a phase III trial.

Percentage of Viral Load Reduction/ Elimination

