

# CANTOS

**Principal Investigators:**

Rodney Diehl, DO (MidMichigan Physicians Group)

Peter Fattal, MD (MCVI)

Rao Gudipati, MD (MCVI)

**Sponsor:**

Novartis Pharmaceuticals

**Study Purpose:**

The purpose of this trial is to test the hypothesis that canakinumab treatment of patients with MI at least one month prior to study entry and elevated hsCRP will prevent recurrent cardiovascular events.

**Criteria****Inclusion Criteria:**

- Written informed consent
- Male, or Female of non-child-bearing potential
- Age  $\geq$  18 years.
- Spontaneous MI at least 30 days before randomization.
- hsCRP  $\geq$  2 mg/L

**Exclusion Criteria:**

- Pregnant or nursing (lactating) women
- Women of child-bearing potential
- Any of the following concomitant diseases
- Planned coronary revascularization (PCI or CABG)
- Major non-cardiac surgical or endoscopic procedure within past 6 months
- Multi-vessel CABG surgery within the past 3 years
- Symptomatic patients with Class IV heart failure (HF) (New York Heart Association [NYHA]).
- Uncontrolled hypertension
- Uncontrolled diabetes
- History or evidence of active tuberculosis (TB) infection

Other protocol-defined inclusion/exclusion criteria may apply