

## **POST-MARKET REGISTRY STUDY PROPOSAL**

The ALERTS Study has demonstrated that the AngelMed Guardian System prompted high-risk patients to seek medical attention for coronary occlusive events in a timely manner, largely independent of recognized symptoms.

AngelMed proposes to continue capturing information on key metrics in a similar high-risk patient population in the post-marketing environment to increase the size of the population (and incidence of relatively rare events) to capture clinical outcome metrics based on what was learned from the ALERTS Study. In order to achieve this goal, AngelMed proposes a prospective, event-driven, post-market registry study with an appropriate control group. The enrollment and closure of the registry would be determined in a dialogue with FDA to ensure adequate precision is attained for all endpoints in the study. AngelMed is planning to have patients enrolled in the post-market study to be included in the American College of Cardiology's ACTION Registry which is already directed at measuring outcomes for patients experiencing STEMI or NSTEMI.

The following metrics are being proposed for the post-market registry study:

- Time from occlusion-to-door for qualified ACS events
- Patient Emergency Alarm compliance
- PPV for qualified Emergency Alarms
- Assessment of preservation of LVEF using a standardized protocol
- Identification of new Q-waves from using dual baselines
- 1-year mortality following recurrent STEMI/NSTEMI
- Safety data related to initial implant and replacement procedures