

ARCA expands scope of beta-blocker

BROOMFIELD - ARCA biopharma Inc. in Broomfield has submitted a request for a special protocol assessment, or SPA, with the FDA for the design of a clinical trial to assess the safety and effectiveness of the biopharma's beta-blocker Gencaro.

An SPA is an agreement with the FDA that the proposed trial protocol design, clinical endpoints and statistical analyses are acceptable to support regulatory approval.

ARCA (Nasdaq: ABIO) wants to test the drug on approximately 3,000 patients with chronic heart failure who have the genotype that appears to respond most favorably to Gencaro.

Gencaro is ARCA's beta-blocker and mild vasodilator. The FDA has previously designated the investigation of Gencaro for the reduction of cardiovascular mortality and cardiovascular hospitalizations in a genotype-defined group of people with heart failure as a fast-track development program.

The proposed trial would compare Gencaro with the beta-blocker metoprolol CR/XL, which is approved for heart failure and other indications.