T89 ORESA Phase III study (Clinical Trial No.: NCT03789552)

Another multi-center, double-blind, randomized, placebo-controlled, parallel-group phase III clinical trial is currently ongoing to confirm the safety and efficacy of T89 in patients with stable angina pectoris, with an extended open-label period to evaluate the long-term safety of T89.

This clinical study is being conducted in 42 clinical sites across the United States. Approximately 765 patients who met inclusion and exclusion criteria are being randomized into one of three groups to ensure at least 612 evaluable patients for the efficacy assessment: T89 high dose (300 mg, twice a day), T89 low dose (225 mg, twice a day) and placebo control group, with 204 evaluable patients in each group. For safety assessment, at least 360 patients will be followed for a total of 6 months and 120 patients for a total of 12 months. The primary efficacy endpoint is the change in symptom-limited total exercise duration (TED) at trough drug levels on standard Bruce protocol from baseline to Day 57. The estimated study completion time is in year 2022.