

CAMELLIA-TIMI 61 - Cardiovascular and Metabolic Effects of Lorcaserin in Overweight and Obese Patients-Thrombolysis in Myocardial Infarction

Purpose: To evaluate the long-term effects of long-term lorcaserin in obese and overweight patients with cardiovascular disease (CVD) or multiple risk factors.

Trial Design: Phase 4, parallel, double-blinded, randomized 1:1 based on established CV disease or CV risk factors without established CV disease; treatment with APD356-Lorcaserin hydrochloride 10 mg twice daily vs placebo for 3.3 years and N= 12,000.

Primary Endpoints: Safety: First MACE. **Efficacy:** Composite of other MACE events (hospitalization due to unstable angina, heart failure, or any coronary revascularization).

	lorcaserin	placebo	P value
≥5% weight loss @ 1 year	38.7%	17.4%	<0.001
First MACE (safety)	6.1%	6.2%	<0.001 non-inferiority
Composite of other MACE events (efficacy)	11.8%	12.1%	0.55

Results: In these overweight and obese high-risk patients, weight loss was sustained with lorcaserin compared to placebo with a similar cardiovascular event rate as placebo.

