

TIMI 31



Protocol Design

A Phase II, Open-Label, Multi-Center, Dose Escalation Study to Determine the Efficacy, Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of BB-10153 in ST Segment Elevation Myocardial Infarction

Patient with Acute ST Elevation MI < 6 hours

Randomize (n=21 to 84 depending upon dose finding)

**1 mg/kg
BB-10153**

**2 mg/kg
BB-10153**

**3 mg/kg
BB-101530**

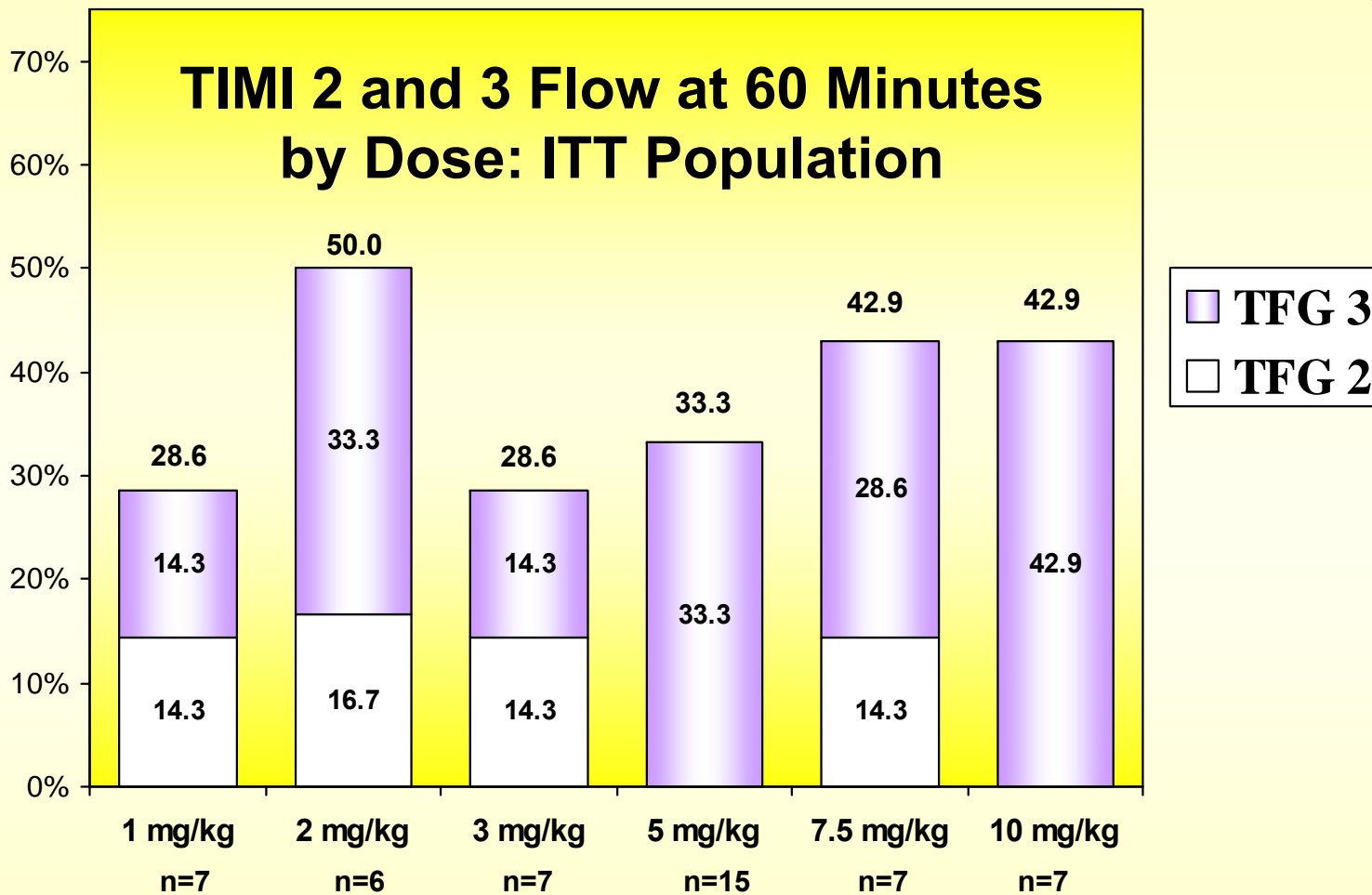
**5 mg/kg
BB-10153**

ASA, IV Heparin

Angio 60 Minutes

30 Day Follow-up
Death, recurrent MI, recurrent angina

1° Endpoint:
TIMI Grade 3 Flow
2° Endpoint:
ST Resolution (1 & 3 hrs),
Pharmacokinetics and
Pharmacokinetics



TFG 3 95% CI

0% -
40.2%

0% -
62.0%

0% -
40.2%

9.5% -
57.2%

0% -
62.0%

6.2% -
79.5%