Bio-Engineered Genous™ Technology

Key Clinical Trials

SINGAPORE AMI Physician Initiated — **N= 321**

- Physician initiated study
- Primary endpoint: MACE at 30 days, 6 months and 12 months
- Study completed
- Find more information ***here***

ROME REGISTRY Physician Initiated — **N= 80**

- Prospective single-center registry in high-risk patients
- Primary endpoint: Death (cardiac and non-cardiac), MI, in-stent restenosis, TLR, late loss, MACE, re-vascularization, stent thrombosis at 14+/-4 months
- Study completed
- Find more information ***here***

JACK-EPC Physician Initiated — **N= 30**

- Prospective randomized single-center study
- Primary endpoint:
  - Major adverse cardiac events (MACE at 30 days, 3, 6, 9 and 12 months
  - Neointima volume at 6months
  - In-stent late lumen loss and binary restenosis at 6months
- Study completed
- Find more information ***here***

ARGENTO — **N= 384**

- Prospective multicenter registry
- Primary endpoint: MACE (i.e. the composite of cardiac death, MI, TVR and ST)
- DAPT treatment: ≤15-day or >15-day dual antiplatelet therapy (DAPT)
- Study completed
- Find more information ***here***

GENOUS — **N= 49**

- Prospective multicenter registry
- Primary endpoint: the composite of cardiac death, MI, and angiographic evidence of stent thrombosis
- DAPT treatment: life long aspirin plus clopidogrel for 10 days
- Study completed
- Find more information ***here***

HEALING II B — **N= 100**

- Prospective multicenter registry
- Primary endpoint: In-stent late loss by Quantitative Coronary Angiography (QCA) at 6 months
- Study completed
- Find more information ***here***

E-HEALING — **N= 4,996**

- A worldwide multicenter post marketing registry
- Primary endpoint: Target vessel failure at 12 months
- Study completed
- Find more information ***here***

HUMAN AV SHUNT STUDY — **N= 15**

- Physician initiated study
- Method: Patients undergoing PCI received an extracorporeal femoral arteriovenous (AV) shunt containing BMS and Genous Stents. Harvested stents were assessed by confocal and scanning electron microscopic (SEM) analysis for strut coverage. Quantitative polymerase chain reaction (qPCR) analysis of captured cells was used to identify endothelial markers KDR/VEGFR2, E-selectin, pro-thrombogenic markers and plasminogen activator inhibitor-1.
- Study completed
- Find more information ***here***

HEALING II — **N= 63**

- Prospective multicenter registry
- Primary endpoint:
  - Clinical: MACE at 30 days - angiographic late lumen loss
  - In-stent volume obstruction at 6 months by intravascular ultrasound (IVUS)
- Study completed
- Find more information ***here***

HEALING FIM — **N= 16**

- Prospective single-center registry trial
- Primary endpoints:
  - The absence of stent thrombosis up to 6 months
  - In-stent late luminal loss as deter mined by quantitative coronary angiography and percent in-stent volume obstruction by IVUS at 6 months
- Study completed
- Find more information ***here***