

# AES Safety

## Preclinical Study

- Preclinical in vivo study
- 24 swines studied at 7 days, 30 days and 90 days
- Results:
  - Cre8™ Demonstrates an early complete endothelialization (7 days) and no sign of inflammation/ adverse vessel reaction at a later stage (30 and 90 days).
  - Cre8™ becomes a BMS within 90 days

Cre8™ proves early stent strut endothelialisation. Cre8™ becomes a BMS within 90 days

## Demonstr8

- Randomized OCT study 1:1 Cre8™ vs Abbott Co-Cr BMS
- 38 Patients (+17,000 analyzed struts)
- Results:
  - Cre8™ is non inferior to BMS in terms of strut coverage.
  - Cre8™ at 3 months has 99.8% percentage of sections with RUTTS score < 30%
  - Cre8™ at 3 months shows statistically lower neointima thickness compared to BMS at 1 month

Cre8™ demonstrates numerically higher coverage at 3 months vs latest Co-Cr BMS at 1 month

## Astute DAPT

- Real World, Prospective Registry, Independent
- 1,216 Patients
- Results: Equivalent rates of 6-month and 1 year TVF for short DAPT duration (1-3 Months) and Recommended DAPT (≥6 Months). BARC major bleeding events similar between the two groups at landmark analysis.
  - TVF DAPT 1-3 Months=5.4%, TVF DAPT ≥6 Months=5.3%
  - BARC≥type-3a landmark analysis at 3 months: Short DAPT= 0%, Recommended DAPT= 0.3%

Cre8™ shows no safety issues with DAPT 1-3 Months

## U-Short

- Real world Retrospective Registry, All Comers, Independent. Matched analysis Cre8™ vs. Resolute
- 165 Patients (85:80)
- Results: Excellent results from Efficacy and Safety perspective with average DAPT treatment of 3.65 Months (Cre8™) and 3.55 Months (Resolute)
  - Stent Thrombosis: Cre8™=0%, Resolute=1.3%
  - Major Bleeding Events: Cre8™=0%, Resolute=2.5%
  - 1year event free survival: Cre8™= 92.9%, Resolute=88.8%

Cre8™ couples excellent Efficacy and Safety in diabetics even with 3 months DAPT

## ReCre8

- Randomized 1:1 Cre8™ vs Resolute, All Comers, Independent
- 1,530 Patients
- Primary Endpoint: 12 months NACE

Aiming for confirmed safety in all-comers patients receiving 1 month DAPT