

# AES Efficacy

## Next

- First in man Randomized 1:1 vs Taxus
- 323 Patients
- Results:
  - Cre8™ Superior to Taxus in LLL
  - Cre8™ LLL equivalent for Diabetics (0.12) and Non Diabetics (0.14)

First time that results are equivalent in Diabetics and Non Diabetics

## Investig8

- Unselected Population Retrospective Registry
- 589 Patients
- Results: Very Low MACE and equivalent TLR at 1 year for Diabetics and Non-Diabetics.
  - TLR Diabetics: 1.4%
  - TLR Non-Diabetics: 1.6%

Consistent Results for Diabetics and non Diabetics in All comer/ Unselected Population

## Particip8

- Real world Prospective Registry, All Comers
- 1,186 Patients
- Results: Very Low MACE and TLR in complex population. Equivalent results in diabetic subgroup.
  - TLR Diabetics: 1.4%
  - TLR Overall population: 1.0%

## Reservoir

- Randomized 1:1 vs Xience, Independent, Diabetics only
- 112 Patients
- Results: Numerically better LLL and NVO at 9 Months for Cre8™ vs Xience
  - LLL Cre8™: 0.14±0.24, Neolntima Volume Obstruction: 11.97±5.94
  - LLL Xience: 0.24±0.57, Neolntima Volume Obstruction: 16.11±18.18

First time better numerical results vs DES benchmark (Xience)

## Matched Analysis Cre8™ vs Xience

- Propensity Matched Analysis Cre8™ vs Xience, Independent
- 300 Patients (150:150)
- Results: Numerically better results for Cre8™ in overall population and trend for superiority in diabetics (TLR)
  - TLR in Diabetics: Cre8™= 2.5%, Xience= 15% (p=0.051)

## Astute Diabetics

- Real World, Prospective Registry, Independent
- 1,216 Patients
- Results: Very Low MACE and TLR in overall and diabetic population. Equivalent results at 1 year for insulin dependent and non-insulin dependent patients
  - TLR Insulin Dependent: 3.25%
  - TLR Non-Insulin Dependent: 4.2%

First time Equivalent Results for Insulin dependent and non-insulin dependent Diabetics

## Matched Analysis Cre8™ vs BES

- Propensity Matched Analysis Cre8™ (ASTUTE Registry) vs BES (INSPIRE - 1 Registry), Independent
- Matched among Non-Diabetics (425:425) and Diabetics (240:240) patients
- Results: Excellent Cre8™ results in all the patients. Cre8™ statistically superior to BES in diabetics
  - TLR: Cre8™= 4%, BES= 9% (p=0.005)
  - TLF: Cre8™= 5%, BES= 13% (p<0.001)

First time that a DES shows superiority to a 2<sup>nd</sup> generation DES (BES) in diabetics

## Diab8

- Real World, Randomized 1:1 Cre8™ EVO vs EES, Diabetic Patients only
- 3,040 Patients
- Primary Endpoint for Superiority TLR at 1 Year

Aiming for definitive statistical superiority to current gold DES Standard