**Background**

The arterial venous fistula remains the preferred form of hemodialysis vascular access, providing a survival benefit compared to other forms of access. However, fistulas suffer from high rates of failure within one year of surgical creation:

- 40-60% experience a thrombosis or require a corrective procedure (primary patency loss)\(^1\)
- 30-40% are abandoned (secondary patency loss)\(^2\)
- 40-60% fail to be used for hemodialysis\(^1-3\)

The radiocephalic fistula in the forearm is the preferred fistula location, but failure rates are higher than for upper arm fistula.\(^1\)

**Protocol**

- **Single, local application (10 min)**
- Elastin is the principal component of elastic fibers in blood vessels that impart elasticity
- Single, local application (10 min) to the external surface of the fistula immediately after creation
- Active site at application with no systemic effects observed since inactivated by blood

**Efficacy Results**

**Primary Patency**

- Vonapanitase did not show a significant improvement in primary patency at 12 months compared to placebo (HR 0.80; 95% CI 0.57-1.12, p=0.187)
- Use for hemodialysis was 71% for vonapanitase and 48% for placebo
- Secondary patency was 80% for vonapanitase and 64% for placebo
- Primary patency at 12 months was 46% for vonapanitase and 34% for placebo

**Secondary Patency**

- Number at risk for primary patency loss: Vonapanitase 210, Placebo 103
- Number at risk for secondary patency loss: Vonapanitase 197, Placebo 99

**Safety Results**

- No evidence of immunogenicity
- Adverse events consistent with medical conditions experienced by kidney disease patients undergoing fistula surgery
- Adverse events comparable for vonapanitase and placebo

**Efficacy Results (cont.)**

**Use for Hemodialysis**

- Use was defined as the ability of the fistula to be successfully cannulated with 2 needles for a minimum of 90 days or at least 30 days in use at the patient’s last visit if hemodialysis had not been initiated at least 90 days prior to the last visit. Unassisted use defined as use without a prior procedure to restore or maintain patency.

**Efficacy Population Analysis**

- Pre-specified analysis excluding 29 patients (19 vonapanitase, 10 placebo) who had primary or secondary patency loss or early termination by week 2 visit.
- Primary patency at 12 months was 46% for vonapanitase and 34% for placebo (HR 0.80; 95% CI 0.57-1.12, p=0.187)
- Secondary patency was 80% for vonapanitase and 64% for placebo (HR 0.52; 95% CI 0.32-0.85, p=0.007)
- Use for hemodialysis was 71% for vonapanitase and 48% for placebo (p<0.001)

**Summary**

- Vonapanitase did not show a significant improvement in primary patency in patients undergoing radiocephalic fistula creation.
- Vonapanitase was associated with significant improvements in secondary patency and fistula use for hemodialysis.

**Status**

- Ongoing PATENCY-2 study of vonapanitase evaluating co-primary endpoints of secondary patency and fistula use for hemodialysis in patients undergoing surgical creation of a radiocephalic fistula.

**References**