A New Treatment for Chronic Kidney Disease: Denervation in the Collecting System with the Verve Medical Device

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- Medtronic, Abbott, AngioScore, Speaker
- Acist Medical Systems Grant

**Patents** -- RF, Snares, Wires, Balloon Catheters, Covered Stents, Devices for Arterial Venous Connection, Devices for LV and RV Closure
We are not getting the correct nerves... if we were, why don’t we get an immediate BP drop?

In contrast to the widespread distribution of EFFERENT Sympathetic nerve fibers in the kidney, the majority of the AFFERENT Renal Sensory nerves are located in the renal pelvic area.

» Kopp UC, University of Iowa. Neural Control of Renal Function 2011
We are the only company that has described RDN pathophysiology in a human clinical nephrectomy model.
Preclinical-Clinical Data Results

Pre-Clinical
55 acute and chronic pigs – up to 90 days follow up
End point- 60% avg. drop in tissue Norepinephrine (marker of nerve activity)

Clinical - 14 Patients
Safety Trial - 9 pre-nephrectomy patients
No adverse effects – treatment 1 mo. prior to removal of kidney
Efficacy Trial - 4 RHTN patients
Average systolic BP drop 44 mmHg – immediately post treatment
Efficacy Trial - 1 ESRD dialysis patient
14 mmHg systolic BP drop at 60 days post treatment
Reduction of blood pressure medications from 5 to 2
Kidney nerve anatomy

Afferent nerves originate in the collecting system

Rotated view 30 degrees
The bulk of the nerves (N) are located less than 1 mm deep in the treatment zone (red)
Major Global Problem

13.4 % of the world population has CKD

U.S. Statistics

49 Million people have chronic kidney disease

490,000 are on dialysis

Life expectancy on dialysis < 5 years

Each year Kidney Disease kills more people than breast or prostate cancer - 47,000 in 2013

Orphan disease with no treatment options
In the early stages of kidney disease, sympathetic activation is detectable being directly proportional to the severity of renal failure.
Verve TUSK Procedure

- Minimally invasive “natural orifice” procedure
- Treating Physician - Urologist/ Nephrologist
- Standard equipment used by the Urologist
- Radiofrequency monopolar ablation
- Over the guidewire ablation catheter/cystoscopic guidance
- Short duration- total procedural time < 15 minutes
- Local or spinal anesthesia
- Fluoroscopic / ultrasound Imaging
- Outpatient or Office procedure
Verve TUSK Procedure ESRD Patient

Pre op condition
ESRD -10yrs
BP (mmHg): 174/105
Medications:
2 Alpha/Beta Blockers
3 RAAS Inhibitors
5 Total Drugs

Post op 60 days
BP (mmHg) 160/99
Medications:
2 RAAS Inhibitors
Removal of 3 drugs
Impact with Verve Procedure

Treating the patient at Stages 2-3 CKD

Verve’s TUSK Procedure
15 min/Outpatient

1. >90 ml/min
   - 0-1700

2. 60-89 ml/min Mild
   - 3400

3. 30-59 GFR Moderate
   - 15000

4. 15-29 ml/min Severe
   - 28000

5. ESRD <15 ml/min
   - 70000

Transplant

Medicare spending for CKD > 65yr old exceeds $50 Billion dollars
Represents 20% of all Medicare spending in this age group*

Medicare spending for ESRD patients rose to $30.9 Billion dollars
Represents 7.1% of overall Medicare paid claims costs*

* National Institute of Health /Kidney Disease Statistics for the US 2013
Verves Impact

• Treating and Inhibiting the progression of CKD at Stages 2-3 will have an annual cost savings in excess of $130 Billion dollars to the U.S. healthcare system.

• Treating the ESRD patient with an alternative to drugs will greatly impact quality of life, reduce treatment regime and holds the potential to increase life expectancy- increasing the odds of receiving a donor kidney*

*Median Kidney recipient wait time 3.6 years /NIH 2013
Treating Kidney Disease at the Source
Chronic Pain in CKD

- 70% of pre-ESRD patients have chronic pain
- ~ 50% of ESRD have chronic pain
- ~ 80% of polycystic kidney disease patients have chronic pain...only treatment option can be nephrectomy
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Review

• Technical Feasibility and Efficacy
  Disruption of the key nerves (afferent) at their origin (kidney)

• Clinical Evidence
  5 patients show significant sustained drop in BP results in reduction of medications

• Market Strategy
  Unmet Clinical Need
  Pain Management early US approval / sales
  CKD Only Option and Only true minimally invasive approach
  Moderate/RHT patient- Alternative to drugs

• Intellectual Property
  Early filing- little prior IP overlap
The Value of Verve

• Orphan disease with an unmet clinical need
• Massive and expanding markets
  $ 36 Billion Pain/$96 Billion CKD/$400 Billion HTN & Diabetes
• Proprietary technology / Intellectual Property
• Experienced management team: Medical Devices & Clinical Specialty- Nephrology/Urology
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• If you are one of the 50% of us with hypertension, would you like to...
• Take a drug or drugs for the rest of you life?
• Would you like to have a one time procedure that would be done with no contrast in a doctor’s office in 15 minutes
Remember a 2mmHg decrease in mean SBP results in a 7% reduction in CVD mortality and 10% reduction in stroke mortality.

Adapted from Lewington, et al., Lancet 2002;360:1903-1913.
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