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WAVE I Study of Renal Denervation Therapy for Hypertension

Kona Medical has announced that three and six month results from the WAVE I study were presented today at the late-breaking clinical trials session of EuroPCR in Paris by Robert Whitbourn, MD, of St. Vincent's Hospital in Melbourne, Australia.

WAVE I is a first-in-man study evaluating the safety and efficacy of Kona Medical's Surround Sound® Renal Denervation System for the treatment of resistant hypertension. Unlike other renal denervation methods which rely on a catheter emitting energy through the wall of the renal artery, Kona's system delivers ultrasound energy to the nerves from outside the body. This targeted energy "surrounds" the artery and treats the nerves located in the vicinity of the vessel. Data presented from WAVE I demonstrated that patients treated with the Surround Sound® Renal Denervation System had no device-related serious adverse events and experienced a 22 mmHg drop in systolic blood pressure and 9 mmHg drop in diastolic blood pressure at three months (N=24). In those patients who had reached 6 months follow up (N=14) there was a 29 mmHg drop in systolic blood pressure and 9 mmHg drop in diastolic blood pressure.

"The results from this initial study of external ultrasound for renal denervation are very promising," Dr. Whitbourn reported. "Blood pressure reduction in this very severe hypertensive cohort grows over time. We've also seen that the ultrasound energy leads to effective denervation without any discernible effect on the renal artery. While more studies are required to confirm these results, external ultrasound appears to have strong potential as an alternative to catheter-based energy delivery for patients with hypertension."

Additional data reported on WAVE I at EuroPCR included:

- On average, clinical subjects had a baseline blood pressure of 190 mmHg systolic and 100 mmHg diastolic and were taking an average of 4.5 anti-hypertension medications.
- 11 / 14 subjects (78%) reaching the six month efficacy endpoint had a clinically significant drop in systolic blood pressure of 10 mmHg or more.
- Results from norepinephrine spillover studies indicate strong evidence of sympathetic denervation.
- There were no adverse findings in the subjects' renal vasculature based on six-week angiogram (n=9) and 24 week MRI (n=14).

The clinical study group included St. Vincent's Hospital in Melbourne, Australia (Dr. Robert Whitbourn, Primary Investigator), Nemocnice NA Holmoce in Prague, Czech Republic (Dr. Petr Neuzil, Primary Investigator), and St. Anne's Hospital, Brno, Czech Republic (Dr. Zdenek Starek, Primary Investigator). Dr. Murray Esler of Baker Heart and Diabetes Institute served as norepinephrine core lab director. The study was sponsored by Kona Medical, Inc.

Currently, the clinical sites are enrolling and treating subjects in a follow-on study, WAVE II, which utilises an optimised treatment protocol that reduces therapy delivery time from approximately 12 minutes per side (in WAVE I) to under three minutes. The study sponsor, Kona Medical, also has announced plans to initiate the WAVE III study, which will evaluate the safety and efficacy of a fully external (non-invasive) version of its ultrasound-based therapy. Non-invasive renal denervation has the potential to expand patients' access to renal denervation while also lowering the cost of treatment.

"We thank our clinical investigators for this important research," said Michael Gertner, MD, founder and CEO of Kona Medical. "The positive WAVE I results presented today show the promise of external ultrasound therapy for the millions of people who suffer from drug-resistant hypertension. We look forward to bringing our fully non-

invasive Surround Sound system into clinical trials.”

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