Evaluate Vantage

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TCT 2022 – Otsuka's renal denervation system shines

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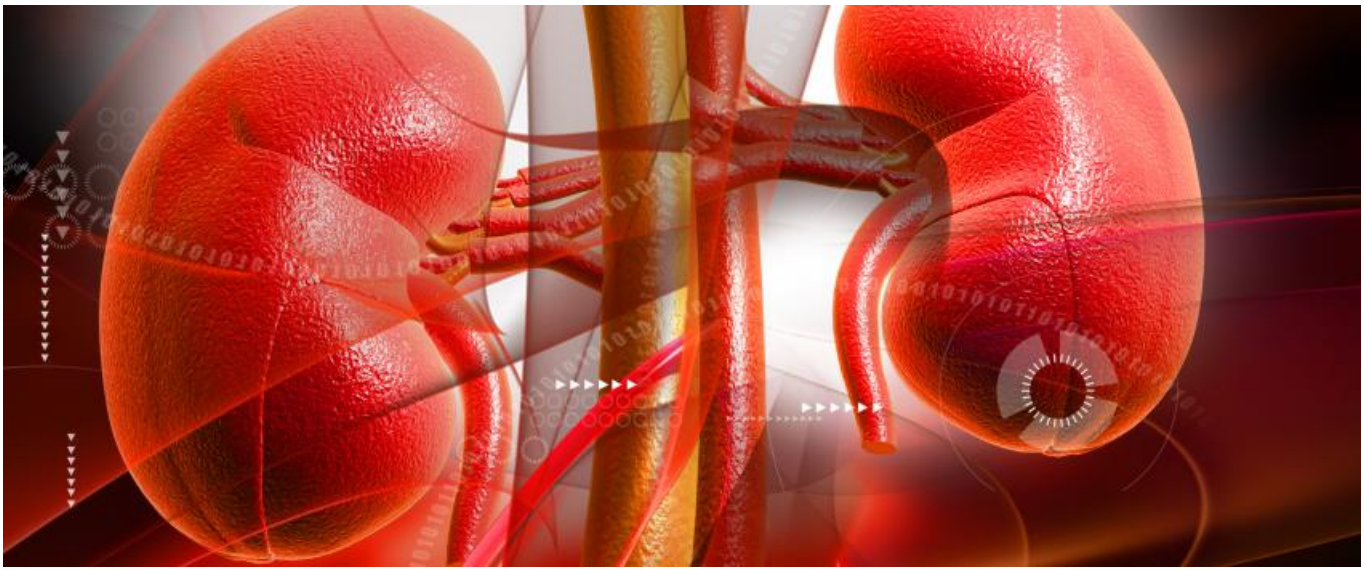

Paradise is now odds-on for US approval – but Medtronic's rival device is not far behind.

It is rare that the performance of a medical device is better in its pivotal trial than in mid-stage studies. So pats on backs all round at Recor, the Otsuka subsidiary whose renal denervation system, Paradise, has posted substantial reductions in blood pressure according to pivotal data presented at the weekend.

The company must capitalise on this quickly. Assuming this data are good enough, US approval could come within a year or so. By then Medtronic, a much larger company than Otsuka and one with greater experience in medical technology, will have the last data it needs for submission of its own system, and will also be racing towards the US market.

Renal denervation is a technique whereby the nerves surrounding the renal arteries are burned from within the arteries themselves, using a catheter treated through the vasculature from the groin. Ablating the nerves disrupts overactive sympathetic signalling between the kidneys and brain, reducing blood pressure.

It is used in patients whose hypertension cannot be controlled with drug therapy.

Radiant

Recor top-lined its Radiance II study as a hit in July, but detailed data presented at the TCT meeting on Sunday showed clean safety, with no major adverse events seen at 30 days, and a stronger treatment effect than in the two cohorts from the mid-stage Radiance-HTN trial.

Moreover, they make Paradise look competitive with – perhaps even better than – Medtronic's Symplicity Spyral device, which kicked off a resurgence of interest in this technique with an unexpected clinical hit five years ago.

Medtronic has had a difficult time with its device. The pivotal trial, Spyral HTN-Off Med, came in positive in 2020. But the company opted to wait for data from its sister trial, Spyral HTN-On Med, on the grounds that this better represented the target patient population, before going to the FDA.

Hopes that On Med could be stopped early for efficacy were thwarted last year, and full data are expected in the next few months.

Recor has had a relatively simple development path by comparison, its acquisition by Otsuka in 2018 notwithstanding. the data in the table below show how the two therapies stack up across various trials – they have not been studied head-to-head. The data from the On Med trial in the table are taken from an early interim cut reported in May 2018.

Cross-trial comparisons of renal denervation data from Recor and Medtronic					
Company	Recor (Otsuka subsidiary)			Medtronic	
Product	Paradise			Symplicity Spyral	
Ablation technology	Ultrasound			Radiofrequency	
Trial	Solo*	Trio*	Radiance II (pivotal)	Off Med (pivotal)	On Med (interim data)
Antihypertensive drugs used?	No	Yes	No	No	Yes
Treatment duration	2mth	2mth	2mth	3mth	6mth
Sham-adjusted daytime ambulatory SBP drop (mmHg)	6.3	4.5	6.3	-	5.7
Sham-adjusted 24-hour SBP drop (mmHg)	4.1	4.2	6.2	3.9	7.4
Sham-adjusted office SBP drop (mmHg)	6.5	7.0	6.7	6.5	6.8

**Different cohorts of the Radiance HTN trial. SBP: systolic blood pressure. Source: company releases & The Lancet.*

Recor plans to submit the Radiance II results to the US FDA, though it has not given a timeline for filing or approval. If it waits for the six-month safety data – it is not clear whether it will do so – it could find itself on a similar timeline to Medtronic.

The renal denervation market will be worth more than $500m by 2026 and $2-3bn by 2030, according to Medtronic's projections. Both companies now have a nervous wait for the final readout of On-Med.