Evaluate Vantage

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Abbott finally enters the leadless pacemaker fray

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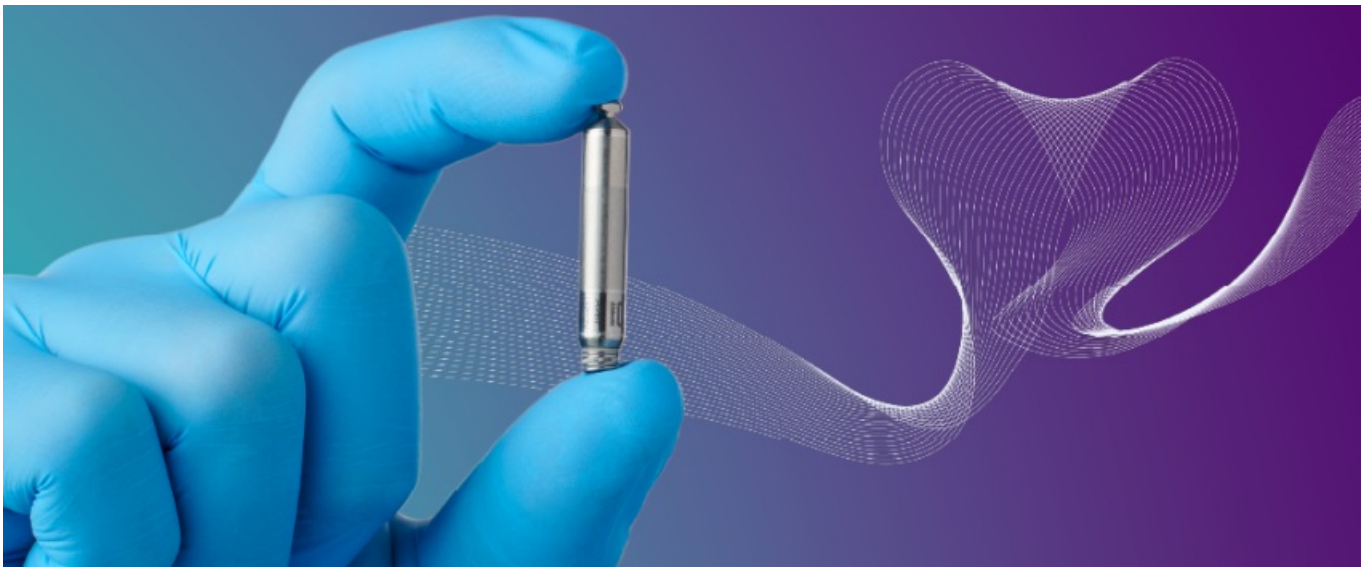

Remember Nanostim? It's back – in a modified form, sold by a different company, and under another name.

Unlike Medtronic's similar Micra device, St Jude Medical's Nanostim leadless pacemaker never received US approval. Nanostim was beset by instances of battery failure and component detachment, and Abbott, which bought St Jude in 2016, went quiet on the subject. But Abbott has in fact been quietly pursuing FDA approval all along, and a retooled version of Nanostim was approved by the FDA as Aveir VR at the end of March.

While the FDA is clearly satisfied that any flaws in Nanostim have been resolved in Aveir VR, competing will be tricky. Medtronic has had the US market for these tiny, innovative devices to itself for six years, and a new challenger, Boston Scientific, is also poised to join the battle.

Leadless pacemakers were a pretty big deal a few years ago. They are implanted via a catheter wholly within the heart, lodging in the right ventricle and delivering electrical impulses to patients with bradycardia or other forms of slow heartbeat. Nanostim was first to reach Europe, but safety concerns prompted St Jude to halt implants in the US clinical trial. Micra was the first and until last week the only leadless pacemaker approved in the US.

Abbott's announcement of the approval of Aveir VR made no mention of Nanostim, perhaps because of the safety woes seen with that device. Neither did the FDA's approval order. But the device's safety and effectiveness data, hosted on the FDA's website, clearly states that "the Nanostim leadless pacemaker was modified prior to market release and renamed the Aveir leadless pacemaker".

Improving

Data on Nanostim form part of the submission for Aveir VR – indeed the submission is the same one that was filed for Nanostim, back in October 2015. It has been amended 15 times since then.

The Nanostim data come from the phase 1 part of the Leadless II study; the registrational phase 2 part of the trial was conducted using Aveir VR. The latter shows numerically better safety and efficacy, though the trials were not designed to be compared against each other.

The data claims significance in terms of p values for safety and efficacy endpoints, but these were derived from a within-trial comparison against a performance goal of 85%. In any case Leadless II had no control arm.

The null hypothesis was to be rejected at the 2.5% significance level if the lower confidence bound exceeded the performance goal of 86%. The p-value from a one-sided exact test for the binomial proportion was

calculated and compared to the 0.025 significance level.

Aveir VR vs Nanostim – safety data					
Analysis population	**N**	**No of events**	**No of subjects with AEs**	**% subjects with no serious AEs**	**P value***
Phase 2 – Aveir	198	9	8	96.0%	<0.001
Phase 1 – Nanostim	300	22	20	93.3%	<0.001
*AEs = adverse events. *Null hypothesis was to be rejected at 2.5% significance level if lower confidence bound exceeded performance goal of 86%. Source: FDA & JACC.*					

Aveir VR vs Nanostim – efficacy data			
Analysis population	**N**	**Success rate***	**P value****
Phase 2 – Aveir	196	95.9%	<0.001
Phase 1 – Nanostim	289	93.4%	<0.001
**Based on pacing thresholds and R-wave amplitudes within the therapeutic range; **null hypothesis was to be rejected at 2.5% significance level if lower confidence bound exceeded performance goal of 86%. Source: FDA & JACC.*			

Abbott also claims an improvement in battery life – not over Nanostim, but over Micra. Aveir VR has “increased projected battery life” of up to twice as long as other commercially available leadless pacemakers, the group said.

Whether this will help Abbott gain share from Micra, the most recent iteration of which, Micra AV, was approved in 2020, is not clear. The company is believed to be seeking European CE mark for Aveir VR, but at press time Abbott had not replied to a request for comment.

More certain is that the company is trialling a new version, Aveir DR, designed to provide dual chamber pacing. Abbott seems to consider Aveir DR a single device, but in fact this consists of two leadless pacemakers, one positioned in the right ventricle and one in the right atrium.

And more competition is on the horizon. Boston Scientific is trialling a leadless pacemaker called Empower, this time in tachycardia rather than a slow heartbeat. Empower can address tachycardia because it is used in tandem with Emblem, a traditional wired implantable cardioverter defibrillator, which was approved in 2016.

This prompts the obvious question of whether Empower can be considered a true wireless pacemaker. Doubtless it will find a market if it excels in the clinic. For now, though, it is up to Abbott to show that it can contest this space.

Leadless pacemakers			
Company	**Device**	**CE mark**	**FDA approval**
St Jude Medical*	Nanostim	Oct 14, 2013	Never granted
Medtronic	Micra	Apr 14, 2015	Apr 6, 2016
Abbott	Aveir VR	Pending?	Mar 31, 2022
Abbott	Aveir DR	In a trial in 550 pts with bradycardia	
Boston Scientific	Empower MPS	In a trial in 300 pts with tachycardia	
**St Jude was bought by Abbott in 2016. Source: company releases & FDA.*			

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