



**EMBARGOED UNTIL 20<sup>th</sup> NOVEMBER 2022 1730HRS SGT**

## ***Chronic Performance of a Novel Leadless Pacemaker: 1 Year Results from the LEADLESS II Trial***

### Context:

Short-term safety and performance of a novel single chamber leadless cardiac pacemaker was previously reported and has since received FDA approval in March 22. Additional follow up was conducted to assess longer-term safety and performance.

### Summary:

Dr Vivek Reddy from Mount Sinai Hospital, USA presented the 1 year primary safety and efficacy endpoint results from the prospective, single=arm, pivotal LEADLESS II phase 2 trial. This was a prospective, non-randomised, multicenter study on 210 patients, showing 93.2% Kaplan Meier estimate for freedom from serious adverse device effects at 1 year (95% CI 88.7 to 95.9), and 97.6% implant success rate. Estimated battery longevity after 1 year exceeded 10 years for majority of patients.

### Message:

The novel single chamber leadless cardiac pacemaker shows stable performance and reassuring safety results after 1 year follow up with good battery longevity. Data regarding its long term safety and efficacy, as well as future clinical trials evaluating the effectiveness and safety of dual chamber leadless pacemaker are eagerly awaited.

### Session details:

Late breaking clinical trials 2: Sunday 20<sup>th</sup> November 2022 9:00-10:10am SGT)

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