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Nanosonics' CORIS® secures first FDA 510(k) clearance for expanded endoscope indications

- First FDA 510(k) clearance expands CORIS coverage to a broader range of endoscopes.
- Next round of scope expansions already in motion, with ongoing FDA engagement and preparation for submission of a second 510(k).
- Controlled Market Release (CMR) underway in the UK, with Australia to follow soon; US CMR to start after initial experience from the first round of CMR sites.

Nanosonics Limited (ASX: NAN), a leader in infection prevention solutions, today announced the US Food and Drug Administration (FDA) has granted 510(k) clearance for the first round of expanded endoscope indications for its innovative CORIS® system.

Building on the De Novo clearance granted for CORIS for its initial endoscope indication, this first 510(k) clearance advances Nanosonics' roadmap to expand CORIS across a broader range of endoscope indications. With the first expansion now secured, the team is progressing preparations for submission of a second 510(k) to further extend CORIS' endoscope coverage.

"This first FDA 510(k) clearance keeps us tracking to plan as we execute against our key milestones. It immediately broadens the range of endoscopes that can be processed with CORIS, building momentum for our upcoming market activities. With our UK Controlled Market Release (CMR) already commenced, we expect to shortly add further CMR sites in Australia and in the UK/Ireland. In parallel, we are progressing preparations to submit our second 510(k) to further expand endoscope coverage. Once we've gained initial experience and insights from the UK and Australian CMR sites, we plan to commence US CMR sites. From FY27, we plan a full commercial launch, with rollout across each region phased in line with completion of the Controlled Market Release in that region," said Michael Kavanagh, CEO & President of Nanosonics.

For more information, please contact:
Catherine Strong, Head of Investor Relations and Corporate Communications
+61 (0)406 759 268, c.strong@nanosonics.com

Authorised by the Chairman of Nanosonics Limited.