FDA Feedback De-Risks U.S. Approval Pathway for StrepSure®

Nexsen Limited (ASX:NXN) ("Nexsen" or the "Company") is pleased to announce the successful completion of a **Pre-Submission meeting conducted under the U.S. Food and Drug Administration (FDA)'s Q-Submission (Q-Sub) program**, representing a key regulatory milestone for StrepSure®, Nexsen's lead diagnostic product in development. **This milestone de-risks the pathway to U.S. approval and highlights the potential commercial impact of StrepSure® in a large, well-established maternal health market.**

- Positive FDA feedback on Nexsen's proposed regulatory strategy, intended use, and clinical validation approach
- Clearer and lower-risk pathway established toward U.S. market authorisation
- Significant milestone for Nexsen's first product progressing through the FDA regulatory pathway
- Activities advancing toward regulatory submission and planned commercial rollout
- Early validation of Nexsen's broader platform for rapid point-of-care diagnostics

The Q-Sub meeting provides formal feedback from the U.S. FDA on Nexsen's proposed regulatory pathway for StrepSure®. The feedback received supports the Company's planned approach to U.S. market authorisation and provides increased clarity on regulatory expectations, reducing execution risk ahead of submission. The U.S. market represents a significant commercial opportunity for StrepSure®, with GBS screening integrated into standard prenatal care across a large annual birth cohort, providing a repeatable and scalable testing opportunity.

As StrepSure® is Nexsen's first product advancing through the U.S. FDA regulatory pathway, this milestone represents an important validation of the Company's regulatory strategy and a meaningful step toward commercialisation.

In anticipation of this milestone, Nexsen has been progressing key workstreams to support regulatory submission and commercial readiness. The Company expects to provide further updates on its regulatory and market rollout plans in due course.

Importantly, this milestone also provides early validation of Nexsen's broader platform to deliver rapid point-of-care diagnostics for time-critical conditions traditionally reliant on lab-based testing. Progress through the U.S. FDA pathway for StrepSure® is expected to inform and streamline regulatory strategies for Nexsen's broader diagnostic pipeline, supporting more efficient advancement of future products and reinforcing the value of the platforms for investors.

Nexsen's Managing Director, Mark Muzzin, commented:

"This is a significant milestone for Nexsen and a meaningful de-risking event for StrepSure®. The FDA's feedback not only provides clarity and confidence in our regulatory pathway toward U.S. approval but also highlights the potential scale and commercial impact of StrepSure® in the maternal health market.

With this alignment in place, we are advancing our regulatory and commercial execution to bring StrepSure® toward the world's largest maternal health market and to leverage learnings for our broader diagnostic pipeline."

About StrepSure®

StrepSure® is a rapid lateral flow point-of-care test for the detection of Group B Streptococcus (GBS) in pregnant women. GBS affects an estimated 18% of pregnant women globally and, if undetected and untreated, can lead to serious neonatal complications including sepsis, pneumonia and meningitis.

Current testing relies on pathology labs, with results taking days, making it unsuitable for use during labour when immediate treatment decisions are required. StrepSure® delivers results in approximately 20-30 minutes at the point of care, enabling real-time clinical decision-making without the need for laboratory equipment.

The global addressable market is approximately 132 million births annually.

StrepSure® is currently an investigational device and has not yet received regulatory approval for clinical use in any jurisdiction.

-ENDS-

ASX release authorised by the Board of Directors.

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About Nexsen Limited (ASX: NXN)

Nexsen is developing a suite of rapid point-of-care diagnostics designed to deliver lab-grade results for conditions that have traditionally depended on delayed laboratory testing. The company is focused on areas of significant unmet clinical need, where faster diagnosis can improve patient outcomes and reduce pressure on healthcare systems.

Nexsen's lead diagnostic is the GBS Rapid Sensor, a rapid point-of-care diagnostic for detecting Group B Streptococcus, addressing a critical unmet need in maternal health.

The Company is also developing rapid kidney function diagnostics for Acute Kidney Injury and Chronic Kidney Disease, two conditions that affect more than 850 million people globally and remain underserved by slow, lab-based diagnostics.

With further diagnostics in development across human health, ag-tech and biosecurity, Nexsen aims to become a global leader in rapid point-of-care diagnostics, delivering on its mission to ensure every person benefits from a Nexsen test at some point in their life.

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