

Rhythm Maintains Ongoing ISO13485 Certification

Highlights

- ✓ Rhythm has retained ISO certification and expanded the coverage scope for its Quality Management System; and
- ✓ ISO certification is the key manufacturers evidence for regulatory compliance and ultimately supports Rhythm's market entry strategy.

Transformative, predictive cancer diagnostics technology company, Rhythm Biosciences Ltd (ASX: **RHY**) (**Rhythm** or the **Company**) is pleased to confirm another regulatory and quality milestone, successfully retaining ISO certification to the International Standard for In-Vitro Diagnostics and Medical Devices (ISO 13485:2016), for ColoSTAT[®], its simple blood test for the detection of colorectal cancer, aimed at global mass market screening.

ISO 13485:2016 is the internationally recognised quality standard to ensure the consistent design, development, manufacture, and sale of medical devices that are safe for their intended purposes. The ISO certification was conducted via an onsite audit by the British Standards Institution (BSI). This marks the fourth year running that Rhythm has achieved and maintained certification with the ISO standard, which is critically important as part of regulatory approvals for the Company's commercial and market entry strategies.

Retaining ISO certification delivers four key things:

- ✓ The scope has now been expanded to include manufacturing and algorithm software development;
- ✓ Certification is valid for three years, subject to annual surveillance audits;
- ✓ The expanded scope covers Rhythm's planned product development pipeline of new products, streamlined manufacturing and development of algorithm based diagnostic test kits; and
- ✓ Supports a key component of the manufacturer's evidence required by the TGA for the approval of ColoSTAT[®].

Rhythm CEO and Managing Director, Glenn Gilbert, commented:

"Our ongoing ISO certification achievement not only validates the rigour, diligence and consistency of our development program, it is also a crucial part of our commercial strategy for ColoSTAT[®], that ensures we have robust systems and processes in place that underpin our transformative lifesaving cancer detection technology."

- ENDS -

Authorised for release by the Board.

Directors

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About Rhythm Biosciences

Rhythm Biosciences is focused on becoming a globally significant, transformative, predictive diagnostics company, specialising in cancer detection technology. The Company is currently developing ColoSTAT® - a simple, low-cost, blood test for global mass market detection of colorectal cancer.

Worldwide, colorectal cancer is the third most common cancer in men and the second most common in women, accounting for an estimated 1.9 million new cases and 935,000 deaths annually.

In an effort to reduce the global burden, many countries have implemented screening programs aimed at early detection. These programs are predominantly administered with a faecal immunochemical test (FIT) for the assessment of colorectal cancer risk, with a positive result referred for a colonoscopy. FIT only analyses the presence of blood in faeces, which can occur for several reasons other than cancer, therefore it is not designed as an accurate test for cancer. Many people simply don't take the test for fear of an unnecessary colonoscopy procedure, unpleasantness, difficulty, or for religious/cultural reasons. There is currently no appropriate blood test alternative.

Rhythm aims to transform the global mass-market for colorectal cancer detection with ColoSTAT® its simple, low-cost blood test that is fit for purpose, meaning that it is designed to actually detect colorectal cancer. Since listing on the ASX in 2017, the Company has run a successful multi-year research and development program that has delivered technical validation of the core biomarker technology, being reproducible and stable. The ColoSTAT® test-kit was manufactured in 2021 and delivered performance testing that outperforms the current market standard faecal immunochemical test (FIT) utilising Rhythm's proprietary algorithm. The Company is currently finalising its clinical trial for ColoSTAT®, and is progressing regulatory, manufacturing and scale up activities ahead of market entry in 2022.

ColoSTAT® is designed to be used easily by laboratories without the need for additional operator training or additional infrastructure. ColoSTAT® has the potential to play a key role in reducing the morbidity and mortality rates and healthcare costs associated with colorectal cancer via increasing current screening rates.

Rhythm's initial targeted global addressable population is over 800 million people which are over 50 years of age. Almost 70%, or 550 million people, are not currently screened for colorectal cancer due to the limitations of the current faecal based testing regime. This "at risk" population is also expanding with the disease growing rapidly in much younger age groups. Early detection and intervention can lead to cure in over 90 per cent of new cases, therefore the need for effective screening and early intervention has the potential to save a significant number of lives. Rhythm estimates today's colorectal cancer screening market alone to be worth in excess of \$38 billion.