

CE Mark Granted for ColoSTAT®

Highlights

- ✓ Rhythm confirms CE Mark certification is complete for ColoSTAT®;
- ✓ CE Mark certification delivers a major milestone allowing ColoSTAT® to be marketed and sold within the European Economic Area (EEA); and
- ✓ Enables access to an addressable market of 231 million people, valued at ~US\$12 billion.

Transformative cancer diagnostics technology company, Rhythm Biosciences Ltd (ASX: **RHY**) (**Rhythm** or the **Company**) is pleased to confirm the achievement of a major regulatory milestone for the commercialisation of ColoSTAT®, its simple blood test for the detection of colorectal cancer, aimed at global mass market screening.

Rhythm's colorectal cancer detection technology product, ColoSTAT®, has been granted CE Mark and fully conforms with the European Directives for IVD Medical Devices (98/79/EC). This critical regulatory achievement is a result of robust and stringent analytical testing and adherence to design and development procedures as per the Essential Requirements.

CE Mark Overview

The Conformité Européenne (**CE**) Mark is the European Union's (**EU**) mandatory conformity marking for regulating products sold within the European Economic Area (**EEA**). The CE Mark represents that a manufacturer's products comply with the EU's IVD Directives - a series of legislative requirements that are in place to ensure ultimate product safety on the European market. Review and acceptance of all required documentation has been performed by the company's Authorised Representative in Europe, Emergo. This includes that the product:

- Meets all the requirements of the relevant recognised European harmonised performance and safety standards; and
- Is compliant to its intended purpose of use.

Commenting on achieving the CE Mark milestone, Rhythm CEO, Glenn Gilbert said:

"The achievement of this regulatory milestone continues to validate our commercial pathway into significant global markets, with Europe alone representing a massive addressable population of over 231 million people.

This significant achievement represents an initial step change in the Company and is a testament to the dedication and commitment of the entire Rhythm team.

Rhythm is currently assessing its commercialisation options to market ColoSTAT® into Europe."

Directors

Commercial Opportunity

Affixing the CE Mark is a critical component in Rhythm's FY'22 Strategic Plan that forms part of the Company's commercial plan and priority market entry strategy. This enables Rhythm to commercialise, market and sell ColoSTAT® in a significant global market across Europe and other countries which recognise CE. Rhythm estimates that, currently, this customer market represents an addressable screening population of over 231 million people, with a combined value of US\$12 billion.

- ENDS -

Authorised for release by the Board.

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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.