

## Commercially Manufactured ColoSTAT® Test Kits Deliver Consistent, High Accuracy Outcomes - Equivalent To Study 6

### Highlights

- ✓ Ongoing testing of commercially manufactured ColoSTAT® test-kits continues to confirm high accuracy, significantly outperforming the current market standard testing regime; and
- ✓ Provides positive backdrop as Rhythm advances Regulatory processes and commercialisation.

Transformative cancer diagnostics technology company, Rhythm Biosciences Ltd (ASX:RHY) (**Rhythm** or the **Company**) is pleased to provide an update on its progress toward the commercialisation of ColoSTAT®, a simple, low-cost blood test for the detection of colorectal cancer, aimed at global mass market screening.

### Continued Testing Drives Further Confidence

Rhythm has continued to conduct confirmatory testing on its commercially manufactured ColoSTAT® test kit following successful completion of Study 6 in March 2021, which demonstrated a 33% higher accuracy than the current market standard Faecal Immunochemical Test (**FIT**) used globally. Consistent and reproducible results, equivalent to the exceptional Study 6 outcomes of 84% Sensitivity<sup>1</sup> and 95% Specificity<sup>2</sup> (refer 16 March 2021 ASX Announcement), have been observed which provide high confidence in Rhythm's cancer diagnostics technology as the Company progresses market entry activities with respect to regulatory submissions and finalisation of the Clinical Trial.

The approval process is advancing with the Therapeutic Goods Administration (TGA) for filing an Australian Register of Therapeutic Goods listing, which is the final step in achieving regulatory approval in Australia. Rhythm also remains on track for European approval, with CE Mark submission and approval due to be completed by the end of CY2021. This recent confirmatory testing is designed to support the requirements for CE Mark submission.

A final Study Report is underway to finalise the Clinical Trial after the completion of the patient recruitment phase last month. This Report is targeted for delivery in 1H CY22.

### Commenting on the testing progress, Rhythm CEO, Glenn Gilbert said:

*"Our visible path to market is emerging as our ongoing testing program continues to provide the Company with confidence moving through the regulatory phase. The high accuracy of our cancer diagnostics technology has the potential to deliver positive outcomes for millions of people around the world. This is an exciting time for all stakeholders as we focus on the massive global market opportunity ahead of us."*

<sup>1</sup>**Sensitivity** is the ability of the test to correctly identify those patients with colorectal cancer, that is, the percentage of people with colorectal cancer who are correctly identified as having illness.

<sup>2</sup>**Specificity** is the ability of the test to correctly identify people who do not have colorectal cancer, that is, the percentage of people without colorectal cancer who are correctly identified as not having cancer.

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#### Directors

**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.