

## ColoSTAT® Authorised For Sale In New Zealand

### Highlights

- ✓ Rhythm registers as a Manufacturer in New Zealand;
- ✓ ColoSTAT® can now be marketed and sold; and
- ✓ Pre-sales and commercial partnership discussions are progressing with the aim of quickly making ColoSTAT® available for use.

Transformative cancer diagnostics technology company, Rhythm Biosciences Ltd (ASX: RHY) (Rhythm or the **Company**) confirms the expansion of its international regulatory footprint, having successfully registered ColoSTAT® with the New Zealand national database of Medical Devices, which allows the lifesaving cancer detection technology to be marketed and sold in the country.

### Regulatory Approval in New Zealand

Medsafe is the New Zealand Medicines and Medical Devices Safety Authority. It is a business unit of the Ministry of Health and is the authority responsible for the regulation of therapeutic products in New Zealand. As a manufacturer of ColoSTAT®, Rhythm has registered with Medsafe and listed ColoSTAT® to its Web Assisted Notification of Devices (WAND) database.

Rhythm has completed the process to achieve authorisation as a manufacturer of ColoSTAT® in New Zealand. The regulatory milestone means that the Company can now:

- market ColoSTAT® for sale in New Zealand;
- progress pre-sales activities immediately; and
- commence partnership discussions.

### Commenting on the regulatory milestone, Rhythm CEO and Managing Director, Glenn Gilbert, said:

*"Rhythm is pleased to expand its international regulatory approval footprint into New Zealand which enables the Company to commence marketing and sales activities for ColoSTAT®.*

*Bowel cancer is the second highest cause of cancer death in New Zealand and a growing issue with 1 in 10 now diagnosed under the age of 50.*

*ColoSTAT® is a simple blood test which has the potential to make a material impact on health outcomes through mass screening for higher participation to achieve early diagnosis. We look forward to working with the Ministry of Health's National Screening Unit to enhance New Zealand's National Bowel Screening Programme."*

- ENDS -

#### 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.