Study 7 Confirms ColoSTAT® Meets Primary Endpoint

Highlights

- ✓ **Primary Endpoint of the clinical trial successfully achieved;**
- ✓ **Statistically significant and outstanding performance, recording 81% Sensitivity and a Specificity of 91%;**
- ✓ **All Secondary Endpoints of the clinical trial were successfully achieved;**
- ✓ **ColoSTAT® was shown to be 35% more accurate than the market standard Faecal Immunochemical Test (FIT) for detecting cancer;**
- ✓ **ColoSTAT® was shown to be more accurate than the market standard Faecal Immunochemical Test (FIT) for detecting advanced adenomas; and**
- ✓ **TGA submission remains on track for 1HCY'22.**

Transformative, predictive cancer diagnostics technology company, Rhythm Biosciences Ltd (ASX: **RHY**) (**Rhythm** or the **Company**) today announces the statistical analysis outcomes of its clinical trial (Study 7) as verified by Rhythm's third-party statisticians, for ColoSTAT®, its simple blood test for the detection of colorectal cancer, aimed at global mass market screening.

Clinical Trial (Study 7) Outcome

The clinical confirmed ColoSTAT® exhibited very high accuracy for the detection of colorectal cancer, recording a sensitivity[1] of 81% and a specificity[2] of 91%.

Comparison against Faecal Immunochemical Test (FIT)

Previous ASX announcements of testing outcomes demonstrated ColoSTAT® to be 33% more accurate than the current market standard Faecal Immunochemical Test (FIT).

Pleasingly, the clinical trial (Study 7) has not only confirmed this performance but in fact **increased** to demonstrate that ColoSTAT® is **35% more accurate than the globally adopted FIT** for detecting colorectal cancer.

Further, the trial also showed ColoSTAT® to be **more accurate than FIT at detecting advanced adenomas.**

ColoSTAT® was not directly related to any adverse events recorded, all of which were classified as minor.

Rhythm CEO and Managing Director, Glenn Gilbert, commented:

"We are extremely pleased with the significant positive outcomes from this study. It further supports our conviction that ColoSTAT® has the potential to transform the way colorectal cancer is detected, on a global scale. We express our gratitude to the patients and thank our partners for the work completed thus far, including our Clinical Research Organisation, Accelagen, our statisticians, Statistical Revelations, the individual trial sites and our analytical testing partner Sonic Clinical Trials (a 100% owned subsidiary of Sonic

Healthcare ASX: SHL). To achieve such a strong overall performance result and further, the meaningful clinical significance versus the current market standard, FIT, further strengthens Rhythm's position for significant positive outcomes moving forward, both economically and socially".

The formal closure of the final clinical trial site, completion of the clinical study report and collation within the technical file are all underway. Subsequently, final submission of documentation for approval to the Therapeutic Goods Administration (TGA) by 1HCY'22 remains on track.

Rhythm will continue to provide further progress updates in due course.

About the clinical trial

The clinical trial (Study 7) protocol describes a prospective, cross sectional, multicentre, study to evaluate the diagnostic performance of the ColoSTAT® In Vitro Diagnostic (IVD) relative to colonoscopy (Primary Endpoint). Secondary endpoints of the study include assessing the ColoSTAT® test kit to detect advanced adenomas and a comparison of the performance of ColoSTAT® with the currently used Faecal Immunochemical Test (FIT); both relative to colonoscopy.

A total of 989 samples were collected, across a total of 12 sites of which 737 made up the final statistical analysis set. The reduction in patient samples was due to various reasons including incomplete or unavailable data, colonoscopies were often delayed (COVID related) outside the specified timeframe within the trial protocol and various other typical trial related events.

[1]**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.

[2]**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.

- 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.