ASX Announcement
ASX: RHY

Rhythm Successfully Concludes Study 6 for ColoSTAT®
Exceptional Study Results further surpassing the current market standard faecal test

Highlights:

- **Excellent, further improvements observed, surpassing all prior testing results;**
- **Significantly greater accuracy exhibited compared to current market standard faecal test (FIT); and**
- **Confirms the mass screening potential for ColoSTAT® across global markets.**

16 March 2021, Melbourne: Rhythm Biosciences Limited (ASX: RHY) (**Rhythm** or the **Company**) is pleased to confirm that it has successfully concluded Study 6, allowing the Company to move its focus to:

- recruitment for its final Study 7;
- preparation for regulatory submissions;
- commercialisation and potential partnership discussions; and
- prosecution of offshore market entries, particularly the USA.

Study 6 Outcome

Study 6 confirmed that the third-party commercially manufactured ColoSTAT® prototype test-kit exhibited very high accuracy for the detection of colorectal cancer via a simple blood test. The test was run across all genders and clearly distinguished between cancerous and healthy blood samples at a sensitivity[1] of 84% and a specificity[2] of 95%, surpassing all prior test results.

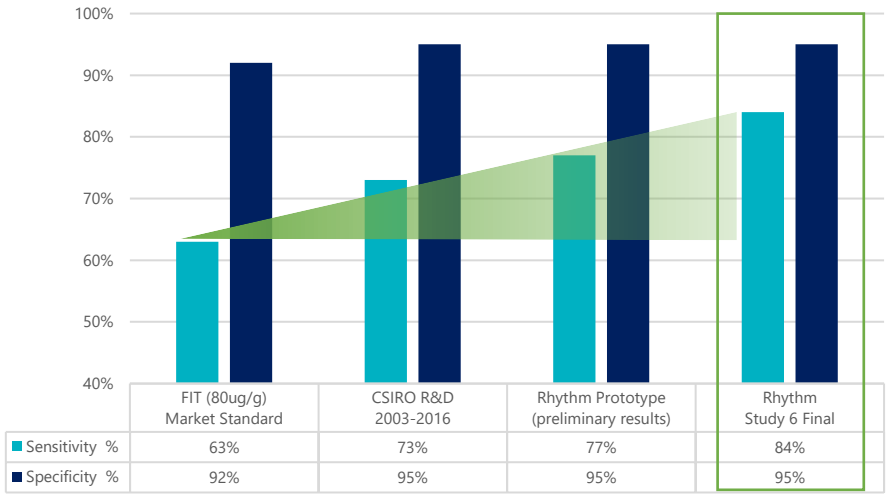

Figure 1: Summary of ColoSTAT® prototype test-kit performance – Study 6 vs previous test work, and the current market standard faecal immunochemical test (FIT)

As well as demonstrating accurate performance, Study 6 testing of the third-party, commercially developed ColoSTAT® test-kit proved that the test was reproducible, robust, scalable, consistent and can meet the performance expectations of patients, clinicians and testing laboratories. The increase in performance over Rhythm's earlier testing results announced in November 2020, were largely achieved due to continued improvements in Rhythm's proprietary algorithm.

Importantly, the very high accuracy achieved by ColoSTAT® in Study 6, provides confidence for ongoing further testing and the potential outcome for Rhythm's Clinical Trial (Study 7) currently underway, which will ultimately demonstrate the clinical utility of ColoSTAT® to the relevant regulatory bodies, such as the Conformitè Europëenne (CE) Mark and in Australia to the Therapeutic Goods Administration (TGA).

Global Opportunity

The US is currently leading the call to address the growing burden of colorectal cancer by increasing the number of people being screened. Recently, the US Preventative Services Task Force recommended the **screening age be reduced from 50 to 45 years.** This would increase the targeted screening population in the US to ~114 million people, up from 94 million. The reduction of screening age is expected to occur in all major global markets.

As part of the push to screen more people in the US for colorectal cancer, the US Centers for Medicare and Medicaid Services released a draft decision outlining the criteria for the reimbursement of current and future blood-based colorectal cancer screening tests. The requirements include the patient being age 50 or over, asymptomatic, and without known risk factors such as family history of colorectal cancer (CRC) or its precursors. **Tests must also demonstrate both sensitivity greater than or equal to 74 percent and specificity greater than or equal to 90 percent.**

Rhythm notes that ColoSTAT® would **meet the requirements for reimbursement eligibility in the US based on the Study 6 performance of 84% sensitivity and 95% specificity.** Rhythm's ColoSTAT® Clinical Trial (Study 7) is also expected to meet the broader requirements of the proposed code.

Rhythm CEO, Glenn Gilbert, commented:

"We continue to target ColoSTAT® as a disruptive cancer detection technology for the global mass screening market to address the growing burden of colorectal cancer. The completion, increase in performance and generally positive outcome of Study 6, is a critical milestone for the Company as we progress our clinical trial, and importantly, how we now consider our entry plans for the global markets, including the US."

[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.

Overview of Study

Rhythm's development program was designed to predominantly establish its own sources of antibodies and target antigen materials that are scalable, with ColoSTAT® test-kits that can be commercially produced by a third-party manufacturer. Such test-kits would then be tested in a detailed study, referred to as Study 6. The objective of Study 6 was to provide evidence of analytical performance of the In-Vitro Diagnostic device (IVD) product by testing the manufactured ColoSTAT® test-kits on patient blood samples, in both cancerous and healthy blood scenarios. Study 6 involved 300 cancerous and healthy blood samples (n=300), with the above stated performance confirmed on an independent set of 100 cancerous and healthy blood samples (n=100).

Released with the authority of the Board**.**

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About Rhythm Biosciences

Rhythm Biosciences (ASX: RHY) is a transformative, predictive diagnostics company, specialising in early cancer detection. Rhythm's initial business pursuit is centred upon technology originally developed by the CSIRO and involves the development and commercialisation of a screening and diagnostic test for the early detection of colorectal cancer, the third biggest cause of cancer-related deaths globally.

Rhythm's lead product, ColoSTAT®, is intended to be a simple, affordable, minimally invasive and effective blood test for the early detection of bowel cancer for the global mass market. It is expected to be comparable to, if not better than, the current standard of care, the faecal immunochemical test (FIT), at a lower cost. ColoSTAT® also provides an alternative for those who choose not to, or are unable to, be assessed using standard screening programs.

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 an important role in reducing the morbidity and mortality rates and healthcare costs associated with colorectal cancer via increasing current screening rates.

Globally, over 850,000 people die from colorectal cancer each year. Colorectal cancer is typically diagnosed at a later stage when there is a poor prognosis for long-term survival. Annual estimated unscreened 50-74-year old's is estimated at +130m for the US, EU and AU alone, with this market potential being more than $6.5b.