ASX Announcement
ASX: RHY

Initial Manufacturing of ColoSTAT® Test-Kits Complete

- ✓ **Initial manufacturing by Biotem of ColoSTAT® prototype test-kits completed;**
- ✓ **Performance and verification testing by Rhythm in process;**
- ✓ **Early test results on par with Rhythm's performance testing of ColoSTAT® which outperformed current market standard faecal test (FIT); and**
- ✓ **Study 6 completion remains on track by end of March 2021.**

20 January 2021, Melbourne: Rhythm Biosciences Limited (ASX: **RHY**) (**Rhythm** or the **Company**) is pleased to provide an update on the initial manufacturing of the ColoSTAT® test-kit by its global manufacturer, Biotem.

Manufacturing of ColoSTAT®

Design transfer of the core technology to Rhythm's global manufacturer, Biotem, has been successfully completed. The initial small-scale manufacturing of ColoSTAT® prototype test-kits by Biotem commenced in December 2020 (as announced on 2 December 2020) and were subsequently delivered to Rhythm ahead of schedule in late December.

Performance Testing

Rhythm has commenced initial performance testing on the Biotem manufactured ColoSTAT® prototype test-kits on cancerous and healthy blood samples, which will form Study 6. Full testing of all samples is ongoing.

Early quality assurance and performance test work on the Biotem manufactured test-kits indicate comparable performance to the Rhythm prototype test-kit results (see ASX announcement 12 November 2020), which were found to be consistent and reproducible. The Company is highly encouraged by these early results.

Rhythm CEO, Glenn Gilbert, commented:

"The objective of design transfer of the core ColoSTAT® technology to our global manufacturer, Biotem, is to demonstrate that they are able to produce, in a commercial setting, the same consistent and high performing ColoSTAT® test-kit that Rhythm had achieved in lab.

The early view on the performance of the test-kits manufactured by Biotem provides further confidence on our underlying technology that will drive the success of ColoSTAT® into the future."

Algorithm Development

As part of the ongoing development plan for ColoSTAT®, Rhythm continues to improve on the performance of the algorithm and software development that underpins the test-kit technology. The current version has already demonstrated that it outperforms the current market standard faecal test (FIT). Buoyed by this, Rhythm has decided to increase resourcing within its algorithm and software development division, with the aim to improve on the existing and already successful algorithm.

Given the nature of the algorithm design, the performance of ColoSTAT® may be able to be improved even further as more samples create a larger dataset to assess. Machine learning and computer modelling techniques are ongoing. Any improvements will be applied in the clinical trial (Study 7) and onward.

Released with the authority of the Board.

For further information, please contact:

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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.