ASX Announcement



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Rhythm Appoints Global Manufacturer for ColoSTAT®

- Rhythm appoints Biotem as its global manufacturer for ColoSTAT®
- Biotem is a reliable and trusted manufacturer with high volume and global manufacturing capabilities
- ColoSTAT® core technology transfer now underway

2 December 2020, Melbourne: Rhythm Biosciences Limited (ASX: RHY) is pleased to confirm that it has appointed France based Biotem Limited, as the global manufacturer of its ColoSTAT® test-kit.

Biotem were chosen following a robust due diligence process to select a manufacturer for the ColoSTAT® test-kit that could execute on Rhythm's ambition to address the global unmet need for the early detection of colorectal cancer. With over 40 years of immunoassay development and manufacturing experience, Biotem has the capability to deliver the optimisation and process validation of the manufacturing procedure and the ability to economically produce large-scale quantities of the ColoSTAT® test-kit.

Initial design transfer and the broader core technology transfer is currently underway. It is expected that small-scale manufacturing of ColoSTAT® prototype test-kits will have commenced by the end of the 2020 calendar year. The initial batches of test-kits will undergo quality assurance and ongoing product verification testing by Rhythm. The initial batch will used for testing on cancerous and healthy blood samples, forming Study 6, which is on track for completion by Q3FY'21.

"The opportunity to partner with Rhythm to manufacture the ColoSTAT® test-kit really appealed to us in the context of being part of a lifesaving diagnostic test. We understand the cancer screening opportunity and look forward to leveraging our history in developing and manufacturing antibody diagnostic tests to make ColoSTAT® a success" Biotem CEO/CSO, Clarence Deffaud, said.

Rhythm CEO, Mr Glenn Gilbert, commented "following our recent completion of the ColoSTAT® protype test-kit, the appointment of Biotem as our global manufacturer now sets a clear pathway to bring ColoSTAT® to the market. We are focused on an exciting few months ahead as we scale up our development plan activities."

www.rhvthmbio.com

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.