

Final ColoSTAT® Kits Achieve Breakthrough Clinical Performance across the continuum of established colorectal cancer stages – Stage I - IV

Highlights

- ✓ ColoSTAT® kit transitioned to the final production validation stage.
- ✓ First high-quality kits received for final internal testing.
- ✓ ColoSTAT® diagnostic performance is consistent across colorectal cancer stages I to IV.
- ✓ Performance meets clinical requirements for symptomatic patient testing use case, with commercialisation steps underway.

Melbourne, Australia, 4th August 2025: Rhythm Biosciences Ltd ('RHY', the 'Company' or the 'Group') (ASX:RHY), a transformative, predictive cancer diagnostics technology company, is pleased to announce the results of an important study on the diagnostic assay performance on different cancer stages.

Following from the completion of the ColoSTAT® Beta kit verification and validation announced previously, our development team has recently taken receipt of a batch of ColoSTAT® kits that have been produced by Quansys Biosciences using the final manufacturing process.

As part of the process validation a set of new blood samples from patients with no neoplastic disease or stage I to IV cancers were evaluated to establish whether ColoSTAT® was effective across the continuum of neoplastic bowel disease. This study was critical as the initial intended use of ColoSTAT® is for symptomatic patients who could well have early and late-stage disease. While further studies will be completed, the data on 300 patient samples shows that ColoSTAT® is equally effective at detecting colorectal cancer across all stages (I to IV).

"Establishing ColoSTAT® performance across the entire range of neoplastic conditions is an important requirement for a clinically useful product. I'm pleased to see this important milestone has been achieved." shared Dr Andy Feber, Clinical Advisor to Rhythm.

The Company looks forward to reporting the results of the final validation of the kits, algorithm and instrumentation in the near term, ahead of a submission to NATA to add ColoSTAT® to Rhythm's ISO15189 laboratory test portfolio. This will be followed by the commercial launch of ColoSTAT® later in CY2025, subject to NATA regulatory approval timeline.

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This announcement was authorised by the Board of Directors of Rhythm Biosciences Limited.

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About Rhythm Biosciences

Rhythm Biosciences Ltd (ASX: RHY) is an Australian innovative, medical diagnostics company aimed at delivering simple, affordable blood tests for accurate and early detection of cancers. Rhythm is focused on improving patient outcomes through detection at the earliest possible stage, reducing the global burden of cancer and saving lives.

Rhythm Biosciences is committed to working with likeminded global partners to achieve commercialisation and distribution of these simple solutions.

The company was founded in 2017 and is headquartered in Melbourne, Australia. For more information, visit rhythmbio.com and follow the company on LinkedIn and X

About ColoSTAT®

Colorectal cancer (CRC), also referred to as bowel cancer, is the second leading cause of cancer deaths globally. If diagnosed early, colorectal cancer is curable

The ColoSTAT® Test-Kit is Rhythm Bioscience's simple blood-based test for the detection of CRC. It measures five specific protein biomarkers that indicate the likelihood of CRC. The test is an alternative for individuals who are unable or unwilling to participate in current screening programs. It is being updated to meet relevant regulatory standards.

The ColoSTAT* Test-Kit is based on research from Australia's CSIRO and is patent protected internationally. It has the potential to play a key role in reducing the mortality rate and healthcare costs associated with colorectal cancer.

About geneType™

geneType™ is a sophisticated genetic risk assessment testing platform that combines clinical, family history and genetic data to provide comprehensive risk assessments for various diseases. The platform leverages polygenic risk scores and clinical risk factors to generate personalized health insights, helping individuals and healthcare providers make more informed medical decisions. The technology allows for risk assessment across multiple conditions including breast cancer, cardiovascular disease, diabetes, colorectal cancer, prostate cancer and melanoma. The tests are delivered through healthcare providers and genetic counsellors, ensuring appropriate clinical oversight and support for patients receiving their results. The platform's multi-disease assessment capabilities and clinical utility position it well to capture growing demand in the preventative healthcare and precision medicine markets. For more information, please visit www.genetype.com.