

## Rhythm Biosciences achieves commercial deployment milestone: First physician participant enrolled in the ColoSTAT® Access Program

### Highlights

- ✓ First physician participant successfully enrolled in the ColoSTAT® Access Program, marking ColoSTAT®'s entry into structured commercial deployment and Rhythm's first pathway to routine paid clinical use.
- ✓ Establishes a controlled pathway for the safe and effective introduction of ColoSTAT® into routine clinical use in Australia and transitions of participating clinicians to standard commercial pricing once clinical procedures have been established.
- ✓ Creates a platform for clinician adoption, operational readiness and commercial scale-up.
- ✓ Generates real-world performance and utilisation data to support future reimbursement and partner engagement.

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**Melbourne, Australia, 11<sup>th</sup> February 2026:** Rhythm Biosciences Ltd ('RHY', the 'Company' or the 'Group') (ASX:RHY), a predictive cancer diagnostics technology company announces the enrolment of the first physician participant in its ColoSTAT® Access Program (**Access Program**), a key commercial milestone in the Company's transition of ColoSTAT® from clinical development to routine clinical use and revenue-generating clinical deployment.

The Access Program has been established as Rhythm's initial commercial deployment framework for ColoSTAT®, enabling eligible clinicians to begin offering the test to appropriate patients while the Company finalises broader market access pathways and establishes repeat ordering behaviour under standard commercial pricing.

Under the terms of the Access Program, participating clinicians receive an initial allocation of ColoSTAT® tests at no cost to allow a routine test ordering and delivery process to be established. Once the Company and participant are confident that patient safety and clinical efficacy is assured, further tests will be supplied on standard commercial terms. Continued use of ColoSTAT® after the initial allocation is expected to occur on a paid basis, subject to the clinician's independent clinical judgement.

This commercial milestone marks an important step toward demonstrating that ColoSTAT<sup>®</sup> is operationally ready for real-world clinical use and marks the first step in building routine clinical utilisation.

### **What is the ColoSTAT<sup>®</sup> Access Program?**

The ColoSTAT<sup>®</sup> Access Program is designed to ensure this novel clinical assay is delivered in a way that maximises patient safety and clinical efficacy. Furthermore, the program will allow the Company to gain valuable insights by participating clinicians. The Program will be capped at 20 participants in Australia, and each participant will receive an initial supply of no charge ColoSTAT<sup>®</sup> clinical tests while they transition into routine commercial usage. Participation in the Program does not require the participating physicians to commit to a specific clinical testing volume, however the Access Program is structured to support transition to routine clinical use and ongoing ordering under standard commercial terms where clinicians elect to continue using ColoSTAT<sup>®</sup>. The participant in the Access Program will provide summary clinical data to the Company to support the continued development of clinical evidence.

Through the program Rhythm will:

- Strengthen the ColoSTAT<sup>®</sup> clinical and commercial value proposition.
- Demonstrate demand for a blood-based colorectal cancer testing alternative.
- Refine operational workflows and systems for broader market deployment.

### **Why This Matters**

Colorectal cancer is the second leading cause of cancer death globally, yet screening rates remain stubbornly low due to the invasive nature of current screening methods.

ColoSTAT<sup>®</sup> offers a simple blood test alternative that has the potential to dramatically improve screening participation rates and enable earlier detection when treatment is most effective.

The enrolment of the first Access Program participant represents an important step toward demonstrating that ColoSTAT<sup>®</sup> is ready for real-world use and provides early validation of clinician engagement and potential demand for a more accessible blood-based testing option.

This milestone further transitions the Company's profile from a research and product development organisation to a commercial business, establishing a foundation upon which future market access, partnership and distribution strategies can be built and establishing a pathway to recurring test revenue.

The physician participants in the Access Program will remain anonymous for patient privacy reasons. Furthermore, Access Program participants have the option to terminate their participation at any point. The ColoSTAT<sup>®</sup> Access Program is designed to ensure patient safety and clinical efficacy.

For investors, the Access Program represents Rhythm's first structured commercial deployment of ColoSTAT<sup>®</sup> and an important step in establishing routine clinical ordering behaviour. Demonstrating utilisation under commercial terms and real-world adoption are key milestones in the Company's broader commercialisation and reimbursement strategy.

### **Commentary**

Dr. David Atkins, CEO & MD of Rhythm Biosciences, commented:

*"This first clinical participation in the CAP represents a pivotal moment for Rhythm Biosciences and supports our strategy of transitioning ColoSTAT<sup>®</sup> from clinical validation into real-world use. Seeing a physician review the data and deciding to move forward with ColoSTAT<sup>®</sup> is an important step.*

*This is exactly the kind of milestone our stakeholders have been waiting for—tangible evidence that ColoSTAT<sup>®</sup> is transitioning from concept to commercial reality. This Program provides the commercial framework needed to support broader market entry. It enables us to establish clinician relationships, validate workflows and build the real-world evidence base that underpins long-term adoption and strategic partnerships. Importantly, the Program is designed to transition participating clinicians to routine paid clinical use following initial allocations, providing the Company with an important step toward sustainable commercial deployment."*

### **Next Steps**

With the first participant now enrolled, Rhythm Biosciences will focus on:

- Expanding clinician participation in the Access Program with the objective of increasing paid clinical utilisation following initial allocations.

- Generating real-world clinical and operational data.
- Progressing discussions with potential commercial partners and distributors.
- Continuing preparation for broader market entry.

The Company will provide further updates as additional milestones in the Access Program are achieved.

- ENDS -

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

**For further information contact us via [investors@rhythmbio.com](mailto:investors@rhythmbio.com).**

#### **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](http://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 can be curable. The ColoSTAT® Test 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. It is intended for individuals with symptoms associated with Colorectal Cancer (CRC). The ColoSTAT® Test 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](http://www.genetype.com).