

Rhythm Closes Final Clinical Trial Site

Highlights

- ✓ Final ColoSTAT[®] clinical trial (study 7) site has been closed;
- ✓ The collation of clinical data and study results is complete;
- ✓ Signifies the completion of operational aspects and confidence by the Company that all compliance measures have been met for regulatory submission; and
- ✓ Submission package preparation for the TGA is in its late stages.

Transformative cancer diagnostics technology company, Rhythm Biosciences Ltd (ASX: **RHY**) (**Rhythm** or the **Company**) is pleased to confirm another milestone toward commercialisation of its colorectal cancer blood test, with the announcement of the final ColoSTAT[®] clinical trial site closure.

The closure of all ColoSTAT[®] clinical trial sites signifies the finality of clinical trial operations, which follows the recent announcement confirming ColoSTAT[®] delivers very high accuracy for the detection of colorectal cancer, recording a sensitivity¹ of 81% and a specificity² of 91% (ASX Announcement 4 April 2022). The Company is now in the process of completing remaining regulatory submission activities.

Near-term activities ahead of the market release of ColoSTAT[®] later this year, include:

- Final clinical study report completion;
- Partnering / commercialisation deals (Domestic and International);
- International country submissions / registration updates; and
- Submission with the Therapeutic Goods Administration (TGA).

Rhythm CEO and Managing Director, Glenn Gilbert, commented:

“The successful closure of the operational aspects of our clinical trial program places the Company into a critical phase to deliver ColoSTAT[®] into the market later this year. We look ahead with confidence that our lifesaving cancer detection technology will make a meaningful difference to millions of people around the world.”

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

- ENDS -

Authorised for release by the Board.

Rhythm Biosciences Ltd
ACN 619 459 335
ASX: RHY

www.rhythmbio.com

Australian Registered Address
Bio21 Molecular Science & Biotechnology Institute
30 Flemington Road
Parkville VIC 3010 Australia

T +61 3 8256 2880
E info@rhythmbio.com

Directors

Otto Buttula
Glenn Gilbert
Trevor Lockett
Rachel David
Louis Panaccio
Eduardo Vom

Executive Chairman
Managing Director
Executive Director
Non-Executive Director
Non-Executive Director
Non-Executive Director

For further information contact:

Glenn Gilbert
CEO and Managing Director
+61 3 8256 2880

About Rhythm Biosciences

Rhythm Biosciences is focused on becoming a globally significant, transformative, predictive diagnostics company, specialising in cancer detection technology. The Company is currently developing ColoSTAT® - a simple, low-cost, blood test for global mass market detection of colorectal cancer.

Worldwide, colorectal cancer is the third most common cancer in men and the second most common in women, accounting for an estimated 1.9 million new cases and 935,000 deaths annually.

In an effort to reduce the global burden, many countries have implemented screening programs aimed at early detection. These programs are predominantly administered with a faecal immunochemical test (FIT) for the assessment of colorectal cancer risk, with a positive result referred for a colonoscopy. FIT only analyses the presence of blood in faeces, which can occur for several reasons other than cancer, therefore it is not designed as an accurate test for cancer. Many people simply don't take the test for fear of an unnecessary colonoscopy procedure, unpleasantness, difficulty, or for religious/cultural reasons. There is currently no appropriate blood test alternative.

Rhythm aims to transform the global mass-market for colorectal cancer detection with ColoSTAT® its simple, low-cost blood test that is fit for purpose, meaning that it is designed to actually detect colorectal cancer. Since listing on the ASX in 2017, the Company has run a successful multi-year research and development program that has delivered technical validation of the core biomarker technology, being reproducible and stable. The ColoSTAT® test-kit was manufactured in 2021 and delivered performance testing that outperforms the current market standard faecal immunochemical test (FIT) utilising Rhythm's proprietary algorithm. The Company is currently finalising its clinical trial for ColoSTAT®, and is progressing regulatory, manufacturing and scale up activities ahead of market entry in 2022.

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

Rhythm's initial targeted global addressable population is over 800 million people which are over 50 years of age. Almost 70%, or 550 million people, are not currently screened for colorectal cancer due to the limitations of the current faecal based testing regime. This "at risk" population is also expanding with the disease growing rapidly in much younger age groups. Early detection and intervention can lead to cure in over 90 per cent of new cases, therefore the need for effective screening and early intervention has the potential to save a significant number of lives. Rhythm estimates today's colorectal cancer screening market alone to be worth in excess of \$38 billion.