

Completion of Final TGA Submission Step for ColoSTAT[®] Approval

Highlights

- ✓ Rhythm files for Australian Register of Therapeutic Goods (ARTG) listing for ColoSTAT[®];
- ✓ ARTG filing is the final step required to secure market access in Australia; and
- ✓ Focus remains on preparations for market launch in late CY'22.

Transformative cancer diagnostics technology company, Rhythm Biosciences Ltd (ASX: RHY) (**Rhythm** or the **Company**) confirms the filing with the Australian Therapeutic Goods Administration (TGA) for the listing of ColoSTAT[®] on the Australian Register of Therapeutic Goods (ARTG). This marks a significant regulatory milestone for the Company as approval of this case would open the way to the sale of ColoSTAT[®] for clinical use in Australia.

Regulatory Approval - Australia

TGA approval is required for Rhythm and/or its partner(s) to market and sell ColoSTAT[®] in the Australian marketplace. ColoSTAT[®] is a simple blood test developed by Rhythm for the detection of colorectal cancer and is aimed at global mass market screening. The lifesaving cancer detection technology has the potential to make a meaningful difference to millions of people around the world. The TGA approval process spans two key steps by filing a detailed submission for:

- Manufacturers Evidence documentation (ASX announcement 14 September 2021); and
- An Australian Register of Therapeutic Goods (ARTG) listing.

With the application now filed, the TGA will assess Rhythm's ARTG listing submission, along with key technical documents and provide final approval which will enable commercialisation of ColoSTAT[®] in the Australian market. The Company anticipates this review process to be completed within 3-6 months. In the interim, Rhythm is focused on executing across a number of key technical, administrative and logistical activities that will support the pathway to market entry, both domestically and internationally, in late CY'22.

Rhythm CEO and Managing Director, Glenn Gilbert, commented:

"This is an exciting time for all Rhythm stakeholders and indeed global cancer diagnostics markets. The team continues to diligently execute on our plans as we target ColoSTAT[®] revenues in late CY'22.

We are very close to being in a unique position to transform and revolutionise the colorectal diagnostics market with our lifesaving cancer detection technology."

- 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.