

Rhythm Expands CE Mark registration to the UK For ColoSTAT®

Highlights

- ✓ Rhythm confirms expansion of CE Mark registration allowing ColoSTAT® to be marketed and sold within Great Britain (England, Wales and Scotland) and Northern Ireland.

Transformative cancer diagnostics technology company, Rhythm Biosciences Ltd (ASX: RHY) (**Rhythm** or the **Company**) is pleased to confirm the achievement of another regulatory milestone progressing the commercialisation of ColoSTAT®, its simple blood test for the detection of colorectal cancer, aimed at global mass market screening.

Expansion into UK

Further to achieving CE Mark and registration of ColoSTAT® as an IVD in Europe (see ASX Announcement 30 November 2021), Rhythm has now expanded its CE Mark registration with the UK Competent Authority, the Medicines and Healthcare Products Regulatory Agency (**MHRA**).

In addition, the MHRA have also accepted Rhythm's application as a registered manufacturer of IVD products. This allows its colorectal cancer detection technology product, ColoSTAT®, to be marketed and sold within Great Britain (England, Wales and Scotland) and Northern Ireland. The Company has demonstrated that ColoSTAT® fully conforms with the regulatory requirements for IVD products under the European Directives for IVD Medical Devices (98/79/EC).

Europe and UK Commercial Opportunity

Achieving regulatory milestones with this recent CE Mark expansion, provides clear intent for the Company's commercial plan and market entry strategy. Europe and the UK represent a significant addressable screening population for ColoSTAT® of over 231 million people, with a potential combined value of ~US\$12 billion.

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Authorised for release by the Board.

For further information contact:

Glenn Gilbert
CEO and Managing Director
+61 3 8256 2880

Rhythm Biosciences Ltd
ACN 619 459 335
ASX: RHY

www.rhythmbio.com

Australian Registered Address
Level 2, 480 Collins Street
Melbourne VIC 3000 Australia

T +61 3 9614 0600
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

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.