

UKCA Mark Granted for ColoSTAT®

Highlights

- ✓ Rhythm confirms UKCA Mark certification is complete for ColoSTAT®;
- ✓ UKCA Mark certification delivers a major milestone allowing ColoSTAT® to be marketed and sold within the United Kingdom; and
- ✓ Enables access to an addressable market of approximately 24 million people aged from 45 to 74.

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

Rhythm's colorectal cancer detection technology product, ColoSTAT®, has been granted UKCA Mark and fully conforms with the European Directives for IVD Medical Devices (98/79/EC) and the UKCA requirements. This regulatory achievement is a result of analytical testing and adherence to design and development procedures as per the Essential Requirements.

UKCA Mark Overview

The UKCA (UK Conformity Assessment) mark is the new UK product marking (post Brexit) that is required for certain products being placed on the market in Great Britain (England, Wales and Scotland). It replaces most products that previously required only a CE mark.

UKCA marking represents that the manufacturers product meets the Essential Requirements of the UK MDR 2002 and is a legal requirement to place a device on the market in Great Britain / United Kingdom.

Review and acceptance of all required documentation has been performed by the company's Authorised Representative in the UK, Emergo. This includes that the product:

- Meets all the requirements of the relevant recognised analytical, performance and safety standards; and
- Is compliant to its intended purpose of use.

Commercial Opportunity

Affixing the UK CA Mark is a key component in Rhythm's strategic plan that forms part of the Company's commercial plan and priority market entry strategy. This enables Rhythm to commercialise, market and sell ColoSTAT® in a significant global market across the UK. Rhythm estimates that, currently, this customer market represents an addressable screening population of about 24 million people.

Rhythm expects to make further advances on its market entry into the UK in CY'23.

Rhythm Chief Commercial Officer, Elena Deak, commented:

“The achievement of this regulatory milestone continues to validate our commercial pathway into global markets, with the UK alone representing an addressable population of approximately 24 million people.

Importantly, over time we expect the market size to continue expanding, as various bodies encourage earlier age screening.”

- ENDS -

Authorisation & Additional Information

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

For further information contact us via investor@rhythmbio.com or on +61 3 8256 2880:

Mr Otto Buttula Executive Chairman	Ms Elena Deak Chief Commercial Officer	Mr Paul Smith CFO & Company Secretary
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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 Twitter.

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 test for the detection of CRC. It measures five specific protein biomarkers that indicate the likelihood presence of CRC. The test can be used as an alternative for individuals who are unable or unwilling to participate in current screening programs.

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.