ASX Announcement
ASX: RHY

Rhythm Retains ISO13485 Certification

- **Rhythm retains ISO 13485:2016 certification for its Quality Management System**
- **ISO certification is critical for regulatory compliance and ultimately market entry**

31 March 2021, Melbourne: Rhythm Biosciences Limited (ASX: RHY) is pleased to confirm that the Company has maintained its certification to the International Standard for In-Vitro Diagnostics and Medical Devices (ISO 13485:2016).

ISO13485 is the internationally recognised quality standard to ensure the consistent design, development, production, installation and sale of medical devices that are safe for their intended purposes. Compliance to the standard is audited annually.

The ISO13485 certification was conducted via an audit by the British Standards Institution (BSI). This marks the third year running that Rhythm has achieved and maintained certification with the ISO standard, which is critically important as the Company intends to pursue regulatory approvals as part of its commercial and market entry strategy.

Rhythm CEO, Glenn Gilbert, commented:

> *"Having achieved and maintained ISO certification for a number of years now is a fantastic validation for the rigour and consistency the Company has established as part of our development program for ColoSTAT®.*
>
> *This is also a crucial part of our market entry strategy that ensures we have robust systems and processes in place that underpin our disruptive and transformative life saving cancer detection technology."*

With authority by the Board.

For further information, please contact:

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About Rhythm Biosciences

Rhythm Biosciences (ASX: RHY) is a transformative, predictive diagnostics company, specialising in early cancer detection. Rhythm's initial business pursuit is centred upon technology originally developed by the CSIRO and involves the development and commercialisation of a screening and diagnostic test for the early detection of colorectal cancer, the third biggest cause of cancer-related deaths globally.

Rhythm's lead product, ColoSTAT®, is intended to be a simple, affordable, minimally invasive and effective blood test for the early detection of bowel cancer for the global mass market. It is expected to be comparable to, if not better than, the current standard of care, the faecal immunochemical test (FIT), at a lower cost. ColoSTAT® also provides an alternative for those who choose not to, or are unable to, be assessed using standard screening programs.

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

Globally, over 850,000 people die from colorectal cancer each year. Colorectal cancer is typically diagnosed at a later stage when there is a poor prognosis for long-term survival. Annual estimated unscreened 50-74-year old's is estimated at +130m for the US, EU and AU alone, with this market potential being more than $6.5b.