ASX Announcement



ASX code: RHY ACN: 619 459 335

Successful ISO13485 Surveillance Audit

- Rhythm retains ISO13485:2016 certification of its Quality Management System
- ISO certification demonstrates continued compliance and is integral to achieving a pathway to eventual commercialisation

6th April 2020, 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), via another successful audit from the British Standards Institution (BSI).

ISO 13485 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.

ISO13485 certification is an important component in Rhythm's aim to achieve compliance for the European market via a CE Mark and for the Australian market via the Therapeutic Goods Administration (TGA). Compliance to the standard is audited annually.

"We are pleased to have maintained this ongoing certification, as it demonstrates the strength and consistency of our Quality Management Systems, and is consistent with the pathway we have set to continue developing and ultimately commercialise the ColoSTAT® blood test in mass market screening for the early detection of colorectal cancer", commented Rhythm CEO, Glenn Gilbert.

With authority by the Board.

For further information, please contact:

Glenn Gilbert Chief Executive Officer +61 3 8256 2880

About Rhythm Biosciences

ASX-listed Rhythm Biosciences is endeavoring to develop and commercialise 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 overall cost to public health administrations. 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 equipment agnostic and easily used 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. Globally, over 850,000 people die from colorectal cancer each year.