

Rhythm Biosciences receives ISO certification

- **RHY certified to manufacture in-vitro diagnostics and medical devices, using immuno-assay technology**
- **Applicable to Rhythm Biosciences' own products, and licensed products**

22 May 2019, Melbourne: Medical diagnostics company Rhythm Biosciences Limited (ASX: RHY) is pleased to announce that the company's Quality Management System (QMS) has just been certified as compliant with the International Organization for Standardisation (ISO) EN 13485:2016 standard. The assessment was conducted by British Standards Institution (BSI) Group, the business standards company and market leading UK Notified Body.

EN ISO 13485:2016 is the internationally recognised quality standard that ensures the consistent design and development, production, storage and distribution of medical devices that are safe for their intended purposes.

EN ISO 13485:2016 is recognised by the Global Harmonization Task Force (GHTF) and has become the model QMS standard for the medical industry. It is the first step in achieving compliance with European and Australian regulatory requirements and a major milestone in Rhythm Biosciences' pathway to market.

Certification with this standard demonstrates compliance to the laws and regulations of the Medical Device industry and enables Rhythm to be classified as a manufacturer of In Vitro Diagnostics and Medical Devices for its own and in-licensed products for worldwide registration and sale.

"ISO 13485 certification represents another step on Rhythm Biosciences' path to developing and commercialising its ColoSTAT® screening and diagnostic test for the detection of colorectal cancer" said Rhythm Biosciences CEO, Glenn Gilbert.

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Rhythm Biosciences

ACN: 619 459 335
ASX: RHY

Issued Capital

100,750,000 Shares
3,504,200 Options and
Performance Shares

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Directors

Shane Francis Tanner – Chairman of the Board
Trevor John Lockett – Executive Director
Louis James Panaccio – Non-Executive Director
David John White – Non-Executive Director

About Rhythm Biosciences

ASX-listed Rhythm Biosciences is developing and commercialising a screening and diagnostic tool 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, low cost, 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. Globally, over 850,000 people die from colorectal cancer each year.