

Initial TGA Regulatory Documentation Submitted

- **Manufacturers Evidence documentation for TGA approval submitted;**
- **Significant step forward for Australian regulatory approval; and**
- **Recruitment completion for clinical trial (Study 7) on track for 2021.**

19 August 2021, Melbourne: Rhythm Biosciences Limited (ASX: RHY) is pleased to announce it has submitted its initial documentation required for Therapeutic Goods Administration (TGA) approval in Australia for ColoSTAT[®]. ColoSTAT[®] is aimed to be a globally marketed, low-cost, simple blood test for the early detection of colorectal cancer for mass-market screening.

For Rhythm, the TGA submission process will require two key steps, consisting of filing both the Manufacturers Evidence documentation (now completed) and filing for an Australian Register of Therapeutic Goods (ARTG) listing. The ARTG listing will contain further documentation such as the product technical files, clinical evaluation reports and the like.

Commenting on the filing, Rhythm CEO, Glenn Gilbert said:

"Another significant step forward as we move towards commercialisation has been achieved. The progress for regulatory approval in Australia, has now formally commenced. With the expectation of patient recruitment for the clinical trial (Study 7) to be completed in the near term, Rhythm is well positioned to continue delivering on its stated milestones.

For clarity, the application for a CE Mark for European approval is independent of both the clinical trial (Study 7) being completed and TGA application. CE Mark filing remains on track for late this calendar year."

Released with authority of the Board.

For further information, please contact:

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Rhythm Biosciences

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Issued Capital

202,245,811 Shares
10,295,000 Options

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Directors

Otto Buttula – Chairman of the Board
Trevor John Lockett – Executive Director
Louis James Panaccio – Non-Executive Director
Eduardo Vom – Non-Executive Director

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.