

## TGA Accepts Initial Regulatory Documentation

- **Manufacturers Evidence documentation for TGA approval accepted;**
- **Recruitment completion for clinical trial (Study 7) imminent; and**
- **Achieves another important step for Australian regulatory approval.**

**14 September 2021, Melbourne:** Rhythm Biosciences Limited (ASX: RHY) is pleased to announce that the Therapeutic Goods Administration (TGA) has formally accepted Rhythm's Manufacturers Evidence documentation. This documentation is required for approval in Australia for ColoSTAT® and completes the first step for regulatory approval in Australia.

ColoSTAT® is aimed to be a globally marketed, low-cost, simple blood test for the early detection of colorectal cancer for mass-market screening.

As previously outlined, the TGA submission process will require two key steps, consisting of filing both the Manufacturers Evidence documentation (**submitted** and **now accepted**) and filing for an Australian Register of Therapeutic Goods (ARTG) listing. The ARTG listing will contain further comprehensive documentation such as the product technical files, clinical evaluation reports and similar.

### **Commenting on the TGA's formal acceptance, Rhythm CEO, Glenn Gilbert said:**

*"Progress for regulatory approval in Australia has commenced and it is pleasing to have received the TGA's acceptance of our Manufacturers Evidence. Our expectation remains that patient recruitment for the clinical trial (Study 7) is to be completed in the near term.*

*Again, 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**

ACN: 619 459 335  
ASX: RHY

**Issued Capital**

208,800,081 Shares  
16,848,616 Options

**Australian Registered Office**

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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<sup>®</sup>, 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<sup>®</sup> also provides an alternative for those who choose not to, or are unable to, be assessed using standard screening programs.

ColoSTAT<sup>®</sup> is designed to be used easily by laboratories without the need for additional operator training or additional infrastructure. ColoSTAT<sup>®</sup> 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.