

## **Monash Health signed with first patients recruited for ColoSTAT® clinical trial**

- **Melbourne's Monash Health will be the second clinical trial site**
- **Associate Professor Stephen Pianko appointed Principal Investigator**
- **First patients at Monash have been recruited**

**18 June 2019, Melbourne:** Monash Health is the second hospital to join the Rhythm Biosciences Limited (ASX:RHY) prospective clinical trial of ColoSTAT®, its global, low-cost, lifesaving blood test for the early detection of colorectal cancer. The first patients have also been recruited by Monash Health.

With more than 16,000 staff working at over 40 locations, Monash Health is Victoria's largest public health service providing health care to a quarter of Melbourne's population. Associate Professor, Dr Stephen Pianko, the Head of Clinical Trials at Monash Health, has been appointed as the site's Principal Investigator. Dr Pianko, also a gastroenterologist at multiple hospitals including Monash Health, has significant experience in clinical trials and research.

"Monash Health services a significant patient population which will allow us to access a broad spectrum of people for recruitment" said Rhythm's CEO, Glenn Gilbert. "Coupled with Dr Pianko's well recognized experience in and commitment to colonoscopy and his effective track record of clinical trial execution, Monash Health's joining of our trial provides an important boost to recruiting participants to the study by the end of the year," Mr Gilbert said.

The trial involves a prospective, cross-sectional, multi-centre study to evaluate the diagnostic performance of the ColoSTAT® In Vitro Diagnostic relative to colonoscopy (Primary endpoint). Secondary endpoints of the study include assessing the ability of ColoSTAT® to detect advanced adenomas and a comparison of the performance of ColoSTAT® with the currently used Faecal Immune Test (FIT); both relative to colonoscopy.

Recruitment for the trial (circa 1,000 patients) is expected to be completed end of CY19. The trial will form a key component for both CE Mark & TGA registration and ultimately the approval to market ColoSTAT® in Australia and Europe in 2020.

In parallel, Rhythm continues to work with multiple global parties on the most effective assay development, optimization and clinical utility of the reagents that will form the core components to the final ColoSTAT® test.

Colorectal cancer is the second most frequent cause of cancer-related deaths in the industrial world. It is curable in 90% of cases if detected early, therefore participation in early screening is crucial. ColoSTAT® has the potential to provide a simpler method to screening thereby increasing participation and ultimately survival rates.

Rhythm Biosciences expects to sign further hospitals to join the ColoSTAT® trial in the coming months.

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**Rhythm Biosciences**ACN: 619 459 335  
ASX: RHY**Issued Capital**100,750,000 Shares  
3,504,200 Options and  
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### **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<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. Globally, over 850,000 people die from colorectal cancer each year.