

Rhythm signs first study site for clinical trial for new colorectal cancer diagnostic

- **Adelaide's Lyell McEwin Hospital engaged as first study site**
- **First patients to be enrolled in the coming months**
- **Sonic Clinical Trials and Plunkett Consulting Group appointed**
- **Professor Raj Singh appointed site Principal Investigator**

20 February 2019, Melbourne: Adelaide's Lyell McEwin Hospital will be the first study site for Rhythm Biosciences Limited (ASX:RHY) 1,000-patient prospective clinical trial of its blood test, ColoSTAT®, for the early detection of colorectal cancer.

Director of Gastroenterology at the Lyell McEwin Hospital, Prof Rajvinder Singh, will be principal investigator for this site. Prof Singh is internationally recognised for his groundbreaking work in the areas of advanced endoscopic imaging techniques and endoscopic treatment of premalignant and malignant lesions in the gastrointestinal tract. He is a committee member of the American Society of Gastrointestinal Endoscopy's International Initiative and past Chair of the Australian Gastroenterology Endoscopic Association.

"Surgical interventions for colorectal cancer are much more effective when the cancers are detected early stage, particularly when they can be removed during a colonoscopy procedure," said Prof Singh. "There is a real need for inexpensive, minimally invasive screening tests that will attract the public and I am pleased to have been invited to be principal investigator in the critical clinical evaluation of this new test."

"We are delighted to have a clinician of Prof Singh's stature to lead this important study," said Rhythm CEO Glenn Gilbert.

Rhythm has appointed boutique CRO Plunkett Consulting Group to manage the operations of the trial and provide rigour to the recruitment, monitoring and data collection, along side Sonic Clinical Trials (SCT) who will facilitate the sample collection, processing, analytical testing, recording of results, transport and storage across the various participating clinical trial sites. Sonic Clinical Trials is a wholly owned subsidiary of Sonic Healthcare (ASX:SHL), one of the world's largest medical diagnostics companies.

"Sonic Clinical Trials providing the central laboratory services for Study 7 is an ideal testing ground with our ColoSTAT® technology being integrated into Sonic's existing testing platforms, as it will with those of other pathology labs globally," Mr Gilbert went on to say.

"Using experienced partners such as Sonic Clinical Trials and Plunkett Consulting Group, increases our confidence in the robustness of this trial and will mitigate the risks around trial quality and control of samples," added Mr Gilbert.

Rhythm Biosciences

ACN: 619 459 335
ASX: RHY

Issued Capital

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

Australian Registered Office

Level 17, 500 Collins Street
Melbourne VIC 3000
www.rhythmbio.com

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

The study protocol approved by the Central Adelaide Local Area Health Network's (CALHN) Human Research Ethics Committee (HREC) describes 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 to colonoscopy and a comparison of the performance of ColoSTAT® with the currently used Faecal Immune Test (FIT); both relative to colonoscopy.

Along with the technical performance and validation documentation being developed as part of the ColoSTAT® product development program, the final study report of this clinical trial (expected Q4 CY19) will form key components for CE Mark & TGA registration and ultimately the approval to market ColoSTAT® in 2020.

For further information, please contact:

Glenn Gilbert
Chief Executive Officer
+61 3 8256 2880

Shane Tanner
Chairman
+61 411 107 099

Rudi Michelson
Monsoon Communications
+61 3 9620 3333

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, 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. Over 850,000 people die from colorectal cancer each year.