

Rhythm signs Alfred Hospital for ColoSTAT® clinical trial

- Melbourne's Alfred Hospital will be the third clinical trial site
- Associate Professor Gregor Brown appointed principal investigator

26 June 2019, Melbourne: The Alfred Hospital is the third hospital to join 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 are expected to be enrolled by the Alfred in the coming months.

The Alfred Hospital is a leading hospital in Melbourne, with locations in Prahran, Caulfield and Sandringham. Associate Professor, Gregor Brown, Head of Endoscopy at The Alfred Hospital, has been appointed as the site's principal investigator for the trial. Associate Professor Brown is well recognized for his research into improving colonoscopy techniques including polyp removal during colonoscopy and balloon enteroscopy as well for the development of new treatments for coeliac and inflammatory bowel diseases.

"The Alfred Hospital has a long history of supporting clinical trials and a deep expertise in colonoscopic research. Working with The Alfred adds to the credibility of this clinical trial and we look forward to this collaboration and ultimately the results," commented Rhythm CEO Glenn Gilbert.

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.

Rhythm Bioscience also expects in the coming months to welcome further hospitals to the ColoSTAT[®] trial.

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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). ColoSTAT[®] also provides an alternative for those who choose not to or are unable to be assessed using current screening programs.

ColoSTAT[®] is designed to integrates with existing testing equipment and be used easily by laboratories without the need for additional operator training or 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 of colorectal cancer each year.

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