

Rhythm Completes Recruitment For Clinical Trial (Study 7)

- Key milestone achieved for its ColoSTAT[®] clinical trial (Study 7), with the completion of the patient recruitment phase;
- A total of 815 people were recruited from 11 clinical trial sites; and
- Processes have commenced to rapidly move to the next phase including closure of trial sites, testing of samples, statistical analysis and compose a final Clinical Study Report.

22 September 2021, Melbourne: Transformative, predictive cancer diagnostics technology company, Rhythm Biosciences Ltd (ASX: RHY) is pleased to announce it has completed recruitment for its clinical trial (Study 7) for ColoSTAT[®] - a globally marketed, low-cost, simple blood test for the early detection of colorectal cancer aimed at mass-market screening.

Key Milestone Successfully Completed

Rhythm's trial sites successfully recruited 815 patients across 11 clinical trial sites, Australia wide. Following detailed consultation with leading industry professionals, our biostatisticians and Clinical Research Organisation (CRO), they have confirmed an adequate number of patients have been enrolled in the trial. Therefore, the Company has determined that it can close the recruitment phase of the trial.

The recruitment phase is a highly involved and resource intensive component of the clinical trial. The completion of this phase represents a significant milestone towards final completion of the clinical trial study, leading into regulatory and market entry activities.

Next Steps

The process has commenced to close out trial sites, commence testing the collected blood samples, finalise and lock the patient database and other routine associated works.

Rhythm will continue to work with its CRO, Accelagen, and its analytical testing partner Sonic Clinical Trials (SCT)¹ to progress the next stages in finalising the trial, before completing the final Clinical Study Report.

¹ Sonic Clinical Trials is a wholly owned subsidiary of Sonic Healthcare (ASX: SHL), one of the world's largest medical diagnostics companies.

Rhythm Biosciences

ACN: 619 459 335
ASX: RHY

Issued Capital

208,800,081 Shares
16,848,616 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

As part of the validation process, the ColoSTAT® test-kit will be loaded and tested at the SCT facility, on their testing platforms. This will provide further information on ease of integration into the routine process flows of pathology labs globally.

The final Study Report for this clinical trial is targeted for completion in 1H'CY22. The Report is a key component for the TGA registration package and supports the approval to market ColoSTAT® within Australia in CY22 as planned.

CE Mark certification for Europe is independent of this clinical trial activity being completed, with filing remaining on track for late CY21.

Commenting on the clinical trial key milestone, Rhythm CEO, Glenn Gilbert said:

"With the recruitment target now met for the ColoSTAT® clinical trial, the Company remains fully focused on working with our partners to progress through the remaining phases for trial completion.

In the context of market conditions made extremely difficult by COVID-19, I am proud of the achievement by the entire Rhythm team, our trial sites, CRO, operations and laboratory partners. This milestone should not be understated, considering the recruitment phase is typically the most resource, logistically challenging and cost intensive component of completing a clinical trial."

Background

The clinical trial for ColoSTAT® involves a prospective, cross-sectional, multi-centre study to evaluate the diagnostic performance of the ColoSTAT® In-Vitro Diagnostic relative to colonoscopy (the primary endpoint of the trial). Secondary endpoints of the study include assessing the ability of ColoSTAT® to detect advanced adenomas and a comparison of the performance of ColoSTAT® to the current market standard Faecal Immunochemical Test (FIT); both relative to colonoscopy.

Rhythm has been working through its ColoSTAT® clinical trial (Study 7) since 2019 across 11 trial sites nationally, with operations and laboratory partners, Sonic Clinical Trials and CRO, Accelagen. Ethics approvals have also been granted to supplement the clinical trial with archival samples as required.

Released with authority of the Board.

For further information, please contact:

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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 a key 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-olds is estimated at +130m for the US, EU and AU alone, with this market potential being more than \$6.5b.