

## Update to TGA Submission for ColoSTAT® Test-Kit

Transformative cancer diagnostics technology company, Rhythm Biosciences Ltd (ASX: RHY) (Rhythm or the Company) announces that after receipt and analysis of a thorough application review and its most recent engagement with the Australian Therapeutic Goods Administration (TGA), the Company has decided to withdraw its current ColoSTAT® application for an Australian Register of Therapeutic Goods (ARTG) listing (announced 12 May 2022). The Company intends to submit a new ColoSTAT® application with the TGA, in line to better meet their feedback and questions posed. The new ColoSTAT® application will be submitted at a date to be determined, however is expected to be in the current calendar year. A subsequent announcement will be released to the ASX at the time the new application is submitted.

It should be noted, that RHY's submission was detailed, technical and in excess of 1,300 pages. The Company believes it is in a position to be able to answer the majority of questions within the required timeframe sought by the TGA, being 20 business days, however a minority of the questions require new internal analytical testing by RHY, which require three different production batches of commercially made ColoSTAT® test-kits from our overseas based manufacturer Biotem. Coupled with the logistical and supply chain timing, this would prevent RHY being able to receive these commercially made test-kits and answer the minority of questions raised by the TGA. In recent discussions with the TGA, in line with their normal policies, they have advised that they would be reluctant to provide an extension beyond the 20 business days, required by RHY, to sufficiently answer all questions within the 26-page response.

This intended withdrawal does not impede the Company's proposed market entry activities into other CE Mark conforming territories and additional international markets, including the U.S.A.

### **Otto Buttula, Executive Chairman of RHY, commented:**

*"Having decided to withdraw RHY's current TGA submission for ColoSTAT® is clearly disappointing for all stakeholders. Nonetheless, we appreciate the thorough review undertaken and meaningful dialogue with the TGA. Following the TGA's most recent feedback, both written and verbal and management / Board review, we believe that time constraints imposed result in a better opportunity for the Company to submit a new and strengthened application, in line with the questions raised in the TGA application review. Hence, with a new submission to be completed in line with the questions raised by the TGA, we believe we have a better blueprint to follow in framing our new application. Therefore, I remain confident of a TGA registration for ColoSTAT® in the future."*

*"Whilst Australia, as our home, remains important, it represents one of the smaller markets in our global aspirations and the Company has always intended to build the majority of its revenues in overseas territories."*

*"We look forward to keeping the market abreast of other positive developments in the near term."*

**- ENDS -**

**Authorised for release by the Managing Director.**

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## About Rhythm Biosciences

Rhythm Biosciences is focused on becoming a globally significant, transformative, predictive diagnostics company, specialising in cancer detection technology. The Company is currently developing ColoSTAT® - a simple, low-cost, blood test for global mass market detection of colorectal cancer.

Worldwide, colorectal cancer is the third most common cancer in men and the second most common in women, accounting for an estimated 1.9 million new cases and 935,000 deaths annually.

In an effort to reduce the global burden, many countries have implemented screening programs aimed at early detection. These programs are predominantly administered with a faecal immunochemical test (FIT) for the assessment of colorectal cancer risk, with a positive result referred for a colonoscopy. FIT only analyses the presence of blood in faeces, which can occur for several reasons other than cancer, therefore it is not designed as an accurate test for cancer. Many people simply don't take the test for fear of an unnecessary colonoscopy procedure, unpleasantness, difficulty, or for religious/cultural reasons. There is currently no appropriate blood test alternative.

Rhythm aims to transform the global mass-market for colorectal cancer detection with ColoSTAT® its simple, low-cost blood test that is fit for purpose, meaning that it is designed to actually detect colorectal cancer. Since listing on the ASX in 2017, the Company has run a successful multi-year research and development program that has delivered technical validation of the core biomarker technology, being reproducible and stable. The ColoSTAT® test-kit was manufactured in 2021 and delivered performance testing that outperforms the current market standard faecal immunochemical test utilising Rhythm's proprietary algorithm. The Company is progressing regulatory, manufacturing and scale up activities ahead of market entry in FY23.

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.

Rhythm's initial targeted global addressable population is over 800 million people which are over 50 years of age. Almost 70%, or 550 million people, are not currently screened for colorectal cancer due to the limitations of the current faecal based testing regime. This "at risk" population is also expanding with the disease growing rapidly in much younger age groups. Early detection and intervention can lead to cure in over 90 per cent of new cases, therefore the need for effective screening and early intervention has the potential to save a significant number of lives. Rhythm estimates today's colorectal cancer screening market alone to be worth in excess of \$38 billion.