

Platform Expansion: Gastric Cancer Diagnostic Test Update

Highlights

- ✓ **Rhythm Biosciences has previously identified a series of 19 blood-based protein biomarkers that are differentially detected in individuals with cancer.**
- ✓ **Comprehensive analytical data identifies informative subsets of these protein biomarkers with the potential to be developed into a gastric cancer clinical diagnostic assay.**
- ✓ **Multiple effective biomarker combinations that differentiate between gastric cancer and controls with >75% Sensitivity and >90% specificity have been identified.**

Transformative, predictive cancer diagnostics technology company, Rhythm Biosciences Ltd (ASX: RHY) (“Rhythm” or the “Company”) is pleased to provide an update on its cancer diagnostics technology platform expansion program in gastric cancer. Rhythm has identified protein biomarker combinations that effectively differentiate between blood samples from cancer patients and those from healthy controls.

Gastric cancer has poor outcomes in the general population with an observed 5-year survival (2016-2020) of 38% compared to, as an example, 96% or 92% for prostate and breast cancer for the same period¹. Currently, the gold standard method to detect gastric cancer is upper endoscopy in combination with tissue biopsy. This method has sensitivity and specificity values of 69% and 96%, respectively. However, it is an invasive, costly, and time-consuming methodology². Consequently, gastric cancer is largely diagnosed as regional or distant disease in 56% of the cases compared to 25% and 32% for prostate and breast cancer (US Data for 2021³) supporting the conclusion that earlier detection is a priority and blood-based methods of detection being developed by the Company could be valuable clinical tools.

The geographical distribution of the disease differs from the other more common cancers with significantly higher prevalence in Asia with disease rates per population being up to 6X higher in some Asian geographies compared to the USA. Of the approximately 1 million new cases diagnosed globally each year, over 50% are diagnosed in Asia (China 360,000, Japan 127,000, Korea 30,000 and Vietnam 16,000)⁴.

A case/control study was completed to assess the feasibility of identifying combinations of blood protein biomarkers capable of discriminating between blood samples from patients with gastric cancer and those of healthy controls. Rhythm’s collaborators used experimental immunoassays to quantify 19 candidate blood-based protein biomarkers in sera from 100 gastric cancer patients and 100 healthy volunteers (cohort details summarised in the table below). Univariate and multivariate analysis identified promising combinations of 6, 7 and 8 protein biomarkers that can distinguish between patients with and without gastric cancer with sensitivities > 75% at a specificity of >90%.

These encouraging results warrant confirmation in a larger and more diverse population. To this end, the Company is currently preparing plans to develop this potential gastric cancer assay in conjunction with its multiplex assay development partner. Thereafter, the prototype assay will be clinically validated with an aim to produce a commercially scalable, proprietary blood test to detect gastric cancer early when it is most responsive to potentially curative treatments.

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Gastric cancer study population characteristics: Demographics and disease summary

Characteristic	Gastric Cancer Age (yrs)	Healthy Control Age (yrs)
Sex		
Female	47	47
Male	53	53
Median Age, yrs (Range)	63 (41-82)	63 (41-80)
AJCC TNM Staging		
0 + I	28	N/A
II	29	N/A
III	26	N/A
IV	16	N/A

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Authorised for release by the Board.

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About Rhythm Biosciences

Rhythm Biosciences Ltd (ASX: RHY) is an Australian innovative, medical diagnostics company aimed at delivering simple, affordable blood tests for accurate and early detection of cancers. Rhythm is focused on improving patient outcomes through detection at the earliest possible stage, reducing the global burden of cancer and saving lives.

Rhythm Biosciences is committed to working with likeminded global partners to achieve commercialisation and distribution of these simple solutions.

The company was founded in 2017 and is headquartered in Melbourne, Australia. For more information, visit rhythmbio.com and follow the company on LinkedIn and X.

References:

1. Australian Institute of Health and Welfare. Cancer data in Australia, <https://www.aihw.gov.au/reports/cancer/cancer-data-in-australia/contents/overview-of-cancer-in-australia-2023> and A Rare Cancer Moonshot 2024 published by Rare Cancers Australia Ltd.
2. Choi K.S., Jun J.K., Park E.-C., Park S., Jung K.W., Han M.A., Choi I.J., Lee H.-Y. Performance of Different Gastric Cancer Screening Methods in Korea: A Population-Based Study. PLoS ONE. 2012;7:e50041. doi: 10.1371/journal.pone.0050041.
3. SEER*Explorer: An interactive website for SEER cancer statistics [Internet]. Surveillance Research Program, National Cancer Institute; 2024 Apr 17. [updated: 2024 Jun 27; cited 2024 Sep 18]. Available from: <https://seer.cancer.gov/statistics-network/explorer/>.
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