

## Guard Therapeutics: New strengthening data from AKITA study

Redeye briefly comments on Guard Therapeutics announcing additional encouraging data from its completed phase IIa study AKITA, which investigated RMC-035 as a renal protective agent during open-heart surgery. Furthermore, the company announced that topline results from the phase IIb study POINTER are anticipated in early November.

Yesterday, Guard announced new positive efficacy results from planned secondary analysis of the phase IIa AKITA study. The previously reported primary results showed a robust improvement in kidney function after open-heart surgery. The new analyses further support these findings, demonstrating that RMC-035 exhibits kidney-protective effects in patients with both acute kidney injury (AKI) and without AKI. Moreover, RMC-035 reduces key biomarkers of kidney damage, providing additional evidence of its renal-protective potential.

# Share Information Share Price SEK 20.9 Number of shares (M) 20.2 Marketplace First North Stockholm CEO Tobias L Agervald Chairman Johan Bygge

 Key Stats

 Market Cap
 421.5m SEK

 Entprs. Value (EV)
 321.0m SEK

 Net Debt (2025Q2)
 -100.4m SEK

 30 Day Avg Vol
 36 K

 Dividend Yield
 N/A

Top Holders	
Name	Ownership
Jan Ståhlberg	20.65%
Stiftelsen Industrifonden	14.26%
Swedbank Robur Fonder	9.9%
Rutger Arnhult	5.48%
Avanza Pension	4.84%
Nordnet Pensionsförsäkring	4.26%
Strand Kapitalförvaltning	3.77%
Axel Karlsson	1.37%
ALLA Möller AB	1.05%
Fenja Capital Partners A/S	0.64%

The new results demonstrate a statistically significant improvement in kidney function, as measured by eGFR, with RMC-035 compared to placebo. At Day 90, the net difference in eGFR was 5.5 mL/min/1.73 m² (P=0.019) in patients without acute kidney injury (AKI) and 4.9 mL/min/1.73 m² (P=0.056) in those with AKI, suggesting consistent benefits across both groups. The definition of AKI is primarily based on arbitrary biochemical criteria, such as changes in serum creatinine or urine output. These markers do not always reflect the true extent of tissue injury, which can occur even in patients who do not meet the formal AKI definition.

In patients with pre-operative chronic kidney disease (CKD), RMC-035 led to a 34% **reduction** in urinary albumin-to-creatinine ratio (UACR) compared with placebo, which instead showed a 43% **increase** (P=0.020). High UACR levels predict faster progression of CKD and a greater risk of end-stage renal disease, while reductions in UACR are associated with better long-term outcomes.

Additionally, Kidney Injury Molecule-1 (KIM-1), a marker of tubular cell injury, was significantly lower in the RMC-035 group (geometric mean ratio (GMR) 0.66; P=0.004), reinforcing its protective effect at the cellular level. This benefit was consistent across both low and high baseline eGFR subgroups.

Taken together, these findings confirm and expand on the primary AKITA results. RMC-035 has now demonstrated positive effects across a range of key parameters, providing both functional and mechanistic validation of its therapeutic potential. With this body of evidence, a wide-ranging data package now supports the premise that RMC-035 works as intended.

We expect to increase our possibility of success (PoS) for the ongoing phase IIb study POINTER, from 65% to preliminary 70%, which would increase our likelihood of approval (LoA) estimate from 29% to 31%. This would result in a slightly higher valuation. We have a base case of SEK43, a bear case of SEK2 and a bull case of SEK89. We will return shortly with a more detailed commentary and updated estimates.

Guard also announced that POINTER topline data is expected in early November (previously estimated Q4 2025). The study has progressed significantly faster than anticipated, which we view as a testament to Guard's strong operational execution, efficient trial management, and high engagement among participating clinics.

We believe that the news warrants a positive share reaction of above 10%, driven by both the strong new data and the fact that the stock has recently been under pressure without any clear explanation. Yesterday's news could be the spark that triggers the typical biotech pattern of shares rising ahead of study readouts.

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