



Malmö 13 August 2025

**PRESS RELEASE**

## **Aptahem Applies to FDA PreCheck Program – Strategic Step Toward Faster, Higher-Quality Drug Manufacturing**

Aptahem AB (publ), a biotech company developing RNA-based treatments for severe inflammatory conditions, is strengthening its position as a leader in RNA-based therapeutics by applying to the FDA PreCheck Program, the agency's new initiative to accelerate and streamline inspections of drug manufacturing.

The program is reserved for companies with a proven track record of high-quality, GMP-compliant operations, offering prioritized inspections and regulatory transparency. For Aptahem, participation means:

- Faster regulatory pathway for production of Apta-1, our breakthrough RNA aptamer for severe inflammatory conditions.
- Enhanced confidence from partners and investors, demonstrating the company's commitment to top-tier quality and innovation.
- Clear quality milestone reducing risks and timelines, supporting future clinical and commercial expansion.

### **Strategic Value for Investors**

Through the PreCheck program, Aptahem signals not only that it develops groundbreaking therapies, but also that it has the processes and quality systems in place to realize their full potential – a strong marker of competence and long-term value creation.

### **CEO Mikael Lindstam comments**

“Applying to FDA PreCheck is a natural next step for Aptahem. It demonstrates our dedication to the highest standards and our ability to deliver innovative therapies quickly and safely.”

Read more about the program here: <https://www.fda.gov/news-events/press-announcements/fda-announces-new-fda-precheck-program-boost-us-drug-manufacturing>

### **For further information:**

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### **About Aptahem**

Aptahem AB (APTA) is a clinical stage biotechnology company that develops RNA-based pharmaceuticals for the treatment of acute, life-threatening conditions in which a combination of coagulation, inflammation and tissue damage are involved. The company's lead candidate, Apta-1, is currently in early clinical phase. Apta-1 has in preclinical studies, by its anti-thrombotic, immunomodulating and tissue repairing characteristics, shown very positive and promising results as treatment for sepsis and critical conditions associated with sepsis. For more information, please visit [www.aptahem.com](http://www.aptahem.com).