Malmö 27 August 2025 **PRESS RELEASE**

Aptahem is applying to the FDA's CNPV pilot program for accelerated drug review

Aptahem AB (publ), a biotech company developing RNA-based treatments for acute thrombo-inflammatory conditions, announces that the company has submitted an application for participation in the U.S. Food and Drug Administration's (FDA) Commissioner's National Priority Voucher (CNPV) Pilot Program – "Accelerated Drug Review for Companies Supporting U.S. National Interests." The application is made as a next step after Aptahem's previous application to FDA PreCheck on August 13, 2025. It complements the company's application to FDA PreCheck and strengthens the U.S.-focused regulatory strategy.

About the CNPV Program

CNPV is a new pilot program where the FDA, for a limited number of companies, can award a "voucher" that provides significantly shortened regulatory review processing times – from normally around 10–12 months to around 1–2 months – while maintaining applicable safety and efficacy requirements. The selection is directed at development programs that are in line with US national health priorities (e.g., high unmet medical needs, innovation level, crisis management, onshoring, and supply chain robustness). In the first round of the pilot year, a maximum of five participants are intended to be selected. To qualify, it is required, among other things, that the manufacturing part and proposed labeling are submitted at least 60 days before the final application and that the company can maintain a close dialogue with the FDA's cross-functional review team. Read more at: U.S. Food and Drug Administration.

Strategic importance for Aptahem

A decision to participate in CNPV could – when the time is right for future regulatory filings – provide Aptahem with a more predictable and time-efficient path through the review process. Together with the previous PreCheck application, which aims to provide faster and more predictable inspections of pharmaceutical manufacturing in the US, this strengthens Aptahem's long-term goal of building a high-quality, US-adapted development and production chain.

CEO Mikael Lindstam comments:

"The CNPV application is a natural next step in our US-focused regulatory plan. If selected, the program could, at the right stage, contribute to significantly more efficient processing – without compromising quality and safety requirements."

Next steps

FDA is processing CNPV applications on an ongoing basis and contacting selected companies for further dialogue. Aptahem will return when there is new information to communicate.

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.