



News Letter

Lund, November 5th, 2025

Clinical study in infants with febrile kidney infection supports Hamlet BioPharma's strategy for non-antibiotic treatment of bacterial infections

One of the most comprehensive studies ever conducted in childhood urinary tract infection shows that a chaotic immune response causes symptoms and damages the tissues — not the bacteria themselves, please see press releases April 9th and October 24th 2025.

Investor Relations Update

Summary

An international clinical study in infants experiencing their first febrile urinary tract infection included more than 160 infants in Sweden and Singapore. Genome wide technology and a strict clinical pathway makes this one of the most detailed studies ever performed and demonstrates that severe infection and kidney injury are driven by an excessive immune reaction to infection — not by the bacteria themselves.

A new understanding of infection biology

The study followed infants from diagnosis of febrile kidney infection to recovery using advanced molecular analysis to gauge disease severity. Results show that a cytokine storm creates chaos in the immune system and disease in infected kidneys (acute pyelonephritis). In adults, up to 30% of patients with acute pyelonephritis develop urosepsis and mortality is high.

Key findings

- **Global data set:** Two clinical cohorts – 111 children in Singapore and 52 in Sweden – make this one of the most comprehensive molecular datasets generated in this field.
- **Genetic susceptibility:** A distinct genetic profile distinguished infants with severe infection from those without renal involvement, opening future possibilities for screening and individualized therapy.
- **New biomarkers:** The gene *CD177* was found to be 45 times more active in infants with kidney involvement. A **four-gene panel** – a molecular signature capable of identifying children at risk of severe infection – predicted disease severity with 94 % accuracy.

- **Redefined disease mechanism:** Kidney scarring was not caused by acute inflammation but by a later, interferon-driven repair processes – a paradigm shift in understanding infection progression.
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Scientific and commercial significance

The findings confirm that severe infection is fundamentally an immunological disorder, providing strong support for Hamlet BioPharma's immunotherapy platform.

The biomarkers identified in the study will guide patient selection, dosing and efficacy tracking in upcoming clinical trials.

"– Analyzing the genome wide host response offers an overview of the infection process and the molecular causes of disease. DNA sequencing reveals why certain patients are more susceptible to infection. The results confirm earlier observations in animal models and support the clinical development of non-antibiotic approaches to the treatment of bacterial infections," says Ines Ambite, Senior scientist, Lund University.

Why it matters

- **Clinical validation of Hamlet's model:** The study provides strong human evidence that Hamlet's strategy – modulating the immune response instead of attacking bacteria – targets the true cause of disease.
- **Advantage for clinical development:** The identified biomarkers enable precision medicine and will be used for patient selection and efficacy monitoring in future trials.
- **Large market opportunity:** Urinary tract infections affect more than 150 million people annually, and about 30 % of children with severe infection develop long-term kidney damage – an area where antibiotic treatment is insufficient.
- **Enhanced pipeline and partnership value:** The results give Hamlet a science-based position in regulatory and partnership discussions, reinforcing the company's credibility ahead of next clinical phases.
- **Global credibility:** The international, multi-center study – funded by the EU Horizon 2020, the Swedish Research Council and others – strengthens Hamlet BioPharma's reputation as a pioneer in next-generation anti-infective therapies.

"The study highlights the strength of our organization, which combines international networks for clinical studies with advanced techniques and analyses tools," says **Catharina Svanborg**, Professor, CEO Hamlet BioPharma.

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