



Clinical studies paving the way for non-antibiotic treatments of bacterial infections; details from the large-scale international study in infants

Hamlet BioPharma, the pharmaceutical company, specializing in the development of drugs for cancer and infections, announces detailed information from the large-scale international study in infants, communicated on April 9, 2025. The large, international study, conducted by scientists and clinicians in Sweden and Singapore involved over 160 infants with their first febrile urinary tract infection and provides one of the most comprehensive molecular data sets ever generated for acute pyelonephritis. The advanced methodology and the way the clinical study was performed reshape the understanding of severe urinary tract infections (UTIs) and open new paths for treatment beyond antibiotics.

Key Findings from the large-scale international study in infants

- International study in infants, the findings come from one of the largest and most detailed molecular studies ever conducted in childhood urinary tract infection, following over 160 infants during and after their first febrile UTI. Two clinical cohorts, 111 children in Singapore and 52 in Sweden, were studied from diagnosis through six months of follow-up, providing a rare view of the full disease process from onset to recovery.
- Breakthrough in understanding disease biology, the results show that acute pyelonephritis, a severe kidney infection, is not just caused by bacteria but by a dysregulated immune reaction. In affected infants, the body's innate immune system overreacts, while adaptive immune control weakens, triggering a cytokine-storm-like inflammation that damages the kidneys.
- New precision targets identified, genes controlling neutrophil activity, key infection-fighting white blood cells, were found to be highly overactivated in severe cases. The immune marker CD177 was increased 45-fold in infants with kidney involvement and clearly separated acute infection from recovery, making it a strong candidate for biomarker development.
- Strong diagnostic potential, a four-gene panel predicted which infants had kidney involvement with 94% accuracy (AUC 0.944). This provides a solid foundation for biomarker-based diagnostics and patient stratification in future clinical studies.

Rethinking kidney scarring

The study also challenges conventional wisdom. Severe inflammation did not cause kidney scarring. Instead, scarring was linked to interferon-related repair pathways, suggesting that late immune activity, not acute infection, drives long-term kidney damage. Genetic signature of susceptibility, genome-wide sequencing revealed that infants with acute pyelonephritis carry distinct genetic profiles compared with those who recover from mild UTI. Sixty-seven shared genes were linked to immune regulation and renal defense, pointing to a genetic predisposition for severe infection and new opportunities for targeted prevention and therapy.

One of the most comprehensive molecular data sets ever generated for acute pyelonephritis, acute and severe kidney infection

This large, international study, involving over 160 infants with their first febrile urinary tract infection, provides one of the most comprehensive molecular data sets ever generated for acute pyelonephritis. It captures the disease process from the very first infection episode, in a genetically diverse population spanning Asia and Europe. For Hamlet BioPharma, this offers a uniquely credible foundation for its precision immunotherapy platform. The results confirm that the root cause of severe kidney infection is not bacterial overgrowth, but an uncontrolled immune response — exactly the mechanism Hamlet BioPharma's therapies are designed to rebalance.

“The international study provides unprecedented clinical insights as a basis for non-antibiotic treatments of bacterial infections. The scale and design of this infant study provide robust human evidence linking immune dysregulation to disease severity and outcome. It followed patients from initial infection through recovery. It demonstrates that our immune-focused approach addresses the real cause of severe infection, and that our science translates across populations and age groups.” comments Ines Ambite PhD, scientific study coordinator, senior researcher, Lund University.

Market and development

UTIs affect over 150 million people each year and are a major cause of hospitalization. Around 30% of children with APN develop kidney scarring, leading to lifelong complications such as high blood pressure or chronic kidney disease.

A therapy that reduces immune-driven kidney damage could address a large, under-served market, offering benefits for patients, payers, and healthcare systems while helping to combat antibiotic overuse.

Hamlet BioPharma is now advancing its immunomodulatory drug candidates toward clinical evaluation in immune-driven infections. The biomarkers identified in this study will guide patient selection, dosing, and outcome tracking in future clinical trials.

“This achievement illustrates the clinical study competence and international network of scientists associated with HAMLET BioPharma. The data gives us a scientific roadmap for precision treatment of bacterial infections. They strengthen Hamlet's position as a pioneer in next-generation anti-infective therapies” says Catharina Svanborg, Professor, CEO, Hamlet BioPharma.

About the study

The research was conducted by an international team led by Professor Catharina Svanborg (Lund University and Hamlet BioPharma) in collaboration with hospitals in Singapore and Sweden.

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For further information, please contact

Catharina Svanborg, CEO, Hamlet BioPharma AB, +46 709 42 65 49
catharina.svanborg@hamletpharma.com

Ines Ambite, PhD, Scientist, Lund University, +46 762 08 89 58
ines.ambite@med.lu.se

www.hamletbiopharma.com