

# New drug candidate can improve therapy in bladder cancer patients

A promising drug candidate has positive clinical effects in patients with bladder cancer. The number of tumours and tumour sizes were reduced in a majority of patients treated — and without severe side effects often associated with other treatments.



**Catharina Svanborg**  
Chairman of the board, Hamlet BioPharma AB and Professor at Lund University

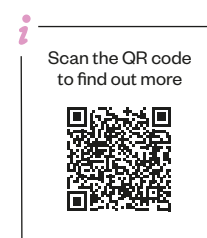
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## Molecular insights can relieve severe symptoms in patients with **chronic bladder pain syndrome**

The exaggerated pain response in patients with chronic bladder pain syndrome is very difficult to treat. New approaches are therefore essential.



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**B**ladder cancer is a disease which has a high likelihood of returning after treatment. Indeed, after the removal of the first tumour, cancer has been found to recur in 80% of these patients — and 15% go on to develop muscle-invasive disease. So, there's an urgent need for safe and effective new treatments that could stop disease progression and prevent recurrences.

### Drug candidate reduces bladder cancer tumour size

Now, a breakthrough may be on the horizon because Sweden-based pharmaceutical company Hamlet BioPharma has announced promising new data from a clinical trial of its drug candidate for the treatment of early non-muscle invasive bladder cancer, Alpha1H. Alpha1H is a synthetic drug candidate developed from HAMLET (human alpha-lactalbumin made lethal to tumour cells), originally discovered in human breast milk.

Combined data analysis from treated patients showed that higher doses of Alpha1H significantly reduced the size of 82% of tumours while lower doses significantly reduced the size of 45% of tumours, compared to a placebo group. Among other benefits, it's hoped that the therapy could improve the treatment of early tumours and possibly reduce the risk of tumour regrowth

post-surgery, paving the way for less invasive surgical interventions.

### Way to treat patients without severe side effects

"Alpha1H kills tumour cells with great precision and is straightforward to produce in large amounts," says Catharina Svanborg, Chairman of the Board at Hamlet BioPharma. "What's more, our studies show there is limited toxicity associated with its administration, so patients can be treated without experiencing the severe side effects associated with chemotherapy." The biopharmaceutical company is now working towards a phase III clinical trial.

### Fast-tracking drug candidate approval

The US Food and Drug Administration (FDA) has granted Fast Track Designation for Alpha1H, accelerating its approval process and potential to reach the US market and opening up dialogue with potential commercial partners. "Fast Track Designation is an exciting development," says Jakob Testad, Chief Financial Officer at Hamlet BioPharma. "It demonstrates the promise of Alpha1H and underlines how vital it is to address bladder cancer and improve the quality of life for patients suffering from this disease."

Hamlet BioPharma is an innovative biotechnology company that develops scientific discoveries from scientists at Lund University into drugs for the treatment of cancer and infections. This joint effort addresses unmet medical needs in large patient groups in need of improved cancer treatments or alternatives to antibiotics.

Find out more at [hamletbiopharma.com](http://hamletbiopharma.com)



Image provided by Hamlet BioPharma



## How to potentially treat bacterial infections — but **without using antibiotics**

Immunotherapy can successfully treat urinary tract infections in mice. If the same results are found in humans, it could be useful in the fight against antimicrobial resistance.

**A**ntimicrobial resistance (AMR) is a growing danger — one that is made worse by the constant over-prescribing and misuse of antibiotics. In fact, the World Health Organization (WHO) has declared AMR to be one of the 'biggest threats to global health, food security and development today' and has highlighted the need to combat it with novel solutions.

### Exploring immunotherapy for bacterial infections

Hamlet BioPharma is investigating alternative ways of treating bacterial infections by strengthening an individual's antibacterial defence with immunotherapy, thus bypassing the need for antibiotic use.

Take urinary tract infections (UTIs), which are among the most prevalent infectious diseases globally and include acute cystitis, which affects around 50% of all women during their lifetime. Hamlet BioPharma has now identified that the registered drug anakinra (IL-1-RA) is an effective treatment for acute cystitis in mice — and hopes that it will also prove efficacious in humans.

**Hoping for success in an ongoing human trial**  
"We have used this treatment in

mice with urinary tract infections and know that it works," says Ines Ambite. "The inflammatory response to infection of the mice's IL-1 gene was controlled by the IL-1RA drug, which also increased bacterial clearance from their bladders and kidneys." Immunotherapy was effective against infections in mice caused by antibiotic-sensitive or antibiotic-resistant bacterial strains.

The results show that these types of infections can be treated with therapies other than antibiotics — an important conceptual advance and one that could be of huge importance in the fight against AMR. "A trial is now ongoing to test the efficacy of IL-1-RA in humans with urinary tract infections," notes Martin Erixon, CEO of Hamlet BioPharma. "The results should be known later this year."

### Using state-of-the-art techniques to analyse treatment effects

"As a company collaborating with the university, we gain access to sophisticated, state-of-the-art techniques to analyse various treatment effects and draw conclusions," says Erixon. "Collaboration with the scientists at Lund University is essential for the successful development of the projects."

## Intestinal health may be improved by a protein complex, **originally from human milk**

Scientists are exploring a milk protein complex that effectively kills cancer cells and prevents tumour growth — especially in colon cancer.

**C**olon cancer is one of the most common types of cancer — 180,000 cases are diagnosed every year in the US alone — and a leading cause of death worldwide. Patients with colon cancer are usually treated with surgery followed by chemotherapy to reduce the risk of recurrence — but recurrence rates are high, and the side effects of chemotherapy are often severe.

### Potential non-toxic treatment for colon cancer

The scientists at Lund University are currently investigating the discovery of a non-toxic treatment approach for colon cancer using a milk protein complex that effectively kills cancer cells. The complex has shown strong effects on tumour tissue growth, especially for colon cancer.

### Promising way of delaying tumour development

"We introduced the complex in the drinking water of mice that were genetically susceptible to developing intestinal tumours," explains Hien Tran, Scientist at Lund University. "The results were exciting because

**We introduced the complex in the drinking water of mice that were genetically susceptible to developing intestinal tumours.**

tumour development was markedly reduced and the long-term survival was increased in these mice." In mice that had already developed cancer, the team found that the complex targeted the tumour rather than healthy intestinal tissue. What's more, it did not cause side effects in mice with cancer or in healthy mice that received the complex in their drinking water — an extremely promising development.