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## **The Phase II trial of recurrent acute cystitis is proceeding according to plan**

SelectImmune Pharma is conducting a randomized single-center Phase II trial in patients with recurrent acute cystitis, investigating the effects of the IL-1 receptor antagonist (IL-1RA). The clinical trial is led by key opinion leaders in the field of urinary tract infection therapy in Giessen, Germany and at Lund University. The efficient study organization includes physicians, monitors, other clinical and laboratory staff. Patient recruitment is proceeding according to plan, and we envisage completion of enrolment by the end of this year (See the WHO registry at <https://trialssearch.who.int/> (insert the EudraCT number 2019-004209-28)).

The aim of the study is to evaluate the efficacy of IL-1RA treatment in patients with recurrent episodes of acute cystitis. The study is based on the scientific discovery that acute cystitis is an interleukin-1 $\beta$  hyper-activation disorder, triggered by infection of the bladder. Characteristic symptoms include urgency, frequency of urination and pain. The therapeutic efficacy of IL-1 receptor inhibition, first demonstrated in susceptible mice, is now tested in the clinic.

The patients are enrolled based on cystitis symptoms and evidence of infection, and are randomised to treatment with IL-1RA or antibiotics. The response to treatment is monitored at repeated visits with a clinical follow up after six months. Extensive laboratory testing is performed to evaluate the response at the molecular level, including effects on inflammation and pain. The study will be unblinded when the last patient has completed the 6-month follow up.

Acute cystitis is one of the most common bacterial infections and increasingly difficult to treat, due to antibiotic resistance. Immunotherapy offers an important new molecular strategy to treat these infections, with the potential of reaching very large patient groups.

*“ We look forward to understanding the potential of IL1RA therapy for this patient group, where there is a great need for treatments that complement antibiotics” says Gabriela Godaly, acting CEO of SelectImmune Pharma.*

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*SelectImmune Pharma is a pharmaceutical company whose shares are traded on the Spotlight Stock Market. The company develops new immunotherapies, which act as immune modulators and offer complements to antibiotics.*

*Bacterial infections affect large parts of the population and are becoming increasingly difficult to treat due to increasing antibiotic resistance. SelectImmune Pharma develops immunotherapies that can supplement or replace antibiotics. Urinary tract infections (UVI) are extremely common, affecting at least 50% of all women. There is an immediate need for treatment alternatives and the potential markets are very large.*