



## **Start of the SelectImmune Pharma Phase II trial of targeted immunotherapy in recurrent acute cystitis**

**SelectImmune Pharma is proud to report that the Phase II trial of the IL-1 receptor antagonist (IL-1RA) in patients with recurrent acute cystitis has started. The clinical trial is led by Professor Wagenlehner, an international key opinion leader in the field of urinary tract infection therapy and antibiotic resistance at the center for such studies in Giessen, Germany, in collaboration with scientists at Lund University and SelectImmune.**

The formal clinical trial preparations to obtain permission for the study from the German regulatory authorities and ethical committee have been completed and the study organization finalized, including preparations for patient enrolment and laboratory analyses. The initiation procedure, involving physicians, monitors, other clinical staff and laboratory staff, is required to start a clinical trial was recently completed.

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. Since IL-1RA is registered for other clinical indications, SelectImmune Pharma has the permission to perform a Phase II trial.

Acute cystitis is one of the most common bacterial infections and increasingly difficult to treat, due to antibiotic resistance. Targeted immunotherapy offers an important new molecular strategy to treat these infections, with the potential of reaching very large patient groups. Importantly, immunotherapy has shown effects against both antibiotic sensitive and antibiotic resistant bacteria in an animal model.

*"We are excited about the study start and delighted to collaborate with international leaders in this field, says Gabriela Godaly, Chief Medical Officer, SelectImmune Pharma.*

*"We look forward to understanding the potential of IL1RA therapy for these patients, who need alternatives to antibiotics" says Catharina Svanborg, Chairman of the board, SelectImmune Pharma.*

*“Targeted Immunotherapy could be an important step forward for these very frequent infections that so many women are suffering from”* says Florian Wagenlehner, Principal Investigator of this Phase II trial.

**For more information, please contact:**

Gabriela Godaly

CMO SelectImmune Pharma AB

Tel: +46 733 38 13 44

E-post: [gabriela.godaly@med.lu.se](mailto:gabriela.godaly@med.lu.se)

Catharina Svanborg

Styrelseordförande SelectImmune Pharma AB

Tel: +46 709 42 65 49

E-post: [catharina.svanborg@med.lu.se](mailto:catharina.svanborg@med.lu.se)

This disclosure contains information that SelectImmune is obliged to make public pursuant to the EU Market Abuse Regulation (EU nr 596/2014). The information was submitted for publication, through the agency of the contact person, on 30-08-2021 13:51 CET.

*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 alternatives 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 (UTI) are extremely common, affecting at least 50% of all women, and being increasingly antibiotic resistant. There is an immediate need for treatment alternatives and the potential markets are very large.*