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## First patient in – a new treatment option for patients with bladder pain

As previously announced, SelectImmune Pharma has successfully completed preparations to start a controlled clinical trial in patients with bladder pain syndrome (severe pain in the bladder). We can now announce that the study has started and the first patient has been included in the study. The patients must be treated with the drug Kineret, which is an Interleukin1 (IL-1) receptor antagonist (IL-1RA).

Patients with bladder pain syndrome have severe pain of unknown cause. Many different treatments have been tried without lasting positive effects. The development of new, more precise drugs has been hampered by the fact that the cause of the pain is unknown. Treatment with IL1RA "off-label" has previously shown positive results in the clinic. Kineret is an IL-1 receptor antagonist that neutralizes the biological activity of the two proinflammatory cytokines IL-1  $\alpha$  and IL-1  $\beta$ .

In the previously treated patients, the pain was reduced and the quality of life increased in this severely disabled patient group. Several patients were able to return to a more normal life. The placebo-controlled study is important to evaluate the treatment effect with greater precision. The study will include a larger number of patients and clinical centers, to address the treatment effect. Research has previously shown that pain is greatly reduced by IL-1RA treatment, even in an animal model.

The study will initially include two centers in Sweden, which have extensive experience with this particular patient group. The company has established the study organization in Sweden, received permission from the Swedish Medicines Agency and the Ethical Review Authority and gained access to placebos through an agreement with Sobi (Swedish Orphan Biovitrum). The possibility of treating this patient group is of great medical interest.

"We have established the organization and to now start this important study to really understand the potency of IL-1RA treatment in this patient group," says Gabriela Godaly, CEO, SelectImmune Pharma.

“It is essential to investigate the effects on pain and quality of life in a larger patient population and with a placebo-controlled protocol” says Björn Wullt, associate professor and senior physician.

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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.*