



PRESS RELEASE 2024-05-06

Clinical data from patients with bladder pain syndrome support anakinra (IL1-RA) as a new, successful treatment option

Hamlet BioPharma - the pharmaceutical company with a strong portfolio of projects for the treatment of cancer and infections - has successfully completed the first part of a controlled clinical trial in patients with bladder pain syndrome (severe pain in the urinary bladder). The patients have been treated with anakinra, which is an Interleukin1 (IL-1) receptor antagonist (IL-1RA). The company can now announce that a significant proportion of the treated patients have responded positively to the treatment.

Patients with bladder pain syndrome have severe pain, which is socially debilitating. Broadly used pain killers are not effective. Some patients are helped by morphine or surgery, but often without lasting effects.

Hamlet BioPharma has patented the use of anakinra for bladder pain and is conducting a placebo-controlled study to evaluate the treatment effect in patients with bladder pain syndrome. The pro-inflammatory cytokine IL-1 increases pain in the bladder and blocking of the IL-1 effect with anakinra treatment reduces the pain response in animal models. Anakinra is an IL-1 receptor antagonist that neutralizes the biological activity of the two potent pro-inflammatory molecules IL-1 α and IL-1 β .

In the initial part of the clinical study, the recruited patients were treated with anakinra to define the responder group for the later placebo-controlled part of the trial. Significant effects were detected in the majority of the treated patients. The pain score was reduced after treatment and the quality of life increased in this severely disabled patient group. In addition, laboratory tests showed a convincing reduction in pain molecules after treatment, suggesting a direct effect of treatment at the molecular level.

" We are seeing the potential of IL-1RA treatment in this patient group," says Gabriela Godaly, Professor, Project manager Hamlet BioPharma.

"It is rewarding to follow effects of IL-1RA on pain and quality of life in this patient population" says Björn Wullt, associate professor and senior physician.

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